FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2004-08-12** | Period of Report: **2004-06-30**
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FILER

ZONAGEN INC

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SIC: **2836** Biological products, (no disgnostic substances)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2004

or

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 0-21198

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 [X] No [ ]

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes [ ] No [X]

As of August 11, 2004, there were outstanding 4,992,901 shares of Common Stock, par value $.001 per share, of the Registrant.

ZONAGEN, INC.
(A development stage company)

For the Quarter Ended June 30, 2004

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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 to identify forward-looking statements. Such statements are subject to certain risks, uncertainties and assumptions. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, expected, estimated, projected, suggested or intended. These risks and uncertainties include risks associated with the early stage of development of Progenta(TM) and Androxal(TM), uncertainty relating to the Company's patent portfolio, 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 Progenta(TM), the Company's ability to remain listed on the Nasdaq SmallCap Market, the Company's ability to obtain value from its other technologies 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" and "Item 3. Legal Proceedings" included in the Company's annual report on Form 10-K for the year ended December 31, 2003 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

The following unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States 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 for complete financial statements. In the opinion of management, all necessary adjustments (which include only normal recurring adjustments) considered necessary for a fair presentation have been included. Operating results for the six-month period ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ended December 31, 2004. 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, 2003.

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

BALANCE SHEET
(Unaudited)

<TABLE>
<CAPTION>

	JUNE 30, 2004	DECEMBER 31, 2003
<S>	<C> (unaudited)	<C>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 1,215	$ 20,946
Marketable securities	6,350	2,000
Prepaid expenses and other current assets	224	235
Total current assets	7,789	23,181
FIXED ASSETS, NET	12	-
OTHER ASSETS, NET	637	847
Total assets	$ 8,438	$ 24,028

	=========	=========
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 203	$ 126
Accrued expenses	215	415
Total current liabilities	418	541
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, 11,989,936 and 11,929,048 shares issued, respectively; 4,992,901 and 11,479,648 shares outstanding, respectively	12	12
Additional paid-in capital	114,065	114,065
Cost of treasury stock, 6,997,035 and 449,400 shares, respectively	(21,487)	(7,533)
Deficit accumulated during the development stage	(84,570)	(83,057)
Total stockholders' equity	8,020	23,487
Total liabilities and stockholders' equity	$ 8,438	$ 24,028
	=========	=========

</TABLE>

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

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

STATEMENTS OF OPERATIONS
(Unaudited)

<TABLE>
<CAPTION>

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,		FROM INCEPTION (AUGUST 20, 1987) THROUGH JUNE 30,
	2004	2003	2004	2003	2004
<S>	<C>	<C>	<C>	<C>	<C>
REVENUES					
Licensing fees	$ -	$ -	$ -	$ -	$ 28,755
Product royalties	-	-	-	-	627
Research and development grants	53	217	117	337	1,214
Interest income	22	74	48	186	13,070
Gain on disposal of fixed assets	-	102	-	102	102
Other Income	-	-	35	-	35
Total revenues and other income	75	393	200	625	43,803
EXPENSES					
Research and development	508	579	985	1,143	92,774
General and administrative	294	490	728	1,102	25,868
Interest expense and amortization of intangibles	-	-	-	-	388
Total expenses	802	1,069	1,713	2,245	119,030
Loss from continuing operations	(727)	(676)	(1,513)	(1,620)	(75,227)
Income (loss) from discontinued operations	-	-	-	-	(1,828)
Gain on disposal	-	-	-	-	939
Net loss before cumulative effect of change in accounting principle	(727)	(676)	(1,513)	(1,620)	(76,116)
Cumulative effect of change in accounting principle	-	-	-	-	(8,454)
NET LOSS	$ (727)	$ (676)	$ (1,513)	$ (1,620)	$ (84,570)
	=========	=========	=========	=========	=========
INCOME (LOSS) PER SHARE - BASIC AND DILUTED:	$ (0.15)	$ (0.06)	$ (0.29)	$ (0.14)	
	=========	=========	=========	=========	
Shares used in loss per share calculation:					
Basic	4,993	11,484	5,242	11,494	
Diluted	4,993	11,484	5,242	11,494	

</TABLE>

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

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

STATEMENTS OF CASH FLOWS
(Unaudited)

