

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

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

#### ZONAGEN INC

CIK: **897075** | IRS No.: **760233274** | State of Incorpor.: **DE** | Fiscal Year End: **1231**  
Type: **8-K** | Act: **34** | File No.: **001-15281** | Film No.: **04970948**  
SIC: **2836** Biological products, (no diagnostic substances)

#### Mailing Address

2408 TIMBERLOCH PLACE B-42408 TIMBERLOCH PL  
THE WOODLANDS TX 77380

#### Business Address

SUITE B-4  
WOODLANDS TX 77380  
2813675892

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

FORM 8-K

CURRENT REPORT FILED PURSUANT TO SECTION 13 OR 15(D) OF  
THE SECURITIES EXCHANGE ACT OF 1934

DATE OF REPORT  
(DATE OF EARLIEST EVENT REPORTED): AUGUST 12, 2004

ZONAGEN, INC.  
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

0-21198  
(COMMISSION  
FILE NUMBER)

76-0233274  
(I.R.S. 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)

ITEM 5. OTHER INFORMATION

On August 12, 2004, Zonagen, Inc. (the "Company") announced in a press release that the 2004 Annual Meeting of Stockholders of the Company will be held on Wednesday, September 29, 2004, at 1:00 p.m., Eastern Standard Time, at the Marriott, New York East Side Hotel, 525 Lexington Avenue, New York, New York. A Notice of the Annual Meeting, Proxy Statement and form of Proxy will be provided to shareholders of record as of August 20, 2004.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS

c. Exhibits

Exhibit Number -----	Description -----
99.1	Press Release dated August 12, 2004.

ITEM 12. RESULTS OF OPERATIONS AND FINANCIAL CONDITION

The Company announced in a press release dated August 12, 2004 its financial results for the three months and six months ended June 30, 2004. A copy of the Company's press release is attached hereto as Exhibit 99.1. The press release is incorporated by reference herein and the foregoing description of the press release is qualified in its entirety by reference to the attached exhibit.

The information in this report, including the Exhibit, is being furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. In addition, the information in this report, including the Exhibit, shall not be incorporated by reference into the filings of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZONAGEN, INC.

Date: August 12, 2004.

By: /s/ LOUIS PLOTH, JR.

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

EXHIBIT INDEX

Exhibit  
Number  
-----

Description  
-----

99.1

Press Release dated August 12, 2004.

Contact: Joseph S. Podolski  
 President & CEO  
 (281) 719-3447

ZONAGEN REPORTS SECOND QUARTER 2004 FINANCIAL RESULTS AND  
 PROVIDES INITIAL PROGENTA(TM)CLINICAL STUDY SAFETY DATA

ALSO ANNOUNCES ITS 2004 ANNUAL MEETING OF STOCKHOLDERS

The Woodlands, TX, August 12, 2004 - Zonagen, Inc. (Nasdaq: ZONA and PCX: ZNG) today announced financial results for the three-month and six-month periods ended June 30, 2004.

The Company has continued its focus on its near term business strategy of concentrating its resources on the clinical development of Progenta(TM), for the treatment of uterine fibroids, and the completion of our U.S. human Phase I/II clinical study of Androxal(TM), for the treatment of male hormonal deficiency.

On June 29, 2004, the Company announced that it would initiate a 30 patient European Phase I/II study of its lead program Progenta(TM), which is an orally administered drug being clinically developed for the treatment of uterine fibroids. 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, Progenta(TM) 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 to placebo and to Androgel(R) in testosterone deficient men. 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 high and low doses of Androgel(R). All three doses of Androxal(TM) achieved statistically significant results over the placebo group.

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.

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.

Financial Results

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 grants 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 Small Business Research ("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 for a strategic alternative transaction, which management felt were not required to redeploy the Company's overall assets, for approximate net proceeds of \$225,000, which was \$102,000 over their book value.

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 ("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 ("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.

Net loss for the three-month period ended June 30, 2004, was (\$727,000) or (\$0.15) per share as compared to a net loss of (\$676,000) or (\$0.06) per share for the same period in the prior year. Net loss for the six-month period ended June 30, 2004, was (\$1.5) million or (\$0.29) per share as compared to a net loss of (\$1.6) million or (\$0.14) per share for the same period in the prior year. Although the loss for the three-month and six-month periods ended June 30, 2004 was \$51,000 greater and \$107,000 less, respectively, than the same period in the prior year, the loss per share was significantly greater due to the Company's smaller share base which was the result of the completion of the Company's self tender offer completed in January 2004. The increased loss for the three-month period ended June 30, 2004 was primarily due to a reduction in SBIR grant revenue in 2004 and a one time gain on disposal of fixed assets in 2003 offset by a reduction in total expenses. The decreased loss for the six-month period ended June 30, 2004 as compared to the same period in the prior year was primarily due to reduced total expenses offset by a reduction in revenues from interest income, research and development grants and a one time gain on disposal of fixed assets in 2003.

#### 2004 Annual Meeting of Stockholders

The 2004 Annual Meeting of Stockholders of Zonagen, Inc. will be held on Wednesday, September 29, 2004, at 1:00 p.m., Eastern Standard Time, at the Marriott, New York East Side Hotel, 525 Lexington Avenue, New York, New York. A Notice of the Annual Meeting, Proxy Statement and form of Proxy will be provided to shareholders of record as of August 20, 2004.

Any statements that are not historical facts contained in this release are forward-looking statements that involve risks and uncertainties including Zonagen's ability to have success in the clinical development of its

technologies, Zonagen's ability to raise additional capital on acceptable terms or at all, uncertainty relating to Zonagen's patent portfolio, Zonagen's ability to have success in meeting governmental regulations and the costs and time required to meet such regulatory requirements, manufacturing uncertainties related to Progenta, the Company's ability to remain listed on Nasdaq, and such other risks identified in Zonagen's Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission (SEC). These documents are available on request from Zonagen or at www.sec.gov. Zonagen disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

ZONAGEN, INC. AND SUBSIDIARY  
(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS  
(in thousands except per share amounts)

<TABLE>  
<CAPTION>

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30,		JUNE 30,	
	2004	2003	2004	2003
	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)	(UNAUDITED)
<S>	<C>	<C>	<C>	<C>
Revenues				
Research and development grants	\$ 53	\$ 217	\$ 117	\$ 337
Interest income	22	74	48	186
Gain on disposal of fixed assets	-	102	-	102
Other Income	-	-	35	-
Total revenues	75	393	200	625
EXPENSES				
Research and development	508	579	985	1,143
General and administrative	294	490	728	1,102
Total expenses	802	1,069	1,713	2,245
NET LOSS	\$ (727)	\$ (676)	\$ (1,513)	\$ (1,620)
NET LOSS PER SHARE	\$ (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>

CONSOLIDATED BALANCE SHEETS

<TABLE>  
<CAPTION>

	JUNE 30,	DECEMBER 31,
	2004	2003
	(UNAUDITED)	
<S>	<C>	<C>
Cash and cash equivalents	\$ 1,215	\$ 20,946
Marketable securities	6,350	2,000
Other current assets	224	235
Fixed assets (net)	12	-
Other assets (net)	637	847
Total assets	\$ 8,438	\$ 24,028
Accounts payable and accrued expenses	\$ 418	\$ 541
Stockholders' equity	8,020	23,487
Total liabilities and stockholders' equity	\$ 8,438	\$ 24,028

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