

INTROGEN THERAPEUTICS INC

Form 10-K/A

May 14, 2004

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A
(Amendment No. 2)

(Mark One)

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

For the fiscal year ended December 31, 2003

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: 000-21291

Introgen Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

74-2704230

(I.R.S. Employer Identification Number)

**301 Congress Avenue, Suite 1850
Austin, Texas**

(Address of principal executive offices)

78701

(Zip Code)

Registrant's telephone number, including area code:

(512) 708-9310

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

None

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

Common Stock, \$0.001 par value

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 No

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 the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this

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Form 10-K or any amendment to this Form 10-K.

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

The aggregate market value of the voting stock (common stock) held by non-affiliates of the Registrant, as of the last day of the Registrant's second fiscal quarter, was approximately \$61.6 million based upon the last sale price reported on the Nasdaq National Market for June 30, 2003. For purposes of this disclosure, shares of common stock held by persons who hold more than 5% of the outstanding shares of common stock and shares held by executive officers and directors of the Registrant have been excluded because such persons may be deemed to be affiliates. This determination is not necessarily conclusive.

As of March 31, 2004, the Registrant had 26,583,274 shares of common stock, \$0.001 par value, issued and outstanding.

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EXPLANATORY NOTE

This Amendment No. 2 to the Annual Report on Form 10-K for the year ended December 31, 2003 (the Amendment No. 2) for Introgen Therapeutics, Inc. (the Company) is being filed to correct the beneficial ownership information for executive officers and directors as a group and in the corresponding footnote in the table that contains the beneficial ownership of executive officers, directors and greater than five percent stockholders, which is provided pursuant to Item 12 of Part III of Form 10-K. In addition, in connection with the filing of this Amendment No. 2 and pursuant to the rules of the Securities and Exchange Commission, the Company is including with this Amendment No. 2 certain currently dated certifications. Except for the changes as set forth in this explanatory note, and the currently dated certifications, there are no other changes to the Amendment No. 1 to Form 10-K filed on April 29, 2004 and the originally filed Form 10-K.

INTROGEN THERAPEUTICS, INC.

FORM 10-K/ A

(Amendment No. 2)

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Directors**

The following sets forth information concerning the persons currently serving as our directors, including information as to each executive officer's age, position and business experience:

| Name | Age | Position/Principal Occupation | Director Since |
|---------------------------------------|------------|--|-----------------------|
| William H. Cunningham, Ph.D.(1)(2)(3) | 60 | Professor, The University of Texas at Austin | 2000 |
| S. Malcolm Gillis, Ph.D.(1) | 63 | President, Rice University | 2004 |
| Charles E. Long(1)(2)(3) | 64 | Director; Retired | 2001 |
| Mahendra G. Shah, Ph.D. | 59 | Director | 1993 |
| John N. Kapoor, Ph.D. | 60 | Chairman of the Board; Chairman of the Board of EJ Financial Enterprises, Inc. | 1993 |
| David G. Nance | 52 | President and Chief Executive Officer of Introgen Therapeutics, Inc. | 1993 |

(1) Member of Audit Committee

(2) Member of Compensation Committee

(3) Member of Nominating and Corporate Governance Committee

William H. Cunningham, Ph.D., has served as a member of our Board of Directors since July 2000. Dr. Cunningham served as Chancellor and Chief Executive Officer of The University of Texas System from 1992 to 2000, in addition to holding the Lee Hage and Joseph D. Jamail Regents Chair in Higher Education Leadership. He served as President of The University of Texas at Austin, a component institution of the University of Texas System, from 1985 to 1992. He is currently a Professor of Marketing at The University of Texas at Austin. Dr. Cunningham serves on a number of public commissions, private corporate boards and in a number of advisory roles to corporations. Dr. Cunningham serves on the board of directors of John Hancock Advisers, Inc. He also serves on the board of directors of Jefferson Pilot Corporation, Southwest Airlines, Inc., LIN Television and Hayes Lemmerz International, Inc., each of which is a publicly-traded corporation. Dr. Cunningham received his Ph.D. and M.B.A. from Michigan State University. In 1993, he received an Honorary Doctor of Laws Degree and the Distinguished Alumnus Award from Michigan State University.