<TABLE>
<CAPTION>

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,		FROM INCEPTION (AUGUST 20, 1987) THROUGH JUNE 30,
	2004	2003	2004	2003	2004
<S>	<C>	<C>	<C>	<C>	<C>
CASH FLOWS FROM OPERATING ACTIVITIES					
Net loss	$ (727)	$ (676)	$ (1,513)	$ (1,620)	(84,570)
Gain on disposal of discontinued operations	-	-	-	-	(939)
Gain on disposal of assets	-	(102)	-	(102)	(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	-	1,051
Noncash decrease in accounts payable	-	-	-	-	(1,308)
Depreciation and amortization	3	28	5	73	3,769
Noncash expenses related to stock-based transactions	-	11	-	14	2,572
Common stock issued for agreement not to compete	-	-	-	-	200
Series B Preferred Stock issued for consulting services	-	-	-	-	18
Maturities (purchases) of marketable securities	(250)	(10,334)	(4,350)	(4,241)	22,185
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	55	(322)	11	(100)	75
(Decrease) increase in accounts payable and accrued expenses	22	(157)	(123)	(142)	1,613
Decrease (increase) in other assets	-	-	284	-	-
Net cash used in operating activities	(877)	(11,552)	(5,666)	(6,118)	(55,349)
CASH FLOWS FROM INVESTING ACTIVITIES					
Maturities (purchases) of marketable securities	-	-	-	-	(28,723)
Capital expenditures	(9)	-	(12)	-	(2,280)
Purchase of technology rights and other assets	(46)	(14)	(99)	(15)	(2,368)
Decrease in note receivable	-	1,000	-	1,000	-
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 provided by (used in) investing activities	(55)	986	(111)	985	(30,968)
CASH FLOWS FROM FINANCING ACTIVITIES					
Proceeds from issuance of common stock	-	-	-	-	84,224
Proceeds from issuance of preferred stock	-	-	-	-	23,688
Purchase of treasury stock	-	(49)	(13,954)	(49)	(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	-	(49)	(13,954)	(49)	87,532
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(932)	(10,615)	(19,731)	(5,182)	1,215
CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	2,147	14,116	20,946	8,683	-
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 1,215	$ 3,501	$ 1,215	$ 3,501	$ 1,215

</TABLE>

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

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2004
(Unaudited)

NOTE 1 -- ORGANIZATION AND OPERATIONS

Zonagen, Inc. (the "Company", Zonagen, or "we", "us" or "our") was organized on August 20, 1987 and is a development stage company. The Company is engaged in the development of pharmaceutical products that address diseases and conditions associated with the treatment of hormonal and reproductive system disorders. The Company's two lead product candidates are Progenta(TM), an oral formulation being developed for the treatment of uterine fibroids and endometriosis, and Androxal(TM), an oral formulation being developed for the treatment of testosterone deficiency. During the quarter ended June 30, 2004, the Company continued early development activities of Progenta(TM) as an oral treatment for endometriosis, which was funded under an $836,441 Phase II, Small Business Innovative Research ("SBIR") grant which was essentially depleted as of June 30, 2004.

The Company will continue its efforts to out-license, namely Vasomax(R) and the related phentolamine-based products, its adjuvants and prostate cancer vaccine technologies and its hCG and zona pellucida immuno-contraceptive vaccines. In the future the Company may do additional clinical development relating to its phentolamine-based product candidates as a means to increase their out-licensing value. The Company will no longer maintain its current patent portfolio for both its hCG or zona pellucida immuno-contraceptive vaccines. This decision resulted in the write-off of approximately $20,000 during the quarter ended June 30, 2004 relating to its hCG vaccine patent portfolio. The Company had previously written-off its zona pellucida patent portfolio in December 2001 but continued to maintain that portfolio. There can be no assurance that the Company will be able to create any value from out-licensing activities of its prior development programs.

On June 29, 2004 the Company announced that it would initiate a European Phase I/II study of its lead product candidate, Progenta(TM), for the treatment of uterine fibroids which is being conducted in Warsaw, Poland. As of August 10, 2004, eight patients have entered this clinical study. All eight patients have either entered or are about to enter the second phase of the study, which is the efficacy testing phase. To date, the drug has been both well absorbed and well tolerated at all dose levels administered. The Company believes it may have top level reportable data from this trial by year-end 2004.

On July 1, and July 15, 2004, the Company released results from a randomized clinical trial comparing the Company's Androxal(TM) product candidate to placebo and to Androgel(R) in testosterone deficient men, a condition also known as hypogonadism. Androgel(R) is the current drug treatment of choice for this indication. Androxal(TM) is an orally administered medication that induces increased production of testosterone. This study consisted of 62 eligible subjects which were randomized and dosed into 6 different arms, three doses of Androxal(TM), placebo, and both

ZONAGEN, INC. AND SUBSIDIARY
(A development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
JUNE 30, 2004
(Unaudited)

high and low doses of Androgel(R).

As of June 30, 2004, the Company had an accumulated deficit of $84.6 million. Losses have resulted principally from costs incurred in conducting clinical trials for VASOMAX(R), the Company's oral treatment for male erectile dysfunction, and the related female sexual dysfunction product, in research and development activities related to efforts to develop the Company's other products and from the associated administrative costs required to support those efforts.

Zonagen's results of operations may vary significantly from quarter to quarter and year to year. 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 believes that its existing capital resources under its current operating plan will be sufficient

to fund the Company's operations through the end of June 2005. There can be no assurance that changes in the Company's revised strategic plans or other events will not result in accelerated or unexpected expenditures.

NASDAQ SMALL CAP MARKET LISTING

On July 8, 2004 Zonagen's stock transferred from the Nasdaq National Market to the Nasdaq SmallCap Market after Nasdaq had approved the Company's application for this transfer. The Company applied for a Nasdaq SmallCap Market listing after Nasdaq had informed the Company that it no longer met the $10,000,000 minimum stockholders' equity listing requirement for the Nasdaq National Market. This shortfall was a result of the previously concluded, January 2004, self-tender offer.

