ZONAGEN INC Form 10-K/A April 29, 2005

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

FORM 10-K/A

(Amendment No. 1)

Þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

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 No. 001-15281

ZONAGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 76-0233274 (IRS Employer Identification No.)

2408 Timberloch Place, Suite B-1 The Woodlands, Texas (Address of principal executive offices) 77380 (Zip code)

(281) 719-3400

(Registrant s telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class

Common Stock, \$.001 par value Rights to purchase Series One Junior Participating Preferred Stock Name of Each
Exchange on Which Registered

Pacific Exchange, Inc. Pacific Exchange, Inc.

Securities Registered Pursuant to Section 12(g) of the Act:

Title of Each Class

Name of Each
Exchange on Which Registered

Common Stock, \$.001 par value Rights to purchase Series One Junior Participating Preferred Stock Nasdaq SmallCap Market Nasdaq SmallCap Market

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 preceding 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 b No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. b

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes o No b

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$11,000,000 as of June 30, 2004, the last business day of the registrant s most recently completed second fiscal quarter, based on the closing sales price of the registrant s common stock on the Nasdaq National Market on such date of \$2.56 per share. For purposes of the preceding sentence only, all directors, executive officers and beneficial owners of ten percent or more of the shares of the registrant s common stock are assumed to be affiliates.

As of December 31, 2004, there were 4,992,901 common shares outstanding and as of March 16, 2005, there were 10,079,601 shares of the registrant s common stock outstanding.

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Certification of CEO Pursuant to Rule 13a-14(a)

Certification of CFO Pursuant to Rule 13a-14(a)

Certification of CEO Pursuant to Section 906

Certification of CFO Pursuant to Section 906

EXPLANATORY NOTE

We are filing this amendment to our Annual Report on Form 10-K, originally filed with the Securities and Exchange Commission on March 30, 2005, solely for the purpose of amending and supplementing Part III of the Annual Report on Form 10-K. This amendment changes our Annual Report only by including the information required by Part III (Items 10, 11, 12, 13 and 14) of Form 10-K. In addition, we are also including Exhibits 31.1, 31.2, 32.1 and 32.2 as required by the filing of this amendment.

PART III

Item 10. Directors and Executive Officers of the Registrant

Directors

The names of the Company s directors, and certain additional information with respect to each of them, are set forth below.

| Name | Age | Position with the Company | Year First Became Director |
|---------------------------------------|-----|------------------------------------|-------------------------------------|
| Joseph S. Podolski | 57 | President and Chief Executive | 1992 |
| | | Officer and Director | |
| Louis Ploth, Jr. | 51 | Vice President, Business | 2004 |
| | | Development, Chief Financial | |
| | | Officer and Secretary and Director | |
| Daniel F. Cain | 59 | Director | 2004 |
| Jean L. Fourcroy, M.D., Ph.D., M.P.H. | 74 | Director | 2004 |
| Nola Masterson | 58 | Director | 2004 |
| David Poorvin, Ph.D. | 58 | Director | 2004 |

Joseph S. Podolski. Mr. Podolski joined the Company in 1989 as Vice President of Operations and has served as President and Chief Executive Officer of the Company and as a director since 1992. Previously, Mr. Podolski spent twelve years in various engineering, product development and manufacturing positions at G.D. Searle, a subsidiary of Monsanto Company. Before joining Monsanto, Mr. Podolski held positions in manufacturing, engineering, quality control and development of fine chemicals, antibiotics, pharmaceuticals and hospital products with Abbott Laboratories, Dearborn Chemical Company and Baxter Pharmaceuticals. Mr. Podolski holds a M.S. degree in chemical engineering from the Illinois Institute of Technology.

Louis Ploth, Jr. Since January 2001, Mr. Ploth has served as Chief Financial Officer, Vice President, Business Development and Secretary. He served as Vice President, Finance from March 1999 to January 2001. He had previously served as Chief Financial Officer and Vice President, Business Development from 1993 to 1998 and as Chief Financial Officer from 1998 to March 1999 at which time he also served as General Manager of Fertility Technologies, Inc., a former subsidiary of the Company. Previously, Mr. Ploth was employed by Unisyn Technologies where he served concurrently as Chief Financial Officer and as Vice President of Finance and Administration. Mr. Ploth was also Corporate Controller of Synbiotics Corporation. Mr. Ploth has over 23 years of corporate financial and

business development experience, with over 19 years experience in the biotechnology industry. Mr. Ploth has a B.S. degree from Montclair State College.