S. Malcolm Gillis, Ph.D., has served as a member of our Board of Directors since February 2004. Dr. Gillis has served as the President of Rice University since 1993 and will complete his term in June 2004. He is also the Ervin Kenneth Zingler Professor of Economics. Dr. Gillis has been honored with the designation of University Professor, the highest faculty designation at Rice University, and he will continue to teach when his university leadership concludes. Before entering university leadership, he spent the first 25 years of his professional life teaching economics and applying economic analysis to public policy in almost 20 countries, from the United States and Canada, to Ecuador, Colombia, Ghana and Indonesia. His research and teaching have mainly been in the areas of fiscal economics and environmental policy. Dr. Gillis served as Dean of the Faculty of Arts and Sciences at Duke University from 1991 to 1993, and he served as Dean of the Graduate School and Vice Provost for Academic Affairs at Duke University from 1986 to 1991. Dr. Gillis serves on the board of directors and board of trustees of many foundations, educational associations and community organizations. In 2002, he was appointed to the Governor's Task Force for Texas Economic Growth. Dr. Gillis received his Ph.D. from the University of Illinois. He received his M.A. and B.A. from the University of Florida. In 1992, he was awarded an Honorary Doctor of Laws Degree from Rocky Mountain College.

Charles E. Long has served as a member of our Board of Directors since January 2001. Mr. Long is former vice chairman of Citicorp and its principal subsidiary, Citibank. Mr. Long held various positions during his career with Citicorp, which began in 1972. From 1982 to 1998, he headed Citicorp's External Affairs

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Division, which includes the Government Relations Division in Washington, D.C. From 1976 to 1982, he was responsible for managing Citicorp's international consumer banking business, as well as legal and external affairs for consumer banking worldwide. Mr. Long is a trustee of the Midwest Research Institute and the National Forest Foundation. He has served as an officer, director or trustee on a number of corporate, charitable and public boards, including vice chairman of Georgetown University, vice chairman and director of Woodrow Wilson House Museum and Ford's Theater in Washington, D.C. Mr. Long is a director of Atlas Copco North America and Atlas Copco AB, a public company. Mr. Long is also a member of the board of directors of Gendux AB, our wholly-owned subsidiary. Mr. Long received his B.B.A. in business from St. John's University. In 1998, he received an Honorary Doctor of Business Degree from St. John's University.

Mahendra G. Shah, Ph.D., has served as a member of our Board of Directors since our inception in June 1993. From 1993 to 2000, Dr. Shah served as our Vice President, Corporate and Business Development. From 1991 to January 2001, he served as Vice President, Corporate Development of EJ Financial Enterprises, Inc., a healthcare investment company. Dr. Shah has also served as the chief executive officer and chairman of the board of directors of First Horizon Pharmaceutical Corporation. Dr. Shah received his Ph.D. in industrial pharmacy from St. John's University.

John N. Kapoor, Ph.D. has served as Chairman of our Board of Directors since our inception in June 1993. In 1990, Dr. Kapoor founded EJ Financial Enterprises, Inc., a healthcare investment company and he is presently the chairman of its board of directors. He is also presently chairman of the board of directors of Akorn, Inc., NeoPharm, Inc., Option Care, Inc., and First Horizon Pharmaceuticals Corporation, each of which is a publicly-traded corporation. Dr. Kapoor received his Ph.D. in medicinal chemistry from the State University of New York at Buffalo.

Please see Executive Officers below for information with respect to Mr. Nance.

There are no family relationships among any of our directors or executive officers.

Executive Officers

The following sets forth information concerning the persons currently serving as our executive officers, including information as to each executive officer's age, position and business experience:

| Name | Age | Position |
|------------------------------|-----|---|
| David G. Nance | 52 | President and Chief Executive Officer |
| Max W. Talbott, Ph.D. | 55 | Senior Vice President, Worldwide Commercial Development |
| James W. Albrecht, Jr. | 49 | Chief Financial Officer |
| J. David Enloe, Jr. | 40 | Vice President, Operations |
| David L. Parker, Ph.D., J.D. | 49 | Vice President, Intellectual Property |
| Robert E. Sobol, M.D. | 52 | Senior Vice President, Medical and Scientific Affairs |

David G. Nance has served as a member of our Board of Directors and as our President and Chief Executive Officer since our inception in June 1993. From 1992 to 1996, Mr. Nance served as the Managing Partner of Texas Biomedical Development Partners, the investment group that founded us.

Max W. Talbott, Ph.D. joined Introgen in February 2002 as our Senior Vice President, Worldwide Commercial Development. From 2000 to 2002, Dr. Talbott was Senior Vice President, Worldwide Regulatory Affairs and Pharmacovigilance at DuPont Pharmaceuticals Company and Bristol-Myers Squibb Pharmaceuticals Company, which merged during this period. From 1996 to 2000, he served in various positions with Aventis Pharmaceuticals and Rhône-Poulenc Rorer Pharmaceuticals, most recently as Senior Vice President, Drug Regulatory Affairs and Quality Assurance. Prior to 1996, Dr. Talbott occupied several management positions with Eli Lilly and Company, a major pharmaceuticals company, and he spent five years with the U.S. Food and Drug Administration, first as a Reviewer and then as a Branch Chief and Acting Division Director. He received his Ph.D. in immunology and pharmacology from Rutgers University.