NOTE 2 -- STOCK-BASED COMPENSATION

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

<TABLE>
<CAPTION>

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2004	2003	2004	2003
<S>	<C>	<C>	<C>	<C>
Net loss, as reported.....	$ (727)	$ (676)	$ (1,513)	$ (1,620)
Add: Stock-based employee compensation expense included in reported net income, net of related tax effects	--	11	--	14
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(98)	(163)	(118)	(362)
Pro forma net loss.....	$ (825)	$ (828)	$ (1,631)	$ (1,968)
Loss per share -				
Basic - as reported.....	$ (0.15)	$ (0.06)	$ (0.29)	$ (0.14)
Basic - pro forma	(0.17)	(0.07)	(0.31)	(0.17)
Diluted - as reported	(0.15)	(0.06)	(0.29)	(0.14)
Diluted - pro forma.....	(0.17)	(0.07)	(0.31)	(0.17)

</TABLE>

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 periods ended June 30, 2004 and 2003. The following weighted average assumptions were used for grants in the six-month periods ended June 30, 2004 and 2003, respectively: risk-free interest rates of 3.9% and 3.8%; no expected dividends; expected lives of 5.7 and 9.7 years; and expected volatility of 87% and 90%. The weighted average fair value of options granted at market for the six-month periods ended June 30, 2004 and 2003 was $1.89 and $1.06 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 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, 2004 all securities were classified as trading securities. The cost basis including purchased premium, which approximates fair value, for these securities was $6.4 million and $2.0 million at June 30, 2004 and December 31, 2003, 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, 2004, consist of only short-term investments totaling $6.4 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, 2004, the Company had approximately $637,000 in capitalized patents reflected on its balance sheet. Of this amount $240,000 relates to patents for Progenta(TM), which is being developed as an oral treatment for uterine fibroids and endometriosis; $204,000 relates to vaccine adjuvant technologies; $98,000 relates to Androxal(TM), which is being developed as an oral treatment for testosterone deficiency; $81,000 relates to prostate cancer vaccine technologies; and $14,000 relates to various other technologies. The Company will no longer maintain its current patent portfolio for both its hCG and zona pellucida immuno-contraceptive vaccines. This decision resulted in the write-off of approximately $20,000 during the quarter ended June 30, 2004 relating to its hCG vaccine patent portfolio. The Company had previously written-off its zona pellucida patent portfolio in December 2001 but continued to maintain that portfolio. If Zonagen cannot out-license the technologies that the Company is no longer developing to another entity, then part or all of the value of such capitalized patents value could be impaired.

NOTE 5 -- EARNINGS (LOSS) PER SHARE

Basic EPS is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. Diluted EPS is computed in the same manner as basic EPS, except that, among other changes, the average share price for the period is used in all cases when applying the treasury stock method of potentially dilutive outstanding options.

The following table presents information necessary to calculate earnings per share for the

three-month and six-month periods ended June 30, 2004 and 2003 (in thousands, except per share amounts):

<TABLE>
<CAPTION>

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2004	2003	2004	2003

<S>	<C>	<C>	<C>	<C>
Net Loss	$ (727)	$ (676)	$ (1,513)	$ (1,620)
Average common shares outstanding	4,993	11,484	5,242	11,494
Basic loss per share	$ (0.15)	$ (0.06)	$ (0.29)	$ (0.14)
Diluted loss per share	$ (0.15)	(0.06)	$ (0.29)	$ (0.14)

</TABLE>

Common stock equivalents of 1,290,382 and 1,437,064 for the periods ended June 30, 2004 and 2003, respectively, were excluded from the above calculation of diluted EPS since they were antidilutive.

NOTE 6 -- STOCKHOLDERS' EQUITY

In January 2004, Zonagen purchased 6,547,635 shares of its common stock (approximately 57% of its outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of its self tender offer, which expired on January 7, 2004. This purchase included 60,888 shares issuable upon exercise of options for a total aggregate purchase price of approximately $13.7 million, exclusive of $289,000 in costs associated with the offer. As of June 30, 2004, the Company had 4,992,901 shares outstanding. Shares purchased are included at cost as treasury stock in the accompanying balance sheet.

Pursuant to the terms of the Company's 2000 Non-employee Directors Stock Option Plan, each of the three new non-employee directors that were elected at the Company's 2003 Annual Shareholder Meeting (which concluded on January 14, 2004) were automatically granted options to purchase 40,000 shares of the Company's common stock at an exercise price of $2.40, the closing price on January 14, 2004, the date of grant. On February 24, 2004, the Board of Directors approved an amendment to these options to provide that such options vest in quarterly installments over a three-year period.

Under the terms of the 2000 Non-employee Directors' Stock Option Plan, prior directors who did not stand for re-election at the Company's 2003 Annual Shareholder Meeting were automatically granted an extension to exercise their fully vested options to January 14, 2006. These options consisted of 140,715 shares with exercise prices ranging from $1.70 to $5.65. In addition, these directors also received an extension to January 14, 2006 for any fully vested options granted

under other plans. These options consisted of 112,500 shares with exercise prices ranging from $4.00 to $22.25.