Daniel F. Cain. Since October 1994, Mr. Cain has provided consulting services for small businesses. Since May 2000, he has also served as acting chief executive officer of Wireless Medical, Inc., a Colorado-based medical device company, and Enet Biz, a Colorado-based consulting firm. From 1969 to 1994, Mr. Cain held various positions with Miles Laboratories, Inc., Hexcel Corporation, Scripps-Miles, Inc., Synbiotics Corporation and Heska Corporation. Mr. Cain has 35 years of broad business experience including 26 years with medical companies. Sixteen of these years were with three different biotech startup companies, one of which he co-founded. Mr. Cain has held a wide variety of executive level management positions including chief executive officer, president and chief financial officer. Mr. Cain earned a B.S. degree from LeTourneau College and a M.B.A. degree from Indiana University.

Jean L. Fourcroy, M.D., Ph.D., M.P.H. Dr. Fourcroy was engaged as a Medical Officer with the U.S. Food and Drug Administration (the FDA) from 1988 to 2001. Since leaving the FDA, Dr. Fourcroy has been a consultant to the industry and a featured speaker and panel member in numerous meetings and symposia. Dr. Fourcroy is a member of the Board of Directors of the U.S. Anti-Doping Agency and is a Past President of the American Medical Women s Association. Dr. Fourcroy is the recipient of a 1998 American Urological Association Presidential Citation Award, the 1999 Camille Mermod Award from the American Medical Women s Association, and an Outstanding Service Award from the American Society of Andrology in April 2000. Dr. Fourcroy received her M.D. from the Medical College of

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Pennsylvania and her Ph.D. from the University of California at San Francisco. Her surgery and urology residencies were completed at George Washington University Medical Center with Board Certification in Urology in 1981. In 1999, she received her Masters in Public Heath from the Medical College of Wisconsin.

Nola Masterson. Ms. Masterson has 29 years of experience in the life science industry. Ms. Masterson has been the chief executive officer of Science Futures Inc., an investment and advisory firm, since 1982. Ms. Masterson is currently Managing Member and General Partner of Science Futures LLC, I, II & III, which are all venture capital funds invested in life science funds and companies. She also serves as a Senior Advisor to TVM Techno Venture Management, an international venture capital company. Ms. Masterson was the first biotechnology analyst on Wall Street, working with Drexel Burnham Lambert and Merrill Lynch, and is a co-founder of Sequenom, Inc., a genetic analysis company located in San Diego and Hamburg, Germany. She also started the BioTech Meeting in Laguna Nigel, CA, the annual Biopharmaceutical Conference in Europe, and was nominated to the 100 Irish American Business List in 2003. Ms. Masterson began her career at Ames Company, a division of Bayer, and spent eight years at Millipore Corporation in sales and sales management. She received her Masters in Biological Sciences from George Washington University, and continued Ph.D. work at the University of Florida.

David Poorvin, Ph.D. Dr. Poorvin has over 30 years of experience in the pharmaceutical industry and is currently an Executive-in-Residence at Oxford Bioscience Partners, a venture capital company. Dr. Poorvin also is engaged in private consulting for biotech companies. At the end of 2003, Dr. Poorvin retired from Schering-Plough Corporation as Vice President of their Business Development operations where he negotiated licenses, joint ventures and acquisitions of pharmaceutical products and research technologies. Dr. Poorvin s career at Schering Plough from 1981 to 2003 included 14 years in Business Development as well as tenure as the Director of Clinical Research at Schering-Plough, a position he also held at Pfizer Pharmaceuticals from 1977 to 1981. He was responsible for several NDA programs and product approvals at both companies, including such drugs as Procardia and Imdur. Dr. Poorvin started his career in the pharmaceutical industry at Lederle Laboratories from 1973 to 1977, where he directed pre-clinical research in the cardiovascular area. He received his B.A. degree from Hunter College of the City University of New York and his Ph.D. from Rutgers University.