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James W. Albrecht, Jr. joined Introgen in November 1994 as our Vice President, Operations and Administration, and he has served as our Chief Financial Officer since April 1995. From 1993 to 1996, he operated a consulting business providing chief financial officer services to the technology and real estate industries. Mr. Albrecht worked previously at Arthur Andersen LLP as an accountant and he is a Certified Public Accountant. He received his B.B.A. in accounting from The University of Texas at Austin.

J. David Enloe, Jr. joined Introgen in March 1995. He has served as our General Business Manager and Vice President, Administration, and he is currently Vice President, Operations. From 1989 to 1995, he held various positions at Centrilift, a division of Baker Hughes, Inc., an energy services company, including Region General Manager, Southeast Asia, and he worked at Arthur Andersen LLP as an accountant prior to that time. Mr. Enloe is a Certified Public Accountant. He received his B.B.A. in accounting from The University of Texas at Austin.

David L. Parker, Ph.D., J.D. joined Introgen in March 1999 as our Vice President, Intellectual Property. Since January 2000, Dr. Parker has been a partner with the law firm of Fulbright & Jaworski LLP. From 1992 to January 2000, he was a shareholder of the patent law firm of Arnold White & Durkee, Professional Corporation, where he was previously an associate. Since 1997, Dr. Parker has served as an adjunct professor at The University of Texas School of Law. Dr. Parker received his Ph.D. in molecular pharmacology and molecular biology from Baylor College of Medicine and his J.D. from The University of Texas School of Law.

Robert E. Sobol, M.D. joined Introgen in September 2003 as our Senior Vice President, Medical and Scientific Affairs. He is currently the President and Chief Executive Officer of Magnum Therapeutics Corp., a biopharmaceutical company and was President of Corautus Genetics Inc., a biopharmaceutical company. From 1998 to 2003, Dr. Sobol served as President and Chief Executive Officer of Genstar Therapeutics, a company that developed gene therapy products, which he founded in 1996. Mr. Sobol received his M.D. from The Chicago Medical School.

Significant Employees

The following sets forth information concerning persons currently employed by us who make or are expected to make significant contributions to our business:

Peter Clarke, Ph.D. joined Introgen after 23 years working in the field of biotechnology in both research and manufacturing. Dr. Clarke has held positions of increasing importance in both start-up and established European and U.S.-based biopharmaceutical companies such as Medeva Pharma and Chiron Vaccines. Most recently, Dr. Clarke worked for Bayer Biological Products, where he was Director of Manufacturing and was closely involved in the North American licensure and launch of a novel immunoglobulin. Dr. Clarke received his B.S. in biochemistry from Sheffield University in England. His Ph.D. in microbial physiology and DIC in biochemistry were completed at the Imperial College of Science and Technology in London.

Craig A. Halverson joined Introgen after 20 years of biomedical academic research and commercial experience in oncology, hematology and cardiovascular products emphasizing biologics, regulatory affairs and quality. Mr. Halverson's experience includes successful global product/establishment registrations and strategic planning experience and includes extensive interactions with all levels of the FDA and global ministries of health. He has developed IND & BLA regulatory strategies as well as developed CBER strategic compliance plans for Quality Assurance/ Quality Control, Clinical, Research and Development, Product Transfer, Manufacturing, Engineering and Facilities departments. Prior to joining Introgen in 2004, Mr. Halverson was the Executive Director of Global Regulatory Affairs for Cancervax Corporation and held a similar position for Gen-Probe prior to that. Mr. Halverson also served as Global Regulatory Affairs Director for Baxter Healthcare Corporation and worked in a number of research and managerial positions for Hybritech, Inc. Mr. Halverson received his M.S. in experimental pathology from the University of Southern California, School of Medicine, Department of Pathology, and his B.S. in chemistry and biology from California State at Fullerton.

Kerstin B. Menander, M.D., Ph.D. joined Introgen in 2002 with broad experience in the health care field, including in the pharmaceutical, scientific, regulatory and medical arenas. Dr. Menander has developed expertise in the management of all phases of clinical trials in oncology, rheumatology and other inflammatory diseases, endocrinology (estrogen replacement therapy, osteoporosis prevention and oral contraceptives),