As a result of the expiration of the Company's Amended and Restated 1993 Employee and Consultant Stock Option Plan (the "1993 Plan") in May 2003, the Company's Board of Directors approved the 2004 Employee and Consultant Stock Option Plan ("2004 Plan") on February 24, 2004. The 2004 Plan is subject to stockholder approval at the 2004 Annual Meeting of Stockholders.

On March 29, 2004, the Compensation Committee approved grants to the Company's executive officers of (i) incentive options to purchase 358,763 shares of its common stock that vest quarterly over three years and (ii) incentive options to purchase 79,486 shares of its common stock that vest in the event certain milestones are attained by January 25, 2005. These options replace grants of options to purchase an equal number of shares that were approved in January 2004 under the Company's then-expired 1993 Plan, which grants have been terminated as a result of the expiration of the 1993 Plan.

In addition, the following grants were approved on March 29, 2004 to non-executive employees of the Company: (i) incentive options to purchase 123,350 shares that vest quarterly over three years, (ii) incentive options to purchase 17,504 shares that vest upon the achievement of certain milestones and (iii) incentive options to purchase 22,361 shares (granted in lieu of additional increases in cash compensation) that vest in equal monthly increments through December 31, 2004. All of the options to executive officers and the Company's employees were granted at an exercise price of $2.72, the fair market value of the Company's common stock on the date of grant.

Of all of the options granted to both executive officers and employees, options to purchase 150,000 shares were granted under the Company's 1994

Employee and Consultant Stock Option Plan (of which, options to purchase 56,737 shares were granted to Mr. Podolski, 38,245 shares were granted to Mr. Ploth and 55,018 were granted to the Company's other employees) and the remaining options were granted under the 2004 Plan. All of the options granted under the 1994 Plan are immediately valid while all of the options granted under the 2004 Plan are subject to stockholder approval at the Company's 2004 Annual Meeting of Stockholders to be held in 2004. The measurement date for determining the amount of stock option compensation expense, if any, to be recognized for the options granted under the 2004 Plan (listed above) will be determined based on the closing price of the Company's common stock on the date that the shareholders approve the 2004 Plan.

NOTE 7 -- COMMITMENTS AND CONTINGENCIES

LITIGATION

Certain purported class action complaints alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder were filed against the Company and certain of its officers and directors in 1998. These complaints were filed in the United States District Court for the Southern District of Texas (the "District Court") in Houston, Texas and were consolidated on May 29, 1998. The plaintiffs purported to bring the suit on behalf of all purchasers of Zonagen common stock between February 7, 1996 and January 9, 1998. The plaintiffs asserted that the defendants made materially false and misleading statements and failed to disclose material facts about the patents and patent applications of the Company relating to VASOMAX(R) and Chito-ZN (formerly named ImmuMax(TM)) and about the Company's clinical trials of VASOMAX(R). The plaintiffs sought to have the action declared to be a class action, and to have recessionary or compensatory damages in an unstated amount, along with interest and attorney's fees. On March 30, 1999, the District Court granted the defendants' motion to dismiss and dismissed the case with prejudice. The plaintiffs filed an appeal. On September 25, 2001, the United States Fifth Circuit Court of Appeals (the "Fifth Circuit") affirmed the dismissal of all claims except one; the Fifth Circuit reversed the District Court's dismissal of a claim concerning the Company's disclosure about a patent relating to VASOMAX(R). On June 13, 2003, the District Court granted the defendants' motion for summary judgment as to that last remaining claim, and entered a judgment dismissing the case with prejudice. The plaintiffs filed an appeal. On June 16, 2004, the Fifth Circuit affirmed the June 13, 2003 judgment of the District Court . In addition, on July 15, 2004, the Fifth Circuit denied the plaintiff's request for a rehearing. The time for the plaintiff to file a writ of certiorari with the United States Supreme Court has not yet expired.

OFFICE LEASE

The Company executed a new 74 month lease effective May 1, 2004, for 4,800 square feet of laboratory and office space located in its current building in The Woodlands, Texas. This space replaces its prior 2,518 square foot facility which was under a lease that expired on June 30, 2004.

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.

OVERVIEW

Zonagen, Inc. (the "Company", Zonagen, or "we", "us" or "our") was organized on August 20, 1987 and is a development stage company. The Company is engaged in the development of pharmaceutical products that address diseases and conditions associated with the treatment of hormonal and reproductive system disorders. The Company's two lead product candidates are Progenta(TM), an oral formulation being developed for the treatment of uterine fibroids and

endometriosis, and Androxal(TM), an oral formulation being developed for the treatment of testosterone deficiency. During the quarter ended June 30, 2004, the Company continued early development activities of Progenta(TM) as an oral treatment for endometriosis, which was funded under an $836,441 Phase II, Small Business Innovative Research ("SBIR") grant which was essentially depleted as of June 30, 2004.

