ZONAGEN INC
Form 8-K
July 12, 2001

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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): JULY 10, 2001

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

DELAWARE	0-21198	76-02
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(COMMISSION FILE NUMBER)	(I.R.S. EMPLOYER I

2408 TIMBERLOCH PLACE, SUITE B-4
THE WOODLANDS, TEXAS 77380
(ADDRESS OF PRINCIPAL
EXECUTIVE OFFICES
AND ZIP CODE)

(281) 719-3400
(REGISTRANT'S TELEPHONE NUMBER,
INCLUDING AREA CODE)

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ITEM 9. REGULATION FD DISCLOSURE

Zonagen, Inc. (the "Company") is furnishing the following information under Item 9 of this Current Report on Form 8-K in accordance with Regulation FD promulgated by the Securities and Exchange Commission:

At the Annual Meeting of Stockholders of the Company held July 10, 2001, Company representatives stated that the mechanistic rat study of Vasomax(R) concerning brown fat proliferations was ongoing and that the Company had completed the gross part of the interim 6-month assessment. The Company representatives stated that no hibernomas had been found in any animals, young or old. The Company representatives also stated that the Company will be sending the interim analysis to the Food and Drug Administration ("FDA") as soon as completed, which the Company hopes can occur before the end of the summer.

The Company representatives stated that the interim findings are not conclusive and no results concerning the mechanistic rat study may be based upon, or inferred from, the interim findings. The Company anticipates that final

data from the study will not be available for FDA submission until the first half of 2002.

Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995:

Statements made in this filing which relate to future events are made pursuant to the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based upon current expectations and the Company assumes no obligation to update this information. Because actual results may differ materially from expectations, the Company cautions readers not to place undue reliance on these statements. These forward-looking statements involve risks and uncertainties, including, but not limited to, those relating to the uncertainties involving the Company's early stage of development, clinical trial results and FDA approval in the United States and approval of regulatory authorities in other jurisdictions, substantial dependence on one product, history of operating losses, future capital needs and uncertainty of additional funding, uncertainty of protection for patents and proprietary technology, litigation, governmental regulation, limited sales and marketing experience and dependence upon collaborators, manufacturing uncertainties and reliance on third parties, competition and technology change, product liability and availability of insurance, and other risks identified in the Company's Annual Report on Form 10-K for the year ended December 31, 2000, as filed with the Securities and Exchange Commission.

The information in this Current Report is furnished pursuant to Item 9 and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section. This Current Report will not be deemed an admission as to the materiality of any information contained herein that is required to be disclosed solely by Regulation FD.

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: July 11, 2001

By: /s/ JOSEPH S. PODOLSKI

Joseph S. Podolski
Chief Executive Officer