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orthopedics, allergology, analgesiology, cardiovascular conditions, infectious diseases, wound healing, neurology and dermatology. She has managed groups responsible for Clinical Trials, Adverse Reaction and Medical Information. She has also conducted independent research in histology, endocrinology and in the area of inflammation. She has interacted with regulatory agencies in the U.S., Canada and Europe. In addition, she managed regulatory departments responsible for assembly, submission and approval of INDs, IDEs, NDAs, PLAs and PMAs. Her experience includes responsibilities for final clinical and regulatory approval of promotional materials and package inserts. Prior to joining Introgen, Dr. Menander served as vice president of several divisions for Cell Pathways, Inc., culminating in Vice President of International Operations. She has also served in senior level management for Curative Technologies, Inc., Collagen Corporation and Abbott Laboratories. She also served as President of US 3 D Development, Inc. Dr. Menander is widely published in most major peer reviewed journals. Dr. Menander received her Medical Degree, her Registrar and completed her Ph.D. in histology (cum laude) from the University of Lund in Sweden.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing Audit Committee established in accordance with section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended (Exchange Act). During the fiscal year ended December 31, 2003, the Audit Committee was comprised of William Cunningham, Ph.D., Charles E. Long and Robert L. Moore. In February 2004, S. Malcolm Gillis, Ph.D. filled the vacancy left by Mr. Moore when he resigned as a member of the Board of Directors. The Board of Directors has determined that each of the members of the Audit Committee is independent as defined by the listing standards of the Nasdaq National Market and Section 10A(m)(3) of the Exchange Act. In addition, the Board of Directors has determined that Dr. Gillis is an audit committee financial expert, as that term is defined in Item 401(h) of Regulation S-K of the Exchange Act.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act of 1934, as amended, requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership on Form 3 and changes in ownership on Form 4 or Form 5 with the Securities and Exchange Commission. Such officers, directors and 10% stockholders are also required by the Securities and Exchange Commission rules to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of the copies of such forms we received, we believe that, during the fiscal year ended December 31, 2003, all Section 16(a) filing requirements applicable to our officers, directors and 10% stockholders were satisfied.

Code of Ethics

On February 18, 2004, the Company adopted a Corporate Code of Ethics for All Employees and Directors. At the same time, the Company adopted a Corporate Code of Ethics for Financial Officers, which specifically applies to the Company's Chief Executive Officer, Chief Financial Officer and persons performing similar functions. We plan to make each of the codes of ethics available on our website at www.introgen.com. A copy of the full text of each of our codes of ethics may be obtained by any of our stockholders by writing to our Corporate Secretary at Introgen Therapeutics, Inc., 301 Congress Avenue, Suite 1850, Austin, Texas 78701.

We intend to post on our website any amendment to, or waiver from, a provision of our codes of ethics within five business days following the date of such amendment or waiver.

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Summary Compensation Table**

The following table shows the compensation paid by us to our Chief Executive Officer and our four other most highly compensated executive officers (collectively, the Named Executive Officers) during the last four fiscal periods, including the fiscal year 2003 (January 1, 2003 – December 31, 2003), fiscal year 2002 (January 1, 2002 – December 31, 2002), the six-month transition period ended December 31, 2001, and the fiscal year 2001 (July 1, 2000 – June 30, 2001):

| Name and Principal Position | Period | | Compensation | | Long-Term Compensation Awards | All Other Compensation |
|--|----------|------------|--------------|-------|--|---------------------------|
| | | | Salary | Bonus | Securities Underlying Options (# of Shares) | |
| David G. Nance President and Chief Executive Officer | 1/1/2003 | 12/31/2003 | \$412,124 | \$ | 170,000 | |
| | 1/1/2002 | 12/31/2002 | 344,784 | | 114,600 | |
| | 7/1/2001 | 12/31/2001 | 163,854 | | 69,600 | |
| | 7/1/2000 | 6/30/2001 | 300,208 | 8,835 | 50,000 | |
| James A. Merritt, M.D.(2) Chief Medical Officer | 1/1/2003 | 12/31/2003 | \$250,000 | \$ | 40,000 | |
| | 1/1/2002 | 12/31/2002 | 250,000 | | 35,000 | |
| | 7/1/2001 | 12/31/2001 | 108,333 | | 10,000 | |
| | 7/1/2000 | 6/30/2001 | 200,000 | 5,841 | 40,000 | |
| Shawn L. Gallagher(2) Vice President, Production and Technical Processes | 1/1/2003 | 12/31/2003 | \$211,301 | \$ | 40,000 | |
| | 1/1/2002 | 12/31/2002 | 195,856 | | 35,000 | |
| | 7/1/2001 | 12/31/2001 | 93,750 | | | |
| | 7/1/2000 | 6/30/2001 | 180,000 | 5,257 | 40,000 | |
| David L. Parker, Ph.D., J.D. Vice President, Intellectual Property | 1/1/2003 | 12/31/2003 | \$200,000 | \$ | 40,000 | |
| | 1/1/2002 | 12/31/2002 | 200,000 | | 35,000 | |
| | 7/1/2001 | 12/31/2001 | 100,000 | | | |
| | 7/1/2000 | 6/30/2001 | 190,000 | 5,257 | 40,000 | |
| G. Thomas Finnegan III Vice President, Finance and Corporate Development | 1/1/2003 | 12/31/2003 | \$200,000 | \$ | 40,000 | |
| | 1/1/2002 | 12/31/2002 | 200,000 | | 35,000 | |
| | 7/1/2001 | 12/31/2001 | 91,667 | | 75,000 | |
| | 7/1/2000 | 6/30/2001 | 48,462 | | 150,000 | \$32,692(1) |

(1) Includes consulting fees paid prior to Mr. Finnegan's employment with us and a relocation expense payment.