The Company will continue its efforts to out-license, namely Vasomax(R) and the related phentolamine-based products, its adjuvants and prostate cancer vaccine technologies and its hCG and zona pellucida immuno-contraceptive vaccines. In the future, the Company may do additional clinical development relating to its phentolamine-based product candidates as a means to increase their out-licensing value. The Company will no longer maintain its current patent portfolio for both its hCG or zona pellucida immuno-contraceptive vaccines. This decision resulted in the write-off of approximately $20,000 during the quarter ended June 30, 2004 relating to its hCG vaccine patent portfolio. The Company had previously written-off its zona pellucida patent portfolio in December 2001 but continued to maintain that portfolio. There can be no assurance that the Company will be able to create any value from out-licensing activities of its prior development programs.

The primary focus of the company's existing financial resources will be on the clinical development of Progenta(TM) for uterine fibroids and for Androxal(TM) for the treatment of testosterone deficiency. 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's management feels that its current financial resources are adequate to complete the European Phase I/II clinical study of Progenta(TM) for the oral treatment of uterine fibroids and to complete the data management portion of its recently completed U.S. Phase I/II clinical study of Androxal(TM) for the oral treatment of men with testosterone deficiency but the Company will require substantial additional capital to further develop both Progenta(TM) and Androxal(TM). We intend to raise additional funds through the sale of shares of the Company's

stock sometime in the future. We cannot assure that additional funding will be available on acceptable terms, or at all. The Company believes that its existing capital resources under its current operating plan will be sufficient to fund the Company's operations through the end of June 2005. There can be no assurance that changes in our current strategic plans or other events will not result in accelerated or unexpected expenditures.

As of June 30, 2004, the Company had an accumulated deficit of $84.6 million. Losses have resulted principally from costs incurred in conducting clinical trials for VASOMAX(R), the Company's previous lead product candidate for the oral treatment for male erectile dysfunction, and the related female sexual dysfunction product, in research and development activities related to efforts to develop the Company's other products and from the associated administrative costs required to support those efforts.

PROGENTA(TM)

On June 29, 2004, the Company announced that it would initiate a 30-patient, randomized European Phase I/II clinical trial comparing Progenta(TM) to placebo and to a positive control group consisting of an approved gonadotropin releasing hormone agonist ("GnRHa") in treating women that were previously diagnosed with uterine fibroids. As of August 10, 2004, eight patients have entered this clinical study. All eight patients have entered or are about to enter the second phase of the study, which is the efficacy testing phase. To date, Progenta(TM) has been both well absorbed and well tolerated at all dose levels administered. The Company anticipates top-level data from this trial to be available by the year-end 2004. This clinical trial is being conducted in Warsaw, Poland. Progenta(TM) is an orally-active Selective Progesterone Receptor Modulator ("SPRM") that blocks the progesterone receptor. Progenta(TM) was one of several compounds licensed from the National Institutes of Health ("NIH") in 1999 and was selected as a lead candidate following numerous studies conducted by both the NIH and Zonagen.

Although this study is the first human experience with Progenta(TM), several animal studies, including a long-term (9-month) primate study, had been previously conducted exploring both the safety and activity of the drug. Patients will be referred to the trial by several gynecological practices in Warsaw, Poland. They will be randomized into one of five parallel groups; placebo, three different doses of Progenta(TM), and a positive control group consisting of an approved GnRHa. Currently, GnRHa's are the gold standard of drug therapy for the indication and used most frequently prior to hysterectomy. The placebo and Progenta(TM) groups will be blinded. The study consists of three phases. Day 1 dosing will be followed for both initial safety and pharmacokinetics. Following a one week washout and safety assessment, women will take the drug for an additional 30 days after which time they will be readmitted into the clinic to evaluate steady state pharmacokinetics, effects on fibroid size, bone mineral density and hemoglobin. Women showing positive effects on

fibroid volume and hemoglobin without adverse reactions will be allowed to continue in the trial for an additional two months. Women not experiencing a benefit with the study drug will be allowed to switch to the GnRHa for the duration of the study. At the end of the study, women on Progenta(TM) will be evaluated for changes in bone mineral density, hemoglobin levels and fibroid size and compared against the changes experienced by the positive control group dosed with the GnRHa.

Uterine fibroids are common benign tumors of the uterus. They grow from the muscular wall of the uterus and are made up of muscle and fibrous tissue and may cause heavy bleeding, pelvic discomfort and pain, and create pressure on other organs. As many as 70% of all women have uterine fibroids. While the majority usually have no symptoms, 1 in 4 end up with symptoms severe enough to require treatment. In the United States, roughly 200,000 hysterectomies are performed annually due to uterine fibroids.

Zonagen has also engaged a clinical research organization ("CRO") to prepare for a pre-Investigational New Drug ("IND") meeting it plans to hold with the Food and Drug Adminstration ("FDA") later this year to discuss a U.S. program for Progenta(TM). At a later date, and depending on available funds, Zonagen also plans to test the potential of Progenta(TM) in the treatment of endometriosis. The safety data from this first study should be directly applicable to the endometriosis program.