Audit Committee

The Board of Directors has an Audit Committee, which is currently comprised of Mr. Cain, Chairman, Ms. Masterson and Dr. Poorvin. As required by The Nasdaq Stock Market and the Securities and Exchange Commission (the Commission) rules regarding audit committees, the Board of Directors has reviewed the qualifications of its Audit Committee and has determined that none of the current members of the Audit Committee have a relationship with the Company that might interfere with the exercise of their independence from the Company or its management and has determined that each member of the Audit Committee is independent, as independence is defined in the listing standards for The Nasdaq Stock Market. The Board of Directors has determined that Mr. Cain, Chairman of the Audit Committee, is an audit committee financial expert as described in Item 401(h) of Regulation S-K.

Executive Officers

Set forth below is certain information concerning the executive officers of the Company, including the business experience of each during the past five years.

| Name | Age | Position |
|--------------------|-----|--|
| Joseph S. Podolski | 57 | President, Chief Executive Officer, and Director |
| Louis Ploth, Jr. | 51 | Vice President, Business Development, Chief |

Financial Officer, Secretary and Director

Information pertaining to Messrs. Podolski and Ploth, who are both directors and executive officers of the Company, may be found in Directors.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company s directors and officers, and persons who own more than 10% of the Common Stock, to file initial reports of ownership and reports of changes in ownership (Forms 3, 4, and 5) of Common Stock with the Securities and Exchange Commission (the SEC). Officers,

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directors and greater than 10% stockholders are required by SEC regulation to furnish the Company with copies of all such forms that they file.

To the Company s knowledge, based solely on the Company s review of the copies of such reports received by the Company and on written representations by certain reporting persons that no reports on Form 5 were required, the Company believes that during the fiscal year ended December 31, 2004, all Section 16(a) filing requirements applicable to its officers, directors and 10% stockholders were complied with in a timely manner.

Code of Ethics

The Company has adopted a Code of Business Conduct and Ethics for directors, officers and employees and a Code of Ethics for Senior Financial Officers, which are available on the Corporate Governance Section of the Company s website at http://www.zonagen.com. If any substantive amendments are made to either code, the nature of such amendment will be disclosed on the Company s website. In addition, if a waiver from either code is granted to an executive officer, director or principal accounting officer, the nature of such waiver will be disclosed on the Company s website.

Item 11. Executive Compensation

Directors Meetings and Compensation

The Company's operations are managed under the broad supervision of the Board of Directors, which has ultimate responsibility for the establishment and implementation of the Company's general operating philosophy, objectives, goals and policies. Our Board is currently comprised of a majority of independent directors. The Board has determined that Drs. Fourcroy and Poorvin, Mr. Cain and Ms. Masterson are independent as independence is defined under the listing standards for The Nasdaq Stock Market. The Board based these determinations primarily on a review of the responses our directors provided to questions regarding employment and compensation history, affiliations and family and other relationships. During 2004, the Board of Directors convened on 11 occasions. All directors attended at least 75% of the meetings held by the Board and any committee of the Board on which he or she served during his or her tenure in 2004. The Company's current policy is to have its directors attend the Company's annual meeting of stockholders. All of the Company's directors were available at the Company's 2004 annual meeting of stockholders.

Employee directors do not receive additional compensation for service on the Board of Directors or its committees. The Company reimburses each non-employee director for travel expenses incurred in connection with attendance at Board meetings. For regular board and Committee meetings attended in person or telephonically, non-employee directors currently receive \$2,000 per meeting in cash. Employee directors are eligible to participate in the Company s 2004 Employee and Consultant Stock Option Plan (the Incentive Plan). Non-employee directors are entitled to participate in the Company s 2000 Non-employee Directors Stock Option Plan (the 2000 Director Plan).

Under the 2000 Director Plan, (i) each non-employee director who is first elected to the Board is entitled to receive an option to purchase 40,000 shares of the Company's Common Stock on the date on which he first becomes a non-employee director, and (ii) each non-employee director in office immediately after each subsequent annual meeting of stockholders will receive an option to purchase 5,000 shares of Common Stock effective on such date. Additionally under the 2000 Director Plan, the Chairman of the Board (if a non-employee) who is first elected to the Board is entitled to receive an option to purchase 10,000 shares of Common Stock on the date on which he first becomes Chairman, and the Chairman (if a non-employee) in office immediately after each subsequent annual meeting of stockholders will receive an option to purchase 10,000 shares of Common Stock effective on such date. The Company has not had a Chairman of the Board since January 2004.