(2) Dr. Merritt and Mr. Gallagher served as executive officers with us as of the last fiscal year ended December 31, 2003. They are no longer executive officers with us but continue to provide services to us on a part time, as-needed basis for nominal compensation.

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The following table sets forth grants of stock options made during the fiscal year ended December 31, 2003 to each Named Executive Officer.

| Name | Period | | Individual Grants | | | | Potential Realizable Value | |
|------------------------------|----------|------------|---|--|------------------------|-----------------|--|-----------|
| | | | Number of Securities Underlying Options Granted | % of Total Options Granted to Employees During Period(1) | Exercise or Base Price | Expiration Date | at Assumed Annual Rates of Stock Price Appreciation for Option Term(2) | |
| | | | | | | | 5% | 10% |
| David G. Nance | 1/1/2003 | 12/31/2003 | 100,000 | 10.9% | \$5.00 | 6/22/2013 | \$314,447 | \$796,871 |
| | | | 70,000 | 7.7% | 5.00 | 6/22/2013 | 220,113 | 557,810 |
| James A. Merritt, M.D.(3) | 1/1/2003 | 12/31/2003 | 40,000 | 4.4% | 5.00 | 6/22/2013 | 125,779 | 318,748 |
| Shawn L. Gallagher(3) | 1/1/2003 | 12/31/2003 | 40,000 | 4.4% | 5.00 | 6/22/2013 | 125,779 | 318,748 |
| David L. Parker, Ph.D., J.D. | 1/1/2003 | 12/31/2003 | 40,000 | 4.4% | 5.00 | 6/22/2013 | 125,779 | 318,748 |
| G. Thomas Finnegan III | 1/1/2003 | 12/31/2003 | 40,000 | 4.4% | 5.00 | 6/22/2013 | 125,779 | 318,748 |

- (1) Based on the grant of stock options representing 913,690 shares to employees during the fiscal year ended December 31, 2003.
- (2) The dollar amounts under these columns are the result of calculations at the 5% and 10% rates set by the Securities and Exchange Commission and therefore are not intended to forecast possible future appreciation, if any, of our stock price. We did not use an alternative formula for a grant date valuation, as we do not believe that any formula will determine with reasonable accuracy a present value based on future unknown or volatile factors.
- (3) Dr. Merritt and Mr. Gallagher served as executive officers with us as of the last fiscal year ended December 31, 2003. They are no longer executive officers with us but continue to provide services to us on a part time, as-needed basis for nominal compensation.

Aggregated Option Exercises During the Fiscal Year Ended December 31, 2003 and Option Values as of the End of Such Period

The following table sets forth, for each of the Named Executive Officers, the number of options exercised during the fiscal year ended December 31, 2003, as well as the value of unexercised options at the end of such period:

| Name | Period | | Number of Shares Acquired on Exercise | Value Realized(1) | Number of Securities Underlying Unexercised Options at Fiscal Year-End | | Value of Unexercised In-the-Money Options as of At Fiscal Year-End(2) | |
|------------------------------|----------|------------|---------------------------------------|-------------------|--|---------------|---|---------------|
| | | | | | Exercisable | Unexercisable | Exercisable | Unexercisable |
| David G. Nance | 1/1/2003 | 12/31/2003 | | | 655,130 | 135,710 | \$4,116,184 | \$510,521 |
| James A. Merritt, M.D.(3) | 1/1/2003 | 12/31/2003 | | | 136,566 | 96,722 | 928,590 | 368,013 |
| Shawn L. Gallagher(3) | 1/1/2003 | 12/31/2003 | | | 203,566 | 91,722 | 1,486,415 | 349,163 |
| David L. Parker, Ph.D., J.D. | 1/1/2003 | 12/31/2003 | 10,000 | \$79,613 | 217,566 | 91,722 | 1,594,407 | 349,163 |
| G. Thomas Finnegan III | 1/1/2003 | 12/31/2003 | | | 121,250 | 178,750 | 548,475 | 754,875 |

- (1) Based on a fair market value of \$8.48 per share, which was the closing price of our common stock on December 31, 2003, the date of exercise.
- (2)

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Based on a fair market value of \$8.48 per share, which was the closing price of our common stock on December 31, 2003, as reported on the Nasdaq National Market.