ANDROXAL(TM)

We are developing Androxal(TM) for the treatment of men with abnormally low testosterone levels, a condition also known as hypogonadism. This condition is associated with a host of physical and mental conditions experienced by the aging male, including loss of muscle tone, reduction of libido and deterioration of memory and certain cognitive functions. Androxal(TM) is an orally administered compound that results in increased production of testosterone by the body. Between four and five million men are estimated to have low testosterone in the United States alone.

Current testosterone replacement therapies deliver additional testosterone either orally, transdermally or via injection. However, current products have two significant limitations. First, the use of oral androgens, injectable or transdermal testosterone results in abnormal spikes and drops in testosterone blood levels, instead of naturally-occurring circadian variation of testosterone levels. The leading testosterone replacement product in the United States, Androgel(R), is a topical gel formulation of testosterone. While transdermal drugs can produce more constant drug levels than other products, Androgel(R) causes abnormal spikes after application, which can produce side effects such as excitation, aggressive behavior, sleeplessness, anxiety, depression and headache. Androgel(R) sales in 2003 were approximately $282 million. Further, transdermal delivery of testosterone results in elevated levels of dihydrotestosterone ("DHT"), a conversion product of testosterone. The effects of these high levels are not well known, and we hope that the FDA will respond favorably to the relatively lower levels of DHT produced by Androxal(TM), as described below. We believe that Androxal(TM) could be the first oral therapy approved in this market without the side effects caused by unnatural peaks and troughs in hormone blood levels.

In July 2004, we released results from a randomized clinical trial comparing Androxal(TM) to placebo and to Androgel(R) in hypogonadal men. The trial enrolled 62 clinically diagnosed hypogonadal men with testosterone levels less than 300 ng/dL, whereas normal levels range from 298 to 1034 ng/dL. Patients were randomized into six different arms, three doses of Androxal(TM), placebo, and both high and low doses of Androgel(R). The placebo and Androxal(TM) doses were

administered in a double-blind fashion, and Androgel(R) was administered as an open label treatment. Following a two week drug treatment, patients were followed for an additional seven to 10 days to evaluate their testosterone levels. There were no side effects noted in either the Androxal(TM) or Androgel(R) arms of the study that were statistically different than placebo. Furthermore, all three doses produced statistically significant changes in testosterone from baseline testosterone levels. The low, mid and high doses of Androxal(TM) achieved mean increases of 169, 247 and 294 ng/dL, respectively (p=0.0053, 0.0002 and 0.0005) as compared to baseline. There were no statistically significant changes within the placebo group (mean decrease from baseline of -1 ng/dL, p=0.96). Seven of 10 men in the low dose group, 10 of 11 in the mid dose group and 10 of 10 men in the high dose group had restoration of normal testosterone levels.

Comparing average testosterone levels during the trial period, all three doses of Androxal(TM) achieved blood levels of total testosterone that were statistically indistinguishable from the highest dose of Androgel(R) 10G. In

each patient studied, Androxal(TM) also produced average testosterone levels below 1000 ng/dL at day 14, whereas several Androgel(R) patients had average testosterone levels far above the normal range. In the subset of men whose blood testosterone levels were measured six times over a 24-hour period, three of five men on the higher Androgel(R) dose had multiple measurements above the normal range. In contrast, only one man out of 15 on Androxal(TM) had a single measurement above the normal range.

Our Androxal(TM) product candidate is covered by pending patent applications that cover its use for the treatment of hypogonadism in the United States and the major foreign markets. A third party holds an issued patent covering the use of the parent compound in Androxal, for use in the treatment of hypogonadism. As it stands, this patent may block our use of Androxal(TM) for this indication. However, following our request for reexamination of the cited patent in light of several prior art arguments, the U.S. Patent and Trademark Office ("PTO") has begun reexamination proceedings of the patent. We can not be certain that the existing patent will be reversed.

For a detailed discussion regarding the development, scientific rationale and risks involving both Progenta(TM) and Androxal(TM) and a discussion of our prior product candidates, see "Part I. Item 1. Business" included in the Company's annual report on Form 10-K for the year ended December 31, 2003.

CLASS ACTION LAWSUIT UPDATE

On June 16, 2004, the United States Court of Appeals for the Fifth Circuit affirmed the June 13, 2003 judgment of the United States District Court for the Southern District of Texas dismissing the one claim remaining from the consolidated class action lawsuit described in the Company's SEC filings. In addition, on July 15, 2004, the Court of Appeals denied the plaintiff's request for a rehearing. The time for the plaintiff to file a writ of certiorari with the United States Supreme Court has not yet expired.

NASDAQ SMALLCAP MARKET LISTING

In January 2004, Zonagen purchased of 6,547,635 shares of its common stock (approximately 57% of its outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of its self tender offer, which expired on January 7, 2004. This purchase included 60,888 shares issuable upon exercise of options for a total aggregate purchase price of approximately $13.7 million, exclusive of approximately $289,000 of costs associated with the offer. As of June 30, 2004, the Company had 4,992,901 shares outstanding.

On July 8, 2004 Zonagen's stock transferred from the Nasdaq National Market to the Nasdaq SmallCap Market after Nasdaq had approved the Company's application for this transfer. The Company applied for a Nasdaq SmallCap Market listing after Nasdaq had informed the Company that it no longer met the $10,000,000 minimum stockholders' equity listing requirement for the Nasdaq National Market. This shortfall was a result of the previously concluded, January 2004, self tender offer.