During 2004, the Company paid an aggregate of \$53,000 to its non-employee directors. The Company granted options to purchase an aggregate of 215,000 shares of Common Stock to non-employee directors during 2004.

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Compensation of Executive Officers

Summary Compensation Table

The following table provides certain summary information concerning compensation paid or accrued during the last three years to the Company s President and Chief Executive Officer and to the Company s other executive officer who had compensation in excess of \$100,000 during the last fiscal year (the Named Executive Officers):

| | | | | Long | -Term | | |
|--|------|--------------|-------|------------|----------------|------|-------------------------|
| | Annı | ual Compensa | ation | Compo | ensation | | |
| | | | | Restricted | Securities | | |
| | | | | Stock | Underlying | Al | l Other |
| Name and Principal Position | Year | Salary | Bonus | Awards | Options | Comp | ensation ⁽¹⁾ |
| Joseph S. Podolski | 2004 | \$ 298,898 | | | 272,866 | \$ | 6,000(2) |
| President and Chief Executive | 2003 | \$ 280,000 | | | | \$ | $6,000_{(2)}$ |
| Officer | 2002 | \$ 272,708 | | \$ 26,500 | 275,000 | \$ | 6,000(2) |
| Louis Ploth, Jr. | 2004 | \$ 187,533 | | | 165,383 | | |
| Vice President, Business | 2003 | \$ 150,000 | | | | | |
| Development, Chief Financial Officer and Secretary | 2002 | \$ 150,000 | | \$ 26,500 | | | |

⁽¹⁾ During the periods indicated, perquisites for each individual named in the Summary Compensation Table aggregated less than 10% of the total annual salary and bonus reported for such individual in the Summary Compensation Table. Accordingly, no such amounts are included in the Summary Compensation Table.

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⁽²⁾ Represents car allowance.

Option Grants in 2004

The following table provides certain information with respect to options granted to the President and Chief Executive Officer and the other Named Executive Officer during the fiscal year ended December 31, 2004 under the Company s Incentive Plan:

Potential Realizable Value at Assumed Annual Rates of

Stock **Price Appreciation for Option** $Term^{(1)}$ **Individual Grants** Number **Percent** of of **Total Securities Options** Market **Price** Granted **Underlying** to on **Employees** Date **Options** in **Expiration Exercise** of **Fiscal** Granted⁽¹⁾ Year 10% Name **Price** Grant Date 0% 5% Joseph S. Podolski \$ 2.72 272,866(2) 45.4% \$ 2.72 3/29/2014 \$ 466,763 \$ 1,182,869 Louis Ploth, Jr. 165,383(2) 27.5% \$ 2.72 \$ 2.72 3/29/2014 \$ 282,903 716,932

- (1) The Securities and Exchange Commission (the SEC) requires disclosure of the potential realizable value or present value of each grant. The disclosure assumes the options will be held for the full 10-year term prior to exercise. Such options may be exercised prior to the end of such 10-year term. The actual value, if any, an executive officer may realize will depend on the excess of the stock price over the exercise price on the date the option is exercised. There can be no assurance that the stock price will appreciate at the rates shown in the table.
- (2) Of the total number of shares issuable upon exercise of such options, 58,561 shares issuable upon exercise of Mr. Podolski s options and 20,925 shares issuable upon exercise of Mr. Ploth s options related to performance-based options which were tied to certain milestones to be achieved by January 25, 2005 and some of these milestones were not achieved. As a result, only 46,848 shares issuable upon exercise of Mr. Podolski s performance-based options and 16,740 shares issuable upon exercise of Mr. Ploth s performance-based options remain outstanding and have vested. Options to purchase 11,713 shares and 4,185 shares for Messrs. Podolski and Ploth, respectively, have terminated as a result.

Option Exercises and Holdings

The following table sets forth information concerning option exercises and the value of unexercised options held by the President and Chief Executive Officer and the other Named Executive Officer of the Company named in the Summary Compensation Table as of the end of the last fiscal year:

AGGREGATED OPTION EXERCISES IN 2004 AND OPTION VALUES AT DECEMBER 31, 2004

| | | | - 10,,0 0 - 0 | of Securities Unexercised | | Jnexercised -Money | |
|------------------|--------------------|-------------------|-----------------|------------------------------|-----------------|-----------------------|--|
| | Shares Acquired | | Options Held at | | Options Held at | | |
| | on Exercise | Value Realized | Decembe | er 31, 2004 | December | 31, 2004(1) | |
| Name | (#) | (\$) | Exercisable | Unexercisable | Exercisable | Unexercisable | |
| Joseph S. | | | | | | | |
| Podolski | | | 298,282 | 397,871 | \$ 256,854 | \$ 241,822 | |
| Louis Ploth, Jr. | | | 179,592 | 108,306 | \$ 178,807 | \$ 172,653 | |

⁽¹⁾ Computed based on the difference between aggregate fair market value and aggregate exercise price. The fair market value of the Company s Common Stock on December 31, 2004 was \$4.33, based on the closing sales price on the Nasdaq Stock Market on December 31, 2004.

Employment Agreements

The Company has employment agreements with Messrs. Podolski and Ploth which provide for current annual salaries of \$300,000 and \$190,000, respectively. The agreements provide that the Company will pay Messrs. Podolski and Ploth an annual incentive bonus as may be approved by the Board of Directors and that they are entitled to participate in all employee benefit plans sponsored by the Company.

Mr. Podolski s employment agreement provides for automatic annual renewals each January unless terminated in writing by either party. If terminated for reasons other than cause, Mr. Podolski is entitled to receive his annual base salary and certain employment benefits for 1 year following termination. In addition, he is entitled to the following severance payments in the event he is terminated without cause or resigns for good reason within 12 months following a change of control: a cash lump sum payment equal to the present value of the aggregate amount of payments set forth below, in which the present value is determined as of the closing date of the change of control transaction (as if he was

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terminated or had resigned on such date). Mr. Podolski has agreed to defer payment of such amount, and in lieu of such lump sum payment, he will receive the payments listed in the following table. All of the payments listed below, other than the first payment made at the closing of a change of control, would be made out of an irrevocable Rabbi Trust which would be funded by the Company immediately prior to the closing of a change of control transaction:

| Amount of payment | Payment due date | | |
|---------------------|---|--|--|
| Current base salary | On the closing of the change of control transaction | | |
| \$150,000 | 1st anniversary after closing | | |
| \$150,000 | 2nd anniversary after closing | | |
| \$150,000 | 3rd anniversary after closing | | |
| \$150,000 | 4th anniversary after closing | | |
| \$125,000 | 5th anniversary after closing | | |
| \$75,000 | 6th anniversary after closing | | |

Finally, Mr. Podolski is entitled to acceleration of all unvested options and an extension of the period of exercisability of his options for a 2 year period following the closing of a change of control transaction and is entitled to receive benefits coverage for a period of 12 months following his termination.

Mr. Ploth s employment agreement expires in October 2005 with automatic annual renewals unless otherwise terminated by either party. If terminated for reasons other than cause, Mr. Ploth is entitled to salary and certain employment benefits for 6 months following termination.

Mr. Ploth is entitled to receive a lump sum payment upon the closing of a change of control transaction, regardless of whether he is terminated or continues with the combined company, in an amount equal to his current base salary at the time of the closing. In addition, Mr. Ploth is entitled to acceleration of all unvested options and an extension of the period of exercisability of his options for a 2 year period following the closing of a change of control, and he is entitled to receive benefits coverage for a period of 12 months following closing.

Compensation and Option Committee Interlocks and Insider Participation

The Compensation and Option Committee currently consists of Ms. Masterson and Dr. Poorvin. During fiscal 2004, no executive officer of the Company served as (i) a member of the compensation committee (or other board committee performing equivalent functions) of another entity, one of whose executive officers served on the Compensation Committee of the Board of Directors, (ii) a director of another entity, one of whose executive officers served on the Compensation Committee of the Board of Directors of the Company or (iii) a member of the compensation committee (or other board committee performing equivalent functions) of another entity, one of whose executive officers served as a director of the Company.