- (3) Dr. Merritt and Mr. Gallagher served as executive officers with us as of the last fiscal year ended December 31, 2003. They are no longer executive officers with us but continue to provide services to us on a part time, as-needed basis for nominal compensation.

Board Compensation

Each non-employee director is granted an option to purchase 33,600 shares of our common stock (exercisable at the fair market value on the date of grant) upon first becoming a director. The option vests ratably each month after the date of grant of such option, so that the entire option is fully vested three years after the date of grant. Each incumbent director is annually granted an option to purchase 20,000 shares of our

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common stock (exercisable at the fair market value on the date of grant) on the date of each annual meeting of stockholders. That option vests ratably each month after the date of grant of such option, so that the entire option is fully vested one year after the date of grant. In addition, the chairman of each of the Audit Committee, Compensation Committee and the designated audit committee financial expert on the Audit Committee are all granted annually a fully-vested option to purchase 5,000 shares of our common stock. Directors do not receive any cash or other additional compensation, other than reimbursement of their out-of-pocket expenses, for services provided as a director.

Employment Contracts and Change-In-Control Arrangements

We have an employment agreement with David G. Nance, entered into on August 1, 2003, under which Mr. Nance serves as our President and Chief Executive Officer. Under Mr. Nance's prior employment agreement with us, which was entered into on August 1, 1996, his base salary was \$302,500 per annum effective August 1, 2000, \$332,750 per annum effective August 1, 2001, \$366,025 per annum effective August 1, 2002. The prior employment agreement provided that Mr. Nance would receive an option to purchase 50,000 shares of our common stock on each of August 1, 2000, August 1, 2001, and August 1, 2002 (for a total of 150,000 shares through August 1, 2002). According to the foregoing terms, he was granted an option to purchase 50,000 shares of our common stock upon the completion of our initial public offering in October 2000; he was granted an option to purchase an additional 50,000 shares of our common stock on August 1, 2001 and he was granted an option to purchase an additional 60,000 shares of our common stock on August 1, 2002. The Compensation Committee granted Mr. Nance the option to purchase 60,000 shares of our common stock on August 1, 2002, rather than an option to purchase 50,000 shares of common stock as required under his employment agreement, due to its decision to discontinue option grants to directors who are also employees. Accordingly, the Compensation Committee granted the 60,000 options to Mr. Nance with the understanding that he would not receive options in his capacity as director.

The current employment agreement with Mr. Nance, which was entered into on August 1, 2003, continues through July 31, 2006, and thereafter renews automatically for one-year terms until either party gives timely written notice of non-renewal. Mr. Nance's base salary under the current employment agreement is \$476,000 per annum effective August 1, 2003. His compensation under the current employment agreement is subject to review annually. Under the terms of his prior and current employment agreements with us, Mr. Nance may receive bonuses in the form of cash, stock options, restricted stock or other consideration as determined by our Compensation Committee, which reviews his compensation annually. Mr. Nance has also received bonuses from time to time in the form of options to purchase our common stock, as contemplated in each of his prior and current employment agreements with us. Such options are exercisable at a price determined by the administrator of our 2000 Stock Option Plan and are fully vested when granted.

All of the options granted under our 1995 Stock Plan and the 2000 Stock Option Plan shall immediately vest and become exercisable upon our merger with or into another corporation, entity or person, or the sale of all or substantially all our assets to another corporation, entity or person, unless such options are assumed or an equivalent option or right substituted by the successor corporation or a parent or subsidiary of the successor corporation.

Compensation Committee Interlocks and Insider Participation

We have a Compensation Committee, which currently consists of directors William H. Cunningham, Ph.D. and Charles E. Long (Chairman). The Compensation Committee administers our 1995 Stock Plan and 2000 Stock Option Plan, reviews compensation to be provided to our officers, employees and consultants, including stock compensation, grants options to purchase our common stock to our employees, executive officers, directors and consultants, and reviews and makes recommendations to the Board of Directors regarding all forms of compensation to be provided to the members of the Board of Directors, including stock compensation.

None of the members of the Compensation Committee is currently, or has ever been at any time since our formation, one of our officers or employees. No member of the Compensation Committee serves as a member of the board of directors or compensation committee of any entity that has one or more officers serving as a member of our Board of Directors or Compensation Committee.