OFFICE LEASE

The Company executed a new 74 month lease effective May 1, 2004, for 4,800 square feet of laboratory and office space located in its current building in The Woodlands, Texas. This space replaces its prior 2,518 square foot facility which was under a lease that expired on June 30, 2004.

RESULTS OF OPERATIONS

Three Month and Six Month Periods Ended June 30, 2004 and 2003

Revenues. Total revenues for the three month period ended June 30, 2004 decreased to $75,000 as compared with $393,000 for the same period in the prior year and were approximately $200,000 for the six-month period ended June 30, 2004 as compared to $625,000 for the same period in the prior year.

Research and development grant revenues for the three-month period ended June 30, 2004 were $53,000 as compared to $217,000 for the same period in the prior year and were $117,000 for the six-month period ended June 30, 2004 as compared to $337,000 for the same period in the prior year. Grant revenue relates to three SBIR grants that were awarded to the Company in the third quarter ended September 30, 2002. The Company performed a portion of that paid research under its one existing $836,441 Phase II grant during the three-month period ended June 30, 2004 as compared to the research that was performed under three SBIR grants during the same period in the prior year. Two of the awarded SBIR grants were depleted during 2003 and the last existing grant for $836,441 has essentially been depleted during the second quarter ended June 30, 2004.

Interest income decreased 70% to $22,000 for the three-month period ended June 30, 2004, as compared to $74,000 for the same period in the prior year and was $48,000 for the six-month period ended June 30, 2004 as compared to $186,000

for the same period in the prior year. This decrease is primarily due to the reduction in investment cash on hand as a result of the Company completing its self tender offer for an approximate aggregate purchase price of $13.7 million, which was exclusive of approximately $289,000 of costs associated with the offer, that was completed in January 2004.

In the three-month period ended June 30, 2003 the Company sold substantially all of its fixed assets, in preparation of an anticipated potential strategic alternative transaction, for approximate net proceeds of $225,000, which was $102,000 over their book value. At that time management felt that these assets were not required to redeploy the Company's overall assets.

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

Research and Development Expenses. Research and development ("R&D") expenses include contracted research, regulatory affairs activities and general research and development expenses. R&D expenses decreased 12% to $508,000 for the three-month period ended June 30, 2004 as compared to $579,000 for the same period in the prior year and decreased 14% to $985,000 for the six-month period ended June 30, 2004 as compared to $1.1 million for the same period in the prior year. Reimbursed R&D expenses relating to the Company's SBIR grants were $166,000 less for the three-month period ended June 30, 2004 as compared to the same period in the prior year and were $209,000 less for the six-month period ended June 30, 2004 as compared to the same period in the prior year. In addition, during the six-month period ended June 30, 2003, the Company reduced its research staff and incurred a $122,000 severance charge. During the three and six-month periods ended June 30, 2004 the Company prepared for the start of its Progenta(TM) European Phase I/II clinical study and also continued working toward the completion of its U.S. Phase I/II human clinical study with Androxal(TM). The Company also continued its early development work with Progenta(TM) as an oral treatment for endometriosis, which was funded under a Phase II $836,441 SBIR grant that was essentially depleted by June 30, 2004.

General and Administrative Expenses. General and administrative ("G&A") expenses decreased 40% to $294,000 for the three-month period ended June 30, 2004, as compared to $490,000 for the same period in the prior year and decreased 34% to $728,000 for the six-month period ended June 30, 2004 as compared to $1.1 million for the same period in the prior year. The decrease in expenses for the three-month and six-month periods ended June 30, 2004 is primarily due to a decrease in costs associated with the search for a potential strategic alternative, a reduction in D&O insurance costs and a reduction in facility related costs due to facility downsizing.

LIQUIDITY AND CAPITAL RESOURCES

The Company has incurred losses since its inception in 1987 and expects to continue to incur losses for the foreseeable future. Since inception, the Company has financed its operations primarily with proceeds from private placements and public offerings of equity securities, with funds received under collaborative agreements and SBIR grants. The Company's primary use of cash to date has been in operating activities to fund research and development, including preclinical studies and clinical trials, and general and administrative expenses. The Company believes its current financial resources are adequate to complete its European Phase I/II human safety and efficacy study of Progenta(TM) and to complete its ongoing data management of its U.S. Phase I/II clinical study with Androxal(TM). The Company believes that its existing capital

resources under its current operating plan will be sufficient to fund operations through the end of June 2005.

The Company will require substantial funds to continue the development of Progenta(TM) and Androxal(TM). The ability of the Company to raise additional funds will depend on many factors, including the progress of the Company's clinical development programs. There can be no assurance that the Company will be able to obtain financing on favorable terms in the public or private capital markets, or at all. The failure or inability of the Company to obtain additional financing on acceptable terms would have a material adverse effect on the Company.