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Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table presents certain information regarding the beneficial ownership of Common Stock as of March 31, 2005 by (i) each person who is known by the Company to own beneficially more than 5% of the outstanding shares of Common Stock, (ii) each director and nominee for director of the Company, (iii) the Company s Chief Executive Officer and the other Named Executive Officer, and (iv) all directors and executive officers as a group.

| | Amount and Nature of Beneficial | |
|---|---|--|
| Name of Beneficial Owner | Ownership of Common Stock ⁽¹⁾ | Percentage of Class ⁽²⁾ |
| Joseph Edelman 850 Third Avenue, 8th Floor | $750,000_{(3)}$ | 7.4% |
| New York, New York 10022 | | |
| BVF Partners L.P. 227 West Monroe, Suite 4800 Chicago, Illinois 60606 | 582,743(4) | 5.8% |
| Jeffrey R. Jay, M.D. 2 Pickwick Plaza, Suite 450 Greenwich, Connecticut 06830 | 510,500 ₍₅₎ | 5.1% |
| Daniel F. Cain | 16,666(6) | * |
| Jean L. Fourcroy, M.D., Ph.D., M.P.H | 16,666(6) | * |
| Nola E. Masterson | 6,666(7) | * |
| Joseph S. Podolski | 397,763(8) | 3.8% |
| Louis Ploth | 216,314(9) | 2.1% |
| David Poorvin, Ph.D. | 6,666(7) | * |
| All directors and executive officers as a group (6 persons) | 660,741 ₍₆₎₋₍₉₎ | 6.2% |

^{*} Does not exceed 1%.

- (1) Unless otherwise noted, the Company believes that all persons named in the table have sole voting and investment power with respect to all shares of Common Stock beneficially owned by such persons.
- (2) In accordance with the rules of the Securities and Exchange Commission, each beneficial owner s percentage ownership assumes the exercise or conversion of all options, warrants and other convertible securities held by such person and that are exercisable or convertible within 60 days after March 31, 2005.
- (3) Based on information contained in a Schedule 13G dated February 7, 2005, Mr. Edelman has sole voting and dispositive power with respect to all of the shares, which include (i) 675,000 shares held by Perceptive Life Sciences Master Fund Ltd., a Cayman Islands company of which the investment manager is Perceptive Advisors LLC, a Delaware limited liability company, of which Mr. Edelman is the managing member, and (ii) 75,000 shares held in an account of First New York Trading, LLC, of which Mr. Edelman has sole voting and dispositive power.

- (4) Based on information contained in a Schedule 13G/A dated February 13, 2004, BVF Partners L.P. shares voting and dispositive power with respect to all of the shares listed above with its general partner, BVF Inc., on behalf of the following entities with which it shares voting and dispositive power in the following amounts: Biotechnology Value Fund, L.P., 221,443 shares; Biotechnology Value Fund II, L.P., 116,138 shares; BVF Investments, L.L.C., 217,862 shares; and Investment 10, L.L.C., 27,300 shares.
- (5) Based on information contained in a Schedule 13G dated April 21, 2005, Dr. Jay shares voting and dispositive power with respect to all of the shares listed above with Great Point Partners, LLC, of which Dr. Jay is senior managing member. Great Point Partners is the investment manager of Biomedical Value Fund, L.P., which owns 290,985 shares, and Biomedical Offshore Value Fund, Ltd., which owns 219,515 shares.
- (6) Includes 16,666 shares issuable upon exercise of options.
- (7) Includes 6,666 shares issuable upon exercise of options.
- (8) Includes (i) 300 shares of Common Stock which are held by certain of Mr. Podolski s family members and (ii) 298,282 shares of Common Stock issuable upon the exercise of options. Mr. Podolski disclaims beneficial ownership of the shares owned by his family members.
- (9) Includes 183,592 shares of Common Stock issuable upon the exercise of options.

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Equity Compensation Plan Information

The following table provides information as of December 31, 2004, regarding compensation plans (including individual compensation arrangements) under which equity securities are authorized for issuance:

| Plan category Equity compensation plans approved by shareholders ⁽¹⁾ | Number of securities to be issued upon exercise of outstanding options, warrants and rights 1,786,846 | Weighted-average exercise price of outstanding options, warrants and rights \$4.77 | Number of securities remaining available for future issuance under equity compensation plans (excluding securities shown in the first column) 798,536 |
|---|---|--|--|
| Equity compensation plans not approved by shareholders | | | |
| Total | 1,786,846 | \$4.77 | 798,536 |

⁽¹⁾ Consists of shares of Common Stock issued or remaining available for issuance under the Incentive Plan, 2004 Stock Option Plan and 2000 Director Plan. The material terms of the 2000 Director Plan are described above under Directors Meetings and Compensation.

Item 13. Certain Relationships and Related Transactions

None.

Item 14. Principal Accountant Fees and Services

The following table sets forth the aggregate fees billed to the Company by its independent registered public accounting firm, PricewaterhouseCoopers LLP, for fiscal years ended December 31, 2004 and 2003, respectively:

| | 2004 | 2003 |
|--------------------|---------------|---------------|
| Audit Fees | \$ 302,978 | \$ 127,150 |
| Audit Related Fees | 0 | 70,300 |
| Tax Fees | 4,500 | 9,250 |
| All Other Fees | 0 | 0 |
| Total Fees | \$ 307,478 | \$ 206,700 |

The services provided under the caption Audit Fees for 2004 and 2003 were for professional services rendered for audits of the Company s financial statements and the Company s self tender offer. \$210,178 in services provided under the caption Audit Fees for 2004 relate to accounting consultation services performed in connection with the Company s public offering completed in February 2005 and services related to securities matters. Services provided under the caption Audit Related Fees for 2003 relate to due diligence and accounting consultation services performed

in connection with the company s now-terminated transaction with Lavipharm Corporation. The services provided under the caption Tax Fees for 2004 and 2003 relate to certain compliance related services and tax advice to the Company. The Audit Committee considered whether the provision of the services reflected under Tax Fees above might have affected PricewaterhouseCoopers independence with respect to their audit of the Company s financial statements, and the Audit Committee believes that such services did not affect, and were compatible with, PricewaterhouseCoopers independence.

Audit Committee Pre-Approval Policies and Procedures

The Audit Committee s policy provides that the Company s independent registered public accounting firm (the Audit Firm) may provide only those services pre-approved by the Audit Committee or its designated subcommittee. The

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Audit Committee annually reviews and pre-approves the audit, review, attest and permitted non-audit services to be provided during the next audit cycle by the Audit Firm. To the extent practical, at the same meeting the Audit Committee also reviews and approves a budget for each of such services. The term of any such pre-approval is for the period of the annual audit cycle, unless the Audit Committee specifically provides for a different period.

Services proposed to be provided by the Audit Firm that have not been pre-approved during the annual review and the fees for such proposed services must be pre-approved by the Audit Committee or its designated subcommittee. Additionally, fees for previously approved services that are expected to exceed the previously approved budget must also be pre-approved by the Audit Committee or its designated subcommittee.

All requests or applications for the Audit Firm to provide services to the Company must be submitted to the Audit Committee or its designated subcommittee by the Audit Firm and the Chief Financial Officer and must include a joint statement as to whether, in their view, the request or application is consistent with applicable laws, rules and regulations relating to auditor independence. It is the Company s policy that if any of its employees or any representative of the Audit Firm becomes aware that any services are being, or have been, provided by the Audit Firm to the Company without the requisite pre-approval, such individual must immediately notify the Chief Financial Officer, who must promptly notify the Chairman of the Audit Committee and appropriate members of senior management so that prompt action may be taken to the extent deemed necessary or advisable.

The Audit Committee may form and delegate to a subcommittee composed of one or more of its members, the authority to grant specific pre-approvals under its policy with respect to audit, review, attest and permitted non-audit services, provided that any such grant of pre-approval shall be reported to the full Audit Committee no later than its next scheduled meeting. The Audit Committee may not delegate to management its responsibilities to pre-approve services performed by the Audit Firm.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ZONAGEN, INC.

By: /s/ Joseph S. Podolski Joseph S. Podolski President and Chief Executive Officer

Dated: April 29, 2005

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