Table of Contents**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The following table sets forth the beneficial ownership of our common stock as of March 31, 2004 by (i) all persons known to us, based on statements filed by such persons pursuant to Section 13(d) or 13(g) of the Securities Exchange Act of 1934, as amended, to be the beneficial owners of more than 5% of our common stock and based on the records of EquiServe, N.A., our transfer agent, (ii) each director, (iii) each of the executive officers named in the table under Executive Compensation Summary Compensation Table, and (iv) all current directors and executive officers as a group.

Except as otherwise noted, and subject to applicable community property laws, the persons named in this table have, to our knowledge, sole voting and investing power for all of the shares of common stock held by them.

This table lists applicable percentage ownership based on 26,583,274 shares of common stock outstanding as of March 31, 2004. Options to purchase shares of our common stock that are exercisable within 60 days of March 31, 2004 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage.

Unless otherwise indicated, the address for each stockholder on this table is c/o Introgen Therapeutics, Inc., 301 Congress Avenue, Suite 1850, Austin, Texas 78701.

| Beneficial Owner | Shares Beneficially Owned | Percent Beneficially Owned |
|---|---------------------------------|----------------------------------|
| Aventis Holdings Inc. (formerly known as Rhône-Poulenc Rorer International Holdings Inc.)(1) 500 Arcola Road Collegeville, PA 19426 | 5,045,664 | 19.0% |
| John N. Kapoor, Ph.D.(2) | 3,435,976 | 12.9% |
| David G. Nance(3) | 2,901,445 | 10.6% |
| Mahendra G. Shah, Ph.D.(4) | 515,367 | 1.9% |
| David L. Parker, Ph.D., J.D.(5) | 263,599 | * |
| James A. Merritt, M.D.(6) | 256,788 | * |
| Shawn L. Gallagher(7) | 253,926 | * |
| G. Thomas Finnegan III(8) | 167,500 | * |
| William H. Cunningham, Ph.D.(9) | 153,600 | * |
| Charles E. Long(10) | 181,600 | * |
| S. Malcolm Gillis, Ph.D.(11) | 2,800 | * |
| All directors and executive officers as a group (14 people)(12) | 8,683,569 | 29.5% |

* Represents less than 1% of the outstanding shares of common stock.

- (1) In December 1999, Rhône-Poulenc S.A., the ultimate parent company of Rhône-Poulenc Rorer Pharmaceuticals Inc., combined with Hoechst AG, and the parties have combined Hoechst Marion Roussel, the pharmaceutical business of Hoechst AG, with that of Rhône-Poulenc Rorer to form Aventis Pharma. Rhône-Poulenc Rorer Pharmaceuticals Inc. is now known as Aventis Pharmaceuticals Inc. The share number includes 2,343,721 shares of our common stock issuable within 60 days of March 31, 2004 upon conversion of Series A non-voting convertible preferred stock held by Aventis Pharmaceuticals Inc.
- (2) Consists of 202,109 shares held by EJ Financial Enterprises, Inc., 3,099,067 shares held by EJ Financial/ Introgen Management L.P. and 134,800 shares held by Dr. Kapoor subject to stock options that are exercisable within 60 days of March 31, 2004. EJ Financial/ Introgen Management L.P. is controlled by its general partner, EJ Financial Enterprises. Dr. Kapoor is Chairman of the Board of Directors of EJ Financial Enterprises. Dr. Kapoor disclaims beneficial ownership of the shares held by EJ Financial Enterprises and EJ Financial/ Introgen Management L.P.

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- (3) Consists of 1,346,979 shares held by Developtech Resources Corporation, 18,130 shares held by Domecq Technologies, Inc., 850,496 shares held by Debouchement, Ltd., and 685,840 shares held by Mr. Nance subject to stock options that are exercisable within 60 days of March 31, 2004. Mr. Nance is President and Chief Executive Officer of Developtech Resources Corporation, Domecq Technologies, Inc. and Debouchement, Ltd. Mr. Nance holds the right to vote for each entity and has dispositive control over the shares.
- (4) Consists of 176,279 shares of our common stock and 339,088 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (5) Includes 231,788 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (6) Includes 160,788 shares subject to stock options that are exercisable within 60 days of March 31, 2004. Dr. Merritt is no longer an executive officer with us but continues to provide services to us on a part time, as-needed basis for nominal compensation.
- (7) Includes 227,788 shares subject to stock options that are exercisable within 60 days of March 31, 2004. Mr. Gallagher is no longer an executive officer with us but continues to provide services to us on a part time, as-needed basis for nominal compensation.
- (8) Consists of 167,500 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (9) Consists of 146,600 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (10) Includes 171,600 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (11) Consists of 2,800 shares subject to stock options that are exercisable within 60 days of March 31, 2004.
- (12) Includes an aggregate of 2,817,080 shares subject to stock options held by our directors and executive officers as a group that are exercisable within 60 days of March 31, 2004.