In January 2004, Zonagen purchased 6,547,635 shares of its common stock (approximately 57% of its outstanding common stock) at a purchase price of $2.10 per share in accordance with the terms of its self tender offer, which expired on January 7, 2004. This purchase included 60,888 shares issuable upon exercise of options for a total aggregate purchase price of approximately $13.7 million, exclusive of approximately $289,000 of costs associated with the offer. As of

June 30, 2004, the Company had 4,992,901 shares outstanding.

The Company had cash, cash equivalents and marketable securities of approximately $7.6 million at June 30, 2004, as compared to $22.9 million at December 31, 2003. Excluding maturities and purchases of marketable securities of ($250,000) and ($10.3) million in the three-month period ended June 30, 2004 and 2003, respectively, net cash of approximately $628,000 was used in operating activities during the three-month period ended June 30, 2004 as compared to $1.2 million used for the same period in the prior year. The decreased use of cash for the three-month period ended June 30, 2004 as compared to the same period in the prior year is primarily due to a decrease in research and development costs associated with Androxal(TM), a decrease in costs associated with potential strategic alternatives, a decrease in D&O insurance costs and a reduction in facility related costs due to facility downsizing.

Excluding maturities and purchases of marketable securities of ($4.4) million and ($4.3) million in the six-month period ended June 30, 2004 and 2003, respectively, net cash of approximately $1.3 million was used in operating activities during the six-month period ended June 30, 2004 as compared to $1.9 million used for the same period in the prior year. The decreased use of cash for the six-month period ended June 30, 2004 as compared to the same period in the prior year is primarily due to a decrease in costs associated with potential strategic alternatives, a decrease in D&O insurance costs, a decrease in research and development costs associated with Androxal(TM) and a reduction in facility related costs due to facility downsizing offset by an increase in research and development costs associated with Progenta(TM).

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

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) 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, 2004 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Certain purported class action complaints alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, and Rule 10b-5 thereunder were filed against the Company and certain of its officers and directors in 1998. These complaints were filed in the United States District Court for the Southern District of Texas (the "District Court") in Houston, Texas and were consolidated on May 29, 1998. The plaintiffs purported to bring the suit on behalf of all purchasers of Zonagen common stock between February 7, 1996 and January 9, 1998. The plaintiffs asserted that the defendants made materially false and misleading statements and failed to disclose material facts about the patents and patent applications of the Company relating to VASOMAX(R) and Chito-ZN (formerly named ImmuMax(TM)) and about the Company's clinical trials of VASOMAX(R). The plaintiffs sought to have the action declared to be a class action, and to have recessionary or compensatory damages in an unstated amount, along with interest and attorney's fees. On March 30, 1999, the District Court granted the defendants' motion to dismiss and dismissed the case with prejudice. The plaintiffs filed an appeal. On September 25, 2001, the United States Fifth Circuit Court of Appeals (the "Fifth Circuit") affirmed the dismissal of all claims except one; the Fifth Circuit reversed the District Court's dismissal of a claim concerning the Company's disclosure about a patent relating to VASOMAX(R). On June 13, 2003, the District Court granted the defendants' motion for summary judgment as to that last remaining claim, and entered a judgment dismissing the case with prejudice. The plaintiffs filed an appeal. On June 16, 2004, the Fifth Circuit affirmed the June 13, 2003 judgment of the District Court . In addition, on July 15, 2004, the Fifth Circuit denied the plaintiff's request for a rehearing. The time for the plaintiff to file a writ of certiorari with the United States Supreme Court has not yet expired.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. 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).

b Reports on Form 8-K

The Company filed five current reports on Form 8-K, three of which were filed under Item 5 on April 1, June 28 and June 29, 2004 and two of which were filed under Item 12 on April 1 and May 10, 2004.

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: August 12, 2004

By: /s/ Joseph S. Podolski

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

Date: August 12, 2004

By: /s/ Louis Ploth, Jr.

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

EXHIBIT 31.1

I, Joseph S. Podolski, certify that:

1. I have reviewed this quarterly report of Zonagen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 12, 2004

By: /s/ Joseph S. Podolski

Joseph S. Podolski
President and
Chief Executive Officer
Zonagen, Inc.

EXHIBIT 31.2

I, Louis Ploth, Jr., certify that:

1. I have reviewed this quarterly report of Zonagen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: August 12, 2004

By: /s/ Louis Ploth, Jr.

Louis Ploth, Jr.
Vice President Business Development and
Chief Financial Officer
Zonagen, Inc.

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Zonagen, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joseph S. Podolski, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2004

By: /s/ Joseph S. Podolski

Joseph S. Podolski
President and
Chief Executive Officer
Zonagen, Inc.

A signed original of this written statement required by Section 906 has been provided to Zonagen and will be retained by Zonagen and furnished to the Securities and Exchange Commission or its staff upon request.

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Zonagen, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Louis Ploth, Jr., Vice President Business Development and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 12, 2004

By: /s/ Louis Ploth, Jr.

Louis Ploth, Jr.
Vice President Business Development and
Chief Financial Officer
Zonagen, Inc.

A signed original of this written statement required by Section 906 has been provided to Zonagen and will be retained by Zonagen and furnished to the Securities and Exchange Commission or its staff upon request.