Equity Compensation Plan Information

| Plan Category | (a)Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (in thousands) | (b)Weighted- Average Exercise Price of Outstanding Options, Warrants and Rights | (c)Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (in thousands) |
|--|--|---|--|
| Equity compensation plans approved by security holders | 5,156 | \$3.30 | 1,484 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 5,156 | \$3.30 | 1,484 |

Item 13. Certain Relationships and Related Transactions

Pursuant to a purchase agreement executed on June 30, 2001, we sold and issued 100,000 shares of a new class of Series A Non-Voting Convertible Preferred Stock, \$.001 par value per share, convertible into 2,343,721 shares of our common stock, to Aventis Pharmaceuticals Inc. for \$25,000,000. We received the cash payment and issued the shares on July 2, 2001. Aventis Pharmaceuticals Inc., formerly known as Aventis Pharmaceuticals Products Inc., is an affiliate of Aventis Holdings Inc., which holds greater than five percent of our outstanding common stock.

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Mahendra G. Shah, Ph.D., one of our directors, was, until January 1, 2001, an employee of EJ Financial Enterprises, Inc., one of our stockholders. John N. Kapoor, Ph.D., the Chairman of our Board of Directors, is the sole stockholder of EJ Financial Enterprises. We have a consulting agreement with EJ Financial Enterprises pursuant to which EJ Financial Enterprises provides services to us for \$175,000 per year. The agreement provides for the assistance of EJ Financial Enterprises with our business development, license negotiation, market analysis and general corporate development. This agreement is automatically renewable each July 1 for one-year terms, unless either party gives 30 days advance notice of termination.

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David Parker, Ph.D., J.D., our Vice President, Intellectual Property, is a partner with the law firm Fulbright & Jaworski LLP, which provides legal services to us as our primary outside counsel for intellectual property matters.

We are in negotiations with Dr. Robert Sobol, our Senior Vice President, Medical and Scientific Affairs, to acquire a company of which he is the sole shareholder. The terms of the proposed transaction have not been determined, but the purchase price is likely to be between \$1 million and \$2 million and to be paid in shares of our common stock. We believe the technology which is owned by Dr. Sobol's company will be a valuable addition to our intellectual property portfolio. We have endeavored to conduct the negotiations at arms length, and any transaction would be subject to the approval of our Audit Committee.

Item 14. Principal Accounting Fees and Services Fees Paid to Ernst & Young LLP

The following table sets forth the costs we incurred for services provided by Ernst & Young LLP, our independent auditors, for the years ended December 31, 2003 and December 31, 2002.

| Fee Category | Year Ended December 31, | |
|--------------------|----------------------------|------------|
| | 2002 | 2003 |
| Audit Fees | \$ 70,485 | \$ 113,250 |
| Audit-Related Fees | | |
| Tax Fees | 10,915 | 9,735 |
| All Other Fees | | |
| Total Fees | \$ 81,400 | \$ 122,985 |

Audit Fees. Consists of fees billed for professional services rendered in connection with the audit of the our consolidated financial statements and review of the interim consolidated financial statements included in the our quarterly reports and services that are normally provided by Ernst & Young LLP in connection with statutory and regulatory filings or engagements and includes accounting services in connection with securities offerings.

Audit-Related Fees. Consists of fees billed for assurance and related services that are reasonably related to the performance of the audit or review of the our consolidated financial statements and are not reported under Audit Fees. These services include employee benefit plan audits, accounting consultations in connection with acquisitions and divestitures, attest services that are not required by statute or regulation and consultations concerning financial accounting and reporting standards.

Tax Fees. Consists of fees billed for professional services for tax compliance, tax advice and tax planning. These services include assistance regarding federal, state and international tax compliance, tax audit defense, customs and duties, mergers and acquisitions, divestitures and international tax planning.

All Other Fees. We did not engage Ernst & Young LLP to perform services not covered by the preceding three categories.

Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

The Audit Committee's policy is to pre-approve all services provided by the independent auditors. These services may include audit services, audit-related services, tax services and other services. The Audit Committee may also pre-approve particular services on a case-by-case basis. The independent auditors are required to periodically report to the Audit Committee regarding the extent of services provided by the independent auditors in accordance with such pre-approval. The Audit Committee may also delegate pre-approval authority to one of its members. Such members(s) must report any such pre-approval to the Audit Committee at the next scheduled meeting.

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PART IV

Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) The following documents are filed as part of this Amendment No. 2 on Form 10-K:

(3) Exhibits

| Exhibit Number | Description of Document |
|---------------------------|---|
| 31.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

(c) See Item 15(a)(3) above.

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EXHIBIT INDEX

| Exhibit Number | Description of Document |
|---------------------------|---|
| 31.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |