

AVIGEN

2003 ANNUAL REPORT

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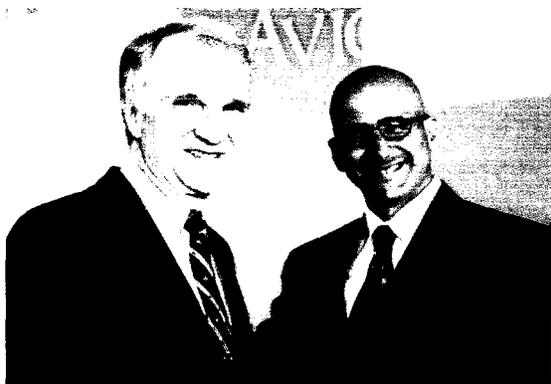
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*Philip J. Whitcome, Ph.D.
Chairman of the Board*

*Kenneth G. Chahine, Ph.D., J.D.
President & Chief Executive Officer*

TO OUR STOCKHOLDERS:

In 2003, Avigen continued to make progress in its clinical trial and preclinical research programs in the areas of hematological and neurological disorders. We resumed subject enrollment for our Coagulin-B clinical trial for the treatment of hemophilia B, filed an investigational new drug application for AV201 for the treatment of Parkinson's Disease and supplemented our preclinical pipeline with AV333, a treatment for neuropathic pain.

In 2003, we also implemented several strategic changes to accelerate our product development timelines. With AV201 for Parkinson's Disease and AV333 for neuropathic pain, we have increased our therapeutic focus on neurological diseases. Although AAV vector-based technologies remain a strong core competency, we initiated our first non-AAV preclinical program with AV333 – a non-viral DNA-based drug. Finally, we are considering opportunities outside the gene therapy field and are evaluating several validated small molecule opportunities in the fields of hematological and neurological disorders in order to broaden our portfolio of development candidates.

The regulatory environment for gene therapy remains challenging. Our hemophilia program has faced numerous delays, and has progressed much more slowly than is common for conventional pharmaceutical drug candidates. We see this heightened level of scrutiny and review of gene therapy trials continuing for the foreseeable future, and we are working with regulatory agencies to address their concerns and improve the overall pace of clinical development. We are also focusing our new product evaluation process toward product candidates that target life-threatening chronic diseases with a risk-benefit profile that favors a more accelerated subject enrollment pace and faster clinical development timelines.

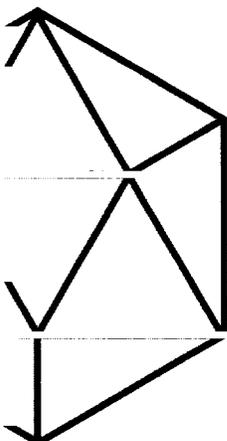
To effectively implement this ambitious strategy, we strengthened our management team with additional therapeutic development expertise. We are pleased that Dawn McGuire, M.D., a board-certified neurologist with extensive experience in drug development from first-in-human studies through New Drug Application approval, and Kirk Johnson, Ph.D., a pharmacologist and toxicologist with extensive protein and small molecule product development experience, joined us in early 2004 as Chief Medical Officer and Associate Vice President, Preclinical Development, respectively. These two management additions complement our strong research and clinical development efforts led by Glenn Pierce, M.D., Ph.D., who has extensive experience in DNA-based drug delivery. With these additions, Avigen has assembled a management team capable of developing a broader range of pharmaceutical products and improving the overall quality and speed of our drug development efforts.

In 2003, we further enhanced our intellectual property position, particularly with regards to our AAV platform, with the issuance of six new U.S. and international patents, bringing our total issued patents to 32 in the U.S. and 18 internationally. We believe our broad intellectual property portfolio places us in a very strong competitive position.

We began 2004 with a solid financial foundation, including approximately \$99 million in cash and securities. While increasing the number of clinical and preclinical candidates in our development pipeline, we were able to reduce our net cash burn (decrease in cash and securities) by 31% for 2003 to \$20 million versus \$29 million in 2002. We expect to increase our spending in 2004, but believe our financial resources are sufficient to support our clinical trials, ongoing research and preclinical development programs for the next three to four years based on our planned cash burn.

Looking forward, Avigen is dedicated to developing a viable commercial enterprise using DNA-based and other drug therapies to address the unmet medical needs of patients who suffer from serious, chronic disorders that are not effectively treated with currently available conventional approaches. Our goal is to make a meaningful difference in the lives of people in need and we believe that day is getting closer.

We are grateful for the contributions of John Monahan, who resigned as Chief Executive Officer in March 2004. John led the company since it was founded twelve years ago, and we wish him well in his future endeavors. We want to thank our stockholders and employees for supporting our efforts over the last year and we look forward to sharing our progress and success with each of you over the coming year.



Philip J. Whitcome

Philip J. Whitcome, Ph.D.
Chairman of the Board



Kenneth G. Chahine, Ph.D., J.D.
President and Chief Executive Officer

Cautionary Statement Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements that involve risks and uncertainties. Such statements include, but are not limited to, trends in cash burn, operating or financial performance, and the potential efficacy of our technology. Words such as "intends," "believes," "expects," "assumes," and "plans," and words of similar meaning, are intended to identify these statements as forward-looking. Actual results may differ materially as a result of any number of factors, including those set forth under "Risk Factors" at the end of Item 1, Part 1 of our Annual Report on Form 10-K, which is included in this report. See also "Information Regarding Forward-Looking Statements at the beginning of our Annual Report on Form 10-K for more information on forward-looking statements

AVIGEN, INC.
1301 Harbor Bay Parkway
Alameda, California 94502

**PROXY STATEMENT
FOR THE 2004 ANNUAL MEETING OF STOCKHOLDERS
MAY 26, 2004**

QUESTIONS AND ANSWERS ABOUT THIS PROXY MATERIAL AND VOTING

Why am I receiving these materials?

We sent you this proxy statement and the enclosed proxy card because the Board of Directors of Avigen, Inc. is soliciting your proxy to vote at Avigen's 2004 Annual Meeting of Stockholders. You are invited to attend the Annual Meeting and we request that you vote on the proposals described in this proxy statement. You do not need to attend the meeting to vote your shares, however. Instead, you may simply complete, sign and return the enclosed proxy card or follow the instructions below to submit your proxy over the telephone or on the Internet.

Avigen intends to mail this proxy statement and accompanying proxy card on or about April 28, 2004 to all stockholders of record entitled to vote at the Annual Meeting.

Who can vote at the Annual Meeting?

Only stockholders of record at the close of business on April 12, 2004 will be entitled to vote at the Annual Meeting. On this record date, there were 20,353,387 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on April 12, 2004, your shares were registered directly in your name with Avigen's transfer agent, American Stock Transfer & Trust Co., then you are a stockholder of record. As a stockholder of record, you may vote in person at the meeting or vote by proxy. Whether or not you plan to attend the meeting, we urge you to fill out and return the enclosed proxy card or vote by proxy over the telephone or on the Internet as instructed below to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker or Bank

If on April 12, 2004, your shares were held in an account at a brokerage firm, bank, dealer, or other similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered the stockholder of record for purposes of voting at the Annual Meeting. As a beneficial owner, you have the right to direct your broker or other agent on how to vote the shares in your account. You are also invited to attend the Annual Meeting. Since you are not the stockholder of record, however, you may not vote your shares in person at the meeting unless you request and obtain a valid proxy from your broker or other agent.

What am I voting on?

There are three matters scheduled for a vote:

- Election of two directors to hold office until the 2007 Annual Meeting of Stockholders;
- The approval of Avigen's 1996 Non-Employee Directors' Stock Option Plan, as amended to increase the aggregate number of shares of common stock authorized for issuance under the plan by 250,000 shares; and
- Ratification of Ernst & Young LLP as Avigen's independent auditors for its fiscal year ending December 31, 2004.

How do I vote?

You may either vote "For" all the nominees to the Board of Directors or you may withhold your vote for any nominee you specify. For each of the other matters to be voted on, you may vote "For" or "Against" or abstain from voting. The procedures for voting are fairly simple:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote in person at the Annual Meeting, vote by proxy using the enclosed proxy card, vote by proxy over the telephone, or vote by proxy on the Internet. If you vote by proxy, your shares will be voted as you specify on the proxy card or over the telephone or by Internet. Whether or not you plan to attend the meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the meeting and vote in person if you have already voted by proxy.

- To vote in person, come to the Annual Meeting and we will give you a ballot when you arrive.
- To vote using the proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the Annual Meeting, we will vote your shares as you direct.
- To vote over the telephone, dial toll-free 1-800-690-6903 using a touch-tone phone and follow the recorded instructions. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 11:59 p.m. Eastern Daylight Time on May 25, 2004 to be counted.
- To vote on the Internet, go to <http://www.proxyvote.com> to complete an electronic proxy card. You will be asked to provide the company number and control number from the enclosed proxy card. Your vote must be received by 11:59 p.m. Eastern Daylight Time on May 25, 2004 to be counted.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner of shares registered in the name of your broker, bank, or other agent, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from Avigen. Simply complete and mail the proxy card to ensure that your vote is counted. Alternatively, you may vote by telephone or over the Internet as instructed by your broker or bank. To vote in person at the Annual Meeting, you must obtain a valid proxy from your broker, bank, or other agent. Follow the instructions from your broker or bank included with these proxy materials, or contact your broker or bank to request a proxy form.

We provide Internet proxy voting to allow you to vote your shares on-line, with procedures designed to ensure the authenticity and correctness of your proxy vote instructions. However, please be aware that you must bear any costs associated with your Internet access, such as usage charges from Internet access providers and telephone companies.

How many votes do I have?

On each matter to be voted upon, you have one vote for each share of common stock you own as of April 12, 2004.

What if I return a proxy card but do not make specific choices?

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted "For" the election of both nominees for director and "For" proposals 2 and 3. If any other matter is properly presented at the meeting, your proxy (i.e., one of the individuals named on your proxy card) will vote your shares using his best judgment.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these mailed proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one proxy card?

If you receive more than one proxy card, your shares are registered in more than one name or are registered in different accounts. Please complete, sign and return **each** proxy card to ensure that all of your shares are voted.

Can I change my vote after submitting my proxy?

Yes. You may revoke your proxy at any time before the final vote at the meeting. You may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy card with a later date.
- You may send a written notice that you are revoking your proxy to Avigen's Secretary at 1301 Harbor Bay Parkway, Alameda, California 94502.
- You may attend the Annual Meeting and vote in person. Simply attending the meeting will not, by itself, revoke your proxy.

When are stockholder proposals due for next year's Annual Meeting?

To be considered for inclusion in next year's proxy materials, your proposal must be submitted in writing by December 29, 2004, to Avigen's Secretary at 1301 Harbor Bay Parkway, Alameda, California 94502. However, if Avigen's 2005 Annual Meeting of Stockholders is not held between April 26, 2005 and June 25, 2005, then the deadline will be a reasonable time prior to the time we begin to print and mail our proxy materials. If you wish to bring a proposal before the stockholders at next year's annual meeting that is not included in next year's proxy materials, you must notify Avigen's Secretary, in writing, not later than the close of business on March 27, 2005, nor earlier than the close of business on February 25, 2005. We also advise you to review Avigen's Bylaws, which contain additional requirements about advance notice of stockholder proposals and director nominations. If you do not comply with these requirements, you will not be able to make a stockholder proposal or director nomination at next year's Annual Meeting.

How are votes counted?

Votes will be counted by the inspector of election appointed for the meeting, who will separately count "For" and (with respect to proposals other than the election of directors) "Against" votes, abstentions and broker non-votes. In addition, with respect to the election of directors, the inspector of election will count the number of "withheld" votes received by each nominee. A "broker non-vote" occurs when a nominee holding shares for a beneficial owner does not vote on a particular proposal because the nominee does not have discretionary voting power with respect to that proposal and has not received instructions with respect to that proposal from the beneficial owner (despite voting on at least one other proposal for which it does have discretionary authority or for which it has received instructions). Abstentions will be counted towards the vote total for each proposal, and will have the same effect as "Against" votes. Broker non-votes have no effect and will not be counted towards the vote total for any proposal.

If your shares are held by your broker as your nominee (that is, in "street name"), you will need to obtain a proxy form from the institution that holds your shares and follow the instructions included on that form regarding how to instruct your broker to vote your shares. If you do not give instructions to your broker, your broker can vote your shares with respect to "discretionary" items, but not with respect to "non-discretionary" items. Discretionary items are proposals considered routine under the rules of the New York Stock Exchange on which your broker may vote shares held in street name in the absence of your voting instructions. On non-discretionary items for which you do not give your broker instructions, the shares will be treated as broker non-votes.

How many votes are needed to approve each proposal?

- For the election of directors, the two nominees receiving the most “For” votes (among votes properly cast in person or by proxy) will be elected. Broker non-votes will count towards the quorum but will have no effect.
- To be approved, Proposal No. 2, the approval of Avigen’s 1996 Non-Employee Directors’ Stock Option Plan, as amended to increase the aggregate number of shares of Common Stock authorized for issuance under the plan by 250,000 shares, must receive a “For” vote from the majority of shares present and entitled to vote either in person or by proxy to be approved. If you “Abstain” from voting, it will have the same effect as an “Against” vote. Broker non-votes will have no effect.
- To be approved, Proposal No. 3, the ratification of Ernst & Young LLP as Avigen’s independent auditors for its fiscal year ending December 31, 2004, must receive a “For” vote from the majority of shares present and entitled to vote either in person or by proxy to be approved. If you “Abstain” from voting, it will have the same effect as an “Against” vote. Broker non-votes will have no effect.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if at least a majority of the outstanding shares entitled to vote are represented by votes at the meeting or by proxy. On the record date, there were 20,371,387 shares outstanding and entitled to vote.

Your shares will be counted towards the quorum only if you submit a valid proxy or vote at the meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum, the chairman of the meeting or a majority of the votes present at the meeting may adjourn the meeting to another date.

How can I find out the results of the voting at the Annual Meeting?

Preliminary voting results will be announced at the Annual Meeting. Final voting results will be published in Avigen’s quarterly report on Form 10-Q for the second quarter of 2004.

PROPOSAL 1

ELECTION OF DIRECTORS

Avigen's Board of Directors is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, with each class having a three-year term. Vacancies on the Board may be filled only by persons elected by a majority of the remaining directors. A director elected by the Board to fill a vacancy (including a vacancy created by an increase in the number of directors) shall serve for the remainder of the full term of the class of directors in which the vacancy occurred and until such director's successor is elected and has qualified, or until such director's earlier death, resignation or removal.

The Board of Directors presently has six members. There are two directors in the class whose term of office expires in 2004—Dr. Vapnek and Dr. Chahine. Dr. Vapnek is currently a director of Avigen who was previously elected by the stockholders. Dr. Chahine, Avigen's President and Chief Executive Officer, is currently a director of Avigen but was not previously elected by the stockholders. Dr. Chahine was elected by the Board to fill the vacancy created by the resignation of John Monahan in March 2004. If elected at the Annual Meeting, each of the nominees would serve until the 2007 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until such director's earlier death, resignation or removal. Avigen does not have a formal policy regarding its directors attendance at the Annual Meeting, but Avigen does encourage its directors to attend the Annual Meeting. All of Avigen's directors attended the 2003 Annual Meeting of Stockholders.

Directors are elected by a plurality of the votes present in person or represented by proxy and entitled to vote at the Annual Meeting. Shares represented by executed proxies will be voted, if authority to do so is not withheld, for the election of the two nominees named below. In the event that any nominee should be unavailable for election as a result of an unexpected occurrence, such shares will be voted for the election of such substitute nominee as management may propose. Each person nominated for election has agreed to serve if elected, and management has no reason to believe that any nominee will be unable to serve.

The following is a brief biography of each nominee and each director whose term will continue after the Annual Meeting.

Nominees for Election for a Three-year Term Expiring at the 2007 Annual Meeting

Class III Directors

Kenneth G. Chahine, Ph.D., J.D.

Kenneth G. Chahine, Ph.D., J.D., 39, was appointed President, Chief Executive Officer and director of Avigen in March 2004. Dr. Chahine joined Avigen in 1998, was appointed Vice President, Business Development in January 1999, and was appointed Chief Operating Officer in July 2002. Prior to joining Avigen, Dr. Chahine worked at the patent law firm of Madson & Metcalf, P.C. in Salt Lake City from 1994 to 1998. Between 1992 and 1993, Dr. Chahine worked as a research scientist at Parke-Davis Pharmaceuticals, a pharmaceutical company, and held another research scientist post at the University of Utah Department of Human Genetics from 1994 through 1996. Dr. Chahine also served as Western Regional News and Legal Correspondent for Nature Biotechnology from 1996 to 2002. Dr. Chahine holds a J.D. from the University of Utah and a Ph.D. in Biochemistry and Molecular Biology from the University of Michigan.

Daniel Vapnek, Ph.D.

Daniel Vapnek, Ph.D., 65, has served as a director of Avigen since February 2002. Dr. Vapnek is currently an adjunct professor at the University of California, Santa Barbara. From 1981 through 1999, Dr. Vapnek held various senior research positions at Amgen Inc., a biopharmaceutical company, including Senior Vice President, Research from 1988 to 1996 and Senior Consultant from 1996 to 1999. Prior to joining Amgen, Dr. Vapnek held various professional positions at the University of Georgia from 1972 to 1981, including Professor of Molecular and Population Genetics, and served as a research associate at the Yale University School of Medicine from 1970 to 1972. Dr. Vapnek is CEO and chairman of the board of directors of Protein Pathways, Inc. and is a director of

BioArray Solutions, Inc., both of which are privately held biotechnology companies. Dr. Vapnek received a Ph.D. in Microbiology and a B.S. in Zoology from the University of Miami.

**THE BOARD OF DIRECTORS RECOMMENDS
A VOTE IN FAVOR OF EACH NAMED NOMINEE.**

Directors Continuing in Office until the 2005 Annual Meeting of Stockholders:

Class I Directors

Zola Horovitz, Ph.D.

Zola Horovitz, Ph.D., 69, has served as a director of Avigen since November 1994. Dr. Horovitz has been an independent consultant to pharmaceutical and biotechnology companies since May 1994. From 1991 to May 1994, Dr. Horovitz served as Vice President, Business Development and Planning and from 1990 to 1991 as Vice President, Licensing at Bristol-Myers Squibb Company, a pharmaceutical and healthcare products company. Prior to this, Dr. Horovitz served from 1959 through 1989 in various positions at the Squibb Institute for Medical Research, including Vice President, Research, Planning & Scientific Liaison, Vice President, Drug Development, and Vice President, Biological and Pharmaceutical R&D. Dr. Horovitz currently serves on the board of directors of BioCryst Pharmaceuticals, Inc., Genvec, Inc., Genaera Corporation, Palatin Technologies, Inc., DOV Pharmaceutical Inc., NitroMed, Inc. and Paligent Inc., all of which are biotechnology companies. From 1975 through 1993 Dr. Horovitz served on the Scientific Advisory Council at Princeton University and from 1976 through 1989 he served on the Advisory Board of Rutgers University College of Pharmacy. Dr. Horovitz received a Ph.D. and an M.S. in Pharmacology and a B.S. in Pharmacy from the University of Pittsburgh.

Yuichi Iwaki, M.D., Ph.D.

Yuichi Iwaki, M.D., Ph.D., 54, has served as a director of Avigen since November 1994. Since September 2000, Dr. Iwaki has served as the chairman of the board of directors of MediciNova, Inc., a private, developmental stage pharmaceutical company. Since 1992, Dr. Iwaki has held three professorships at the University of Southern California School of Medicine in the Departments of Urology, Pathology and Surgery, and currently serves as Director of the Transplantation Immunology and Immunogenetic Laboratory. In addition, he holds visiting professorships at the University of California, Irvine, School of Medicine, Nihon University School of Medicine in Japan. Prior to joining the University of Southern California School of Medicine faculty in 1992, Dr. Iwaki held professorships at the University of Pittsburgh in the Departments of Surgery and Pathology from 1989 through 1991 and was the director of the transplantation laboratory. Dr. Iwaki received an M.D. and a Ph.D. from Sapporo Medicine School in Sapporo, Japan.

Directors Continuing in Office until the 2006 Annual Meeting of Stockholders:

Class II Directors

Philip J. Whitcome, Ph.D.

Philip J. Whitcome, Ph.D., 55, has served as a director of Avigen since December 1992. In April 1995, Dr. Whitcome was elected Chairman of the Board and from March 1996 to December 1996 he served as acting Chief Financial Officer. From 1988 to 1994, Dr. Whitcome was President and Chief Executive Officer of Neurogen Corporation, a biopharmaceutical company. From 1981 to 1988, Dr. Whitcome was employed at Amgen Inc., a biopharmaceutical company, including service as Director of Strategic Planning. Prior to joining Amgen, he served as Manager of Corporate Development for Medical Products at Bristol-Myers Squibb Company, a pharmaceutical and healthcare products company, and held research and marketing management positions with the Diagnostics Division of Abbott Laboratories, a pharmaceutical and medical products company. Dr. Whitcome holds a Ph.D. in Molecular Biology from the University of California at Los Angeles, an M.B.A. from the Wharton School at the University of Pennsylvania and a B.S. in Physics from Providence College.

John K.A. Prendergast, Ph.D.

John K.A. Prendergast, Ph.D., 50, is a co-founder of Avigen and has served as a director of Avigen since December 1992. Since 1993, he has served as President of SummerCloud Bay Inc., a consulting firm providing services to the biotechnology industry. From December 1992 to March 1996, Dr. Prendergast served as a Vice President and the Treasurer of Avigen. Dr. Prendergast is a co-founder and director of AVAX Technologies, Inc. and Palatin Technologies, Inc. ("Palatin"), both of which are biopharmaceutical companies. Dr. Prendergast is currently chairman of the board of directors of Palatin and is currently serving as the executive chairman of the board of directors of Antyra, Inc., a privately held biopharmaceutical company. Dr. Prendergast received M.Sc. and Ph.D. degrees from the University of New South Wales, Sydney, Australia and a C.S.S. in Administration and Management from Harvard University.

Independence of the Board of Directors

As required under the National Association of Securities Dealers, Inc. ("NASD") listing standards, a majority of the members of a listed company's Board of Directors must qualify as "independent," as affirmatively determined by the Board of Directors. The Board consults with Avigen's counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in pertinent listing standards of the NASD, as in effect from time to time.

Consistent with these considerations, after review of all relevant transactions or relationships between each director, or any of his family members, and Avigen, its senior management and its independent auditors, the Board affirmatively has determined that all of Avigen's directors are independent directors within the meaning of the applicable NASD listing standards, except for Dr. Chahine, Avigen's President and Chief Executive Officer, and Dr. Whitcome, the Chairman of the Board.

Information Regarding the Board of Directors and its Committees

As required under new NASD listing standards, Avigen's independent directors will meet in regularly scheduled executive sessions at which only independent directors are present.

Avigen's Board of Directors has an Audit Committee, a Compensation Committee, and a Corporate Governance and Nominating Committee. The following table provides membership information for 2003 for each of these committees:

Name	Audit	Compensation	Governance
Zola Horovitz, Ph.D.	X	X	X
Yuichi Iwaki, M.D., Ph.D.	X		X
John K.A. Prendergast, Ph.D.	X*	X*	X*
Daniel Vapnek, Ph.D.		X	X

* Committee Chairperson

Below is a description of each of these committees of the Board of Directors. The Board of Directors has determined that each member of each committee meets the applicable rules and regulations of the SEC and NASD regarding "independence" for the committees on which they serve, and that each member is free of any relationship that would interfere with his individual exercise of independent judgment with regard to Avigen.

Audit Committee

The Audit Committee of the Board of Directors oversees Avigen's corporate accounting and financial reporting process and has the direct responsibility for the appointment, compensation, retention and oversight of the work of the independent auditors, who report directly and are accountable to the Audit Committee. For this purpose, the Audit Committee performs several functions. The Audit Committee: has the sole authority to select, evaluate, replace and determine the compensation for the independent auditors; evaluates the independent auditors' performance and assesses their qualifications; has the sole authority to approve audit and permissible non-audit services to be performed by the independent auditors; oversees the independence of the independent auditors and is responsible for receiving written statements from the independent auditors delineating all relationships between the

independent auditors and Avigen consistent with Independence Standards Board Standard No. 1; establishes and maintains procedures, as required under applicable law, for the receipt, retention and treatment of complaints received by Avigen regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters; reviews with the independent auditors the adequacy and effectiveness of Avigen's internal controls over financial reporting; reviews the financial statements to be included in Avigen's Annual Report on Form 10-K; and has the specific responsibilities and authority necessary to comply with the NASD listing standards applicable to audit committees. The Audit Committee met eight times during the fiscal year and did not act by unanimous written consent. The Audit Committee is governed by a written Audit Committee Charter that is attached as Appendix A to these proxy materials.

The Board of Directors annually reviews the NASD listing standards definition of independence for audit committee members and has determined that all members of Avigen's Audit Committee are independent. Pursuant to applicable SEC rules, Avigen is required to disclose whether it has an "audit committee financial expert" serving on its Audit Committee. Although each member of the Audit Committee has been selected by the Board based on the Board's determination that they are fully qualified to monitor the performance of management, the public disclosures by Avigen of its financial condition and results of operations, Avigen's internal controls over financing reporting and the performance of Avigen's independent auditors, as well as to analyze and evaluate Avigen's financial statements, the Board has determined that none of the members of the Audit Committee meet all of the criteria set forth in such rules qualifying them as an "audit committee financial expert." The Board has determined that it is appropriate for the Audit Committee not to have an "audit committee financial expert" because Avigen's financial statements are not overly complex, given the current stage of Avigen's development, and the fact that Avigen does not currently have any meaningful revenue, such that, in the judgment of the Board, the financial sophistication of the current members of the Audit Committee, as proven by their service on the Audit Committee over the years as well as in their occupations outside of Avigen, is sufficient for the Audit Committee to ensure the integrity of Avigen's financial statements and to fully and completely fulfill its role under its charter. In addition, the Audit Committee has the ability on its own to retain and determine the compensation for, at Avigen's expense, special legal, accounting or other advisors or consultants whenever it deems necessary or appropriate.

Compensation Committee

The Compensation Committee of the Board of Directors reviews and approves the overall compensation strategy and policies for Avigen. The Compensation Committee: reviews and approves corporate performance goals and objectives relevant to the compensation of Avigen's executive officers and other senior management; recommends to the Board for approval the compensation and other terms of employment of Avigen's Chief Executive Officer; and recommends to the Board for approval the compensation and other terms of employment of the other executive officers. The Compensation Committee met four times during the fiscal year and acted by unanimous written consent once.

Corporate Governance and Nominating Committee

The Corporate Governance and Nominating Committee of the Board of Directors is responsible for identifying, reviewing and evaluating qualified candidates to serve as directors of Avigen, establishing criteria for Board membership, recommending to the Board for selection candidates for election to the Board, including the reelection of current directors to the Board, making recommendations to the Board regarding the membership of the committees of the Board, assessing the performance of the Board, including the committees of the Board, and overseeing all aspects of Avigen's corporate governance functions. In this regard, the Corporate Governance and Nominating Committee recommended to the Board that Dr. Chahine be nominated for election as a Class III director at the Annual Meeting and that Dr. Vapnek be nominated for reelection as a Class III director at the Annual Meeting. Avigen's Corporate Governance and Nominating Committee charter is attached as Appendix B to these proxy materials. The Board established the Corporate Governance and Nominating Committee in February 2004, and, accordingly, it did not meet during the 2003 fiscal year. During the 2003 fiscal year, the Board as a whole performed the functions of a nominating committee.

The Corporate Governance and Nominating Committee will consider all of the relevant qualifications of Board candidates, including such factors as possessing relevant expertise upon which to be able to offer advice and guidance to management, having sufficient time to devote to the affairs of Avigen, demonstrated excellence in his or

her field, having the ability to exercise sound business judgment, having the commitment to rigorously represent the long-term interests of our stockholders, and whether the Board candidates will be independent for purposes of the NASD listing standards, as well as the current needs of the Board and Avigen. In the case of incumbent directors whose terms of office are set to expire, the Committee will also review such directors' overall service to Avigen during their term, and any relationships and transactions that might impair such directors' independence. The Committee will conduct any appropriate and necessary inquiries into the backgrounds and qualifications of possible candidates after considering the function and needs of the Board. To date, the Committee has not paid a fee to any third party to assist in the process of identifying or evaluating director candidates.

The Corporate Governance and Nominating Committee has not yet established a policy with regard to the consideration of director candidates recommended by stockholders. Although the Committee is in the process of determining whether to establish such a policy, at this time, the Committee does not consider director candidates recommended by stockholders. The Board has determined that it is appropriate for the Committee not to have such a policy at this time given the recent establishment of the Committee and the Board's determination that the Committee is in the best position to identify, review, evaluate and select qualified candidates for Board membership. To date, the Corporate Governance and Nominating Committee has not received a timely director nominee from a stockholder of Avigen.

Meetings of the Board of Directors

The Board of Directors met four times during the last fiscal year and acted by unanimous written consent twice. Each Board member attended 75% or more of the aggregate of the meetings of the Board and of the committees on which he served, held during the period for which he was a director or committee member, respectively.

Stockholder Communications with the Board of Directors

Historically, Avigen has not adopted a formal process for stockholder communications with the Board. Nevertheless, every effort has been made to ensure that the views of stockholders are heard by the Board or individual directors, as applicable, and that appropriate responses are provided to stockholders in a timely manner. Avigen believes that its responsiveness to stockholder communications to the Board has been excellent. Nevertheless, during the upcoming year, the Corporate Governance and Nominating Committee will give full consideration to the adoption of a formal process for stockholder communications with the Board.

Code of Business Conduct and Ethics

Avigen has adopted a Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at www.avigen.com. The Code of Business Conduct and Ethics may be found as follows:

- From our main Web page, first click on "Investor Information."
- Next, click on "Corporate Governance."
- Finally, click on "Code of Business Conduct and Ethics."

If Avigen makes any substantive amendments to the Code of Business Conduct and Ethics or grants any waiver from a provision of the Code to any executive officer or director, Avigen will promptly disclose the nature of the amendment or waiver on its website.

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS(1)

The Audit Committee of the Board of Directors for the fiscal year ended December 31, 2003 consisted of Drs. Horovitz, Iwaki and Prendergast. All members of Avigen's Audit Committee are independent (as independence is defined in Rules 4200(a)(15) and 4350(d) of the NASD listing standards). In connection with the review and reassessment of the adequacy of Avigen's written Audit Committee Charter undertaken by the members of the Audit Committee and management, the Board recently revised Avigen's written Audit Committee Charter, a copy of which is attached as Appendix A to these proxy materials.

The Audit Committee oversees Avigen's financial reporting process on behalf of the Board of Directors. Management has primary responsibility for the financial statements and the reporting process including the systems of internal controls and disclosure controls and procedures. In fulfilling its oversight responsibilities, the Audit Committee reviewed the audited financial statements in Avigen's Annual Report with management, including a discussion of the quality, not just the acceptability, of the accounting principles, the reasonableness of significant judgments and the clarity of disclosures in the financial statements.

The Audit Committee is responsible for reviewing, approving and managing the engagement of the independent auditors, including the scope, extent and procedures of the annual audit and compensation to be paid therefor, and all other matters the Audit Committee deems appropriate, including the independent auditors' accountability to the Board and the Audit Committee. The Audit Committee reviewed with the independent auditors, who are responsible for expressing an opinion on the conformity of those audited financial statements with generally accepted accounting principles, their judgments as to the quality, not just the acceptability, of Avigen's accounting principles and such other matters as are required to be discussed with the Audit Committee under generally accepted auditing standards and those matters required to be discussed by the Statement on Auditing Standards No. 61. In addition, the Audit Committee has discussed with the independent auditors the auditors' independence from management and Avigen, including the matters in the written disclosures required by the Independence Standards Board Standard No. 1, and has considered the compatibility of non-audit services with the auditors' independence.

The Audit Committee discussed with Avigen's independent auditors the overall scope and plans for their audits. The Audit Committee meets with the independent auditors, with and without management present, to discuss the results of their examinations, their evaluation of Avigen's internal controls and the overall quality of Avigen's financial reporting. The Audit Committee held eight meetings during the fiscal year ended December 31, 2003.

In reliance on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors, and the Board of Directors has approved, that the audited financial statements be included in Avigen's Annual Report on Form 10-K for the fiscal year ended December 31, 2003 for filing with the Securities and Exchange Commission. The Audit Committee has also retained, subject to stockholder ratification described in Proposal 3, Ernst & Young LLP as Avigen's independent auditors for the fiscal year ending December 31, 2004.

AUDIT COMMITTEE

John K.A. Prendergast, Ph.D., Chairman
Zola Horovitz, Ph.D.
Yuichi Iwaki, M.D., Ph.D.

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- (1) The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

PROPOSAL 2

APPROVAL OF AVIGEN'S 1996 NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN, AS AMENDED

In March 1996, the Board adopted, and the stockholders subsequently approved, Avigen's 1996 Non-Employee Directors' Stock Option Plan ("Directors' Plan"). As a result of an amendment to the Directors' Plan in August 2000, which the stockholders subsequently approved, there were 300,000 shares of common stock reserved for issuance under the Directors' Plan as of December 31, 2003.

In February 2004 and April 2004, the Board amended the Directors' Plan, subject to stockholder approval, to increase the number of shares of common stock authorized for issuance under the Directors' Plan by 250,000 shares from a total of 300,000 shares to a total of 550,000 shares. The Board adopted these amendments in order to ensure that Avigen can continue to grant stock options to its current non-employee directors pursuant to the automatic grant feature of the Directors' Plan and to ensure that there is a sufficient number of shares available to provide for automatic grants to any new non-employee directors that may join Avigen's Board in the future.

As of December 31, 2003, options (net of canceled or expired options) covering an aggregate of 247,000 shares of Avigen's common stock had been granted under the Directors' Plan. Only 53,000 shares of common stock (plus any shares that may in the future be returned to the Directors' Plan as a result of canceled or expired options) remained available for future grant under the Directors' Plan.

Stockholders are requested in this Proposal 2 to approve the Directors' Plan as amended by the Board in February 2004 and April 2004. The affirmative vote of the holders of a majority of the shares present in person or represented by proxy and entitled to vote at the meeting will be required to approve the amendment to the Directors' Plan. Abstentions will be counted toward the tabulation of votes cast on proposals presented to the stockholders and will have the same effect as negative votes. Broker non-votes are counted towards a quorum, but are not counted for any purpose in determining whether this matter has been approved.

THE BOARD OF DIRECTORS RECOMMENDS A VOTE IN FAVOR OF PROPOSAL 2.

The essential features of the Directors' Plan are outlined below:

General

The Directors' Plan provides for the automatic grant of nonstatutory stock options. Options granted under the Directors' Plan are not intended to qualify as "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). See "*Federal Income Tax Information*" for a discussion of the tax treatment of nonstatutory stock options.

Purpose

The Board adopted the Directors' Plan to provide a means by which Avigen's non-employee directors may be given an opportunity to purchase stock in Avigen, to assist in retaining the services of such persons, to secure and retain the services of persons capable of filling such positions and to provide incentives for such persons to exert maximum efforts for Avigen's success. Four of Avigen's current directors are currently eligible to participate in the Directors' Plan.

Administration

The Board administers the Directors' Plan. The Board has the power to construe and interpret the Directors' Plan but not to determine the persons to whom or the dates on which options will be granted, the number of shares to be subject to each option, the time or times during the term of each option within which all or a portion of such option may be exercised, the exercise price, the type of consideration or the other terms of the option.

The Board has the power, which it has not yet exercised, to delegate administration of the Directors' Plan to a committee composed of not fewer than two members of the Board. As used herein with respect to the Directors' Plan, the "Board" refers to any committee the Board appoints as well as to the Board itself.

Stock Subject to the Directors' Plan

Pursuant to the February and April 2004 amendments (and subject to stockholder approval of this Proposal), an aggregate of 550,000 shares of common stock are reserved for issuance under the Directors' Plan. If options granted under the Directors' Plan expire or otherwise terminate without being exercised, the shares of common stock not acquired pursuant to such options again become available for issuance under the Directors' Plan.

Eligibility

The Directors' Plan provides that options may be granted only to non-employee directors of Avigen. A "non-employee director" is defined in the Directors' Plan as a director of Avigen who is not otherwise an employee of Avigen or any affiliate of Avigen.

Terms of Options

The following is a description of the terms of options under the Directors' Plan. Individual option grants may not be more restrictive as to the terms described below.

Automatic Grants. An option to purchase 15,000 shares of Avigen's common stock is automatically granted to each person who is elected for the first time to be a non-employee director of Avigen. In addition, options to purchase 10,000 shares of Avigen's common stock are automatically granted at each annual meeting of Avigen's stockholders to each non-employee director who has served for the entire preceding year. An option to purchase a prorated number of shares is granted each non-employee director who has served for less than the full preceding year.

Exercise Price; Payment. The exercise price of options may not be less than 100% of the fair market value of the stock subject to the option on the date of the grant. At December 31, 2003, the closing price of Avigen's common stock as reported on the NASDAQ National Market was \$5.89 per share.

The exercise price of options granted under the Directors' Plan must be paid in cash at the time the option is exercised if less than 1,000 shares are being purchased upon exercise. If 1,000 or more shares are being purchased upon exercise, the exercise price may be paid in one of the following manners: (i) in cash at the time the option is exercised, (ii) by delivery of other common stock of Avigen, or (iii) a combination of (i) and (ii). Notwithstanding the foregoing, an option also may be exercised pursuant to a cashless exercise program which results in the receipt of cash (or check) by Avigen prior to the issuance of shares.

Option Exercise. Options granted under the Directors' Plan become exercisable in cumulative increments ("vest") with respect to one-third of the shares subject to the option on each anniversary of the date of grant during the optionholder's service as a non-employee director of Avigen and during any subsequent employment of the optionholder by and/or service by the optionholder as a consultant to Avigen or an affiliate (collectively, "service"). The Board does not have the power to accelerate the time during which an option may vest or be exercised. Options granted under the Directors' Plan do not permit exercise prior to vesting. To the extent provided by the terms of an option, an optionholder may satisfy any federal, state or local tax withholding obligation relating to the exercise of such option by a cash payment upon exercise, by authorizing Avigen to withhold a portion of the stock otherwise issuable to the optionholder, by delivering already-owned common stock of Avigen or by a combination of these means.

Term. The term of options granted under the Directors' Plan is 10 years. Options under the Directors' Plan terminate 12 months after termination of the optionholder's service unless such termination is due to the optionholder's death, in which case the option may be exercised (to the extent the option was exercisable at the time of the optionholder's death) within 18 months of the optionholder's death by the person or persons to whom the

rights to such option pass by will or by the laws of descent and distribution. An optionholder may designate a beneficiary who may exercise the option following the optionholder's death. The option term is not extended in the event that exercise of the option within these periods is prohibited.

Other Provisions. The option agreement may contain such other terms, provisions and conditions not inconsistent with the Directors' Plan as determined by the Board.

Restrictions on Transfer

During the lifetime of the optionholder, an option may be exercised only by the optionholder or a transferee pursuant to a qualified domestic relations order.

Adjustment Provisions

Transactions not involving receipt of consideration by Avigen, such as a merger, consolidation, reorganization, stock dividend, or stock split, may change the class(es) and number of shares of common stock subject to the Directors' Plan and outstanding options. In that event, the Directors' Plan will be appropriately adjusted as to the class(es) and the maximum number of shares of common stock subject to the Directors' Plan, and outstanding options will be adjusted as to the class(es), number of shares and price per share of common stock subject to such options.

Effect of Certain Corporate Events

The Directors' Plan provides that, in the event of a dissolution, liquidation or sale of substantially all of the assets of Avigen, specified type of merger, or other corporate reorganization (a "change in control"), the vesting and the time during which such options may be exercised will be accelerated to permit the optionholders to exercise their options in full prior to the change in control. If the options are not exercised prior to the consummation of the change in control, the options will terminate.

The acceleration of an option in the event of an acquisition or similar corporate event may be viewed as an anti-takeover provision, which may have the effect of discouraging a proposal to acquire or otherwise obtain control of Avigen.

Duration, Amendment and Termination

The Board may suspend or terminate the Directors' Plan without stockholder approval or ratification at any time. Unless sooner terminated, the Directors' Plan will terminate on March 28, 2006.

The Board may also amend the Directors' Plan at any time or from time to time. However, no amendment will be effective unless approved by the stockholders of Avigen within 12 months before or after its adoption by the Board if the amendment would change any provision of the Directors' Plan in any way if such modification requires stockholder approval in order to comply with Rule 16b-3 of the Exchange Act or satisfy the requirements of any applicable NASDAQ or securities exchange listing requirements. However, the Board may not amend the Plan more than once every six months with respect to the provisions of the Directors' Plan that relate to the amount, price and timing of grants, other than to comport with changes in the Code, or applicable regulations or rulings thereunder. The Board may submit any other amendment to the Directors' Plan for stockholder approval.

Federal Income Tax Information

Nonstatutory stock options granted under the Directors' Plan generally have the following federal income tax consequences.

There are no tax consequences to the optionholder or Avigen by reason of the grant of a nonstatutory stock option. Upon exercise of a nonstatutory stock option, the optionholder normally will recognize taxable ordinary income equal to the excess of the stock's fair market value on the date of exercise over the option exercise price. If the optionholder becomes an employee, Avigen is required to withhold from regular wages or supplemental wage payments an amount based on the ordinary income recognized. Subject to the requirement of reasonableness and

the satisfaction of a tax reporting obligation, Avigen will generally be entitled to a business expense deduction equal to the taxable ordinary income realized by the optionholder.

Upon disposition of the stock, the optionholder will recognize a capital gain or loss equal to the difference between the selling price and the sum of the amount paid for such stock plus any amount recognized as ordinary income upon exercise of the option (or vesting of the stock). Such gain or loss will be long-term or short-term depending on whether the stock was held for more than one year. Slightly different rules may apply to optionholders who acquire stock subject to certain repurchase options or who are subject to Section 16(b) of the Exchange Act.

New Plan Benefits

The following table presents certain information with respect to options to be granted under the Directors' Plan on the date of the Annual Meeting to all non-employee directors as a group.

NEW PLAN BENEFITS
Avigen, Inc. 1996 Non-Employee Directors' Stock Option Plan, as amended

Name and Position	Number of Shares Underlying Options Granted
Non-Employee Director Group.....	40,000

Equity Compensation Plan Information

The following table provides certain information with respect to all of Avigen's equity compensation plans in effect as of December 31, 2003.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders.....	1,754,457	\$13.20	1,383,197
Equity compensation plans not approved by security holders.....	2,607,985	\$12.23	2,906,426
Total	4,362,442	\$12.62	4,289,623

The following equity compensation plans of Avigen that were in effect as of December 31, 2003 were adopted without the approval of Avigen's security holders:

Avigen's 2000 Equity Incentive Plan

General

Avigen's 2000 Equity Incentive Plan (the "2000 Plan") provides for the grant of nonqualified stock options, stock bonuses and restricted stock purchase awards (collectively, "stock awards"). To date, Avigen has granted only stock options under the 2000 Plan. An aggregate of 5,000,000 shares of common stock are reserved for issuance under the 2000 Plan.

Eligibility

Stock awards may be granted under the 2000 Plan to employees (including officers), directors and consultants of Avigen and its affiliates. The aggregate number of shares issued pursuant to stock awards granted to officers and directors under the 2000 Plan may not exceed 40% of the number of shares reserved for issuance under the 2000 Plan, except that stock awards granted to officers prior to their employment by Avigen as an inducement to entering into employment contracts with Avigen are not included in the 40% limitation.

Terms of Stock Awards

Exercise Price; Payment. The exercise price of options and restricted stock purchase awards may not be less than 85% of the fair market value of the stock on the date of grant. Stock bonuses may be awarded in consideration for past services actually rendered to Avigen or its affiliates.

The exercise price of options and restricted stock purchase awards granted under the 2000 Plan must be paid either in cash at the time the option is exercised or, at the discretion of the Board, (i) pursuant to a deferred payment arrangement or (ii) in any other form of legal consideration acceptable to the Board. The exercise price of options may also be paid, at the discretion of the Board, by delivery of other common stock of Avigen.

Stock Award Vesting. Stock awards granted under the 2000 Plan may become exercisable (in the case of options) or released from a repurchase option in favor of Avigen (in the case of stock bonuses and restricted stock purchase awards) in cumulative increments ("vest") as determined by the Board. The Board has the power to accelerate the time during which stock awards may vest or be exercised. In addition, options granted under the 2000 Plan may permit exercise prior to vesting, but in such event the participant may be required to enter into an early exercise stock purchase agreement that allows Avigen to repurchase unvested shares, generally at their exercise price, should the participant's service terminate before vesting.

Term. The term of options granted under the 2000 Plan are determined by the Board in its discretion. Options under the 2000 Plan generally terminate three months after termination of the participant's service, subject to extension in certain circumstances. Avigen generally may repurchase shares that have been issued pursuant to stock bonuses or restricted stock purchase awards granted under the 2000 Plan, but have not yet vested as of the date the participant terminates his or her service.

Effect of Certain Corporate Events. The 2000 Plan provides that, in the event of a dissolution, liquidation or sale of substantially all of the assets of Avigen, specified type of merger, or other corporate reorganization (a "change in control"), any surviving corporation must either assume any stock awards outstanding under the 2000 Plan or substitute similar stock awards for those outstanding under the 2000 Plan, or else the outstanding stock awards will continue in full force and effect. In the event that any surviving corporation declines to assume or continue the stock awards outstanding under the 2000 Plan, or to substitute similar stock awards, then, with respect to stock awards held by persons then performing services as employees, directors, or consultants of Avigen, the vesting and the time during which these stock awards may be exercised will be accelerated in full.

The Chairman's Grant

The Chairman's Grant is comprised of a single stock option granted to Philip J. Whitcome, Ph.D. to purchase 515,248 shares of Avigen's common stock at an exercise price of \$0.49 per share, the fair market value of the stock as determined by the Board of Directors on the date of grant. This stock option was granted outside of Avigen's equity compensation plans without the approval of Avigen's security holders. The exercise price of the Chairman's Grant may be paid either (i) in cash, (ii) by delivery of other common stock of Avigen, (iii) pursuant to a deferred payment arrangement or (iv) a combination of (i), (ii) and/or (iii). The shares issuable pursuant to the Chairman's Grant were fully vested as of December 31, 2003; however, no part of this option has been exercised. The Chairman's Grant will terminate upon the earlier of three months after termination of Dr. Whitcome's service to Avigen or July 2005.

PROPOSAL 3

RATIFICATION OF SELECTION OF INDEPENDENT AUDITORS

The Audit Committee of the Board of Directors has selected Ernst & Young LLP as Avigen's independent auditors for the fiscal year ending December 31, 2004 and has further directed that management submit the selection of independent auditors for ratification by the stockholders at the Annual Meeting. Ernst & Young LLP has audited Avigen's financial statements since its inception in 1992. Representatives of Ernst & Young LLP are expected to be

present at the Annual Meeting. They will have an opportunity to make a statement if they so desire and will be available to respond to appropriate questions.

Neither Avigen's Bylaws nor other governing documents or law require stockholder ratification of the selection of Ernst & Young LLP as Avigen's independent auditors. However, the Board of Directors, on behalf of the Audit Committee, is submitting the selection of Ernst & Young LLP to the stockholders for ratification as a matter of good corporate practice. If the stockholders fail to ratify the selection, the Audit Committee will reconsider whether or not to retain that firm. Even if the selection is ratified, the Audit Committee in its discretion may direct the appointment of different independent auditors at any time during the year if they determine that such a change would be in the best interests of Avigen and its stockholders.

The affirmative vote of the holders of a majority of the shares present in person or represented by proxy and entitled to vote will be required to ratify the selection of Ernst & Young LLP. Abstentions will be counted toward the tabulation of votes cast on proposals presented to the stockholders and will have the same effect as negative votes. Broker non-votes are counted towards a quorum, but are not counted for any purpose in determining whether this matter has been approved.

Independent Auditors' Fees

The following is a summary of the aggregate fees billed to Avigen by Ernst & Young LLP for professional services rendered for the fiscal years ended December 31, 2003 and 2002.

	Fiscal Year Ended December 31,	
	2003	2002
Audit Fees	\$ 137,000	\$ 116,000
Audit-Related Fees	--	--
Tax Fees	28,895	25,750
All Other Fees	--	--
Total Fees	<u>\$ 165,895</u>	<u>\$ 141,750</u>

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

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 Avigen's financial statements and are not reported under "Audit Fees." During each of the fiscal years ended December 31, 2003 and 2002, no audit-related fees were billed by Ernst & Young LLP.

Tax Fees. Consists of fees billed for professional services for tax compliance, tax advice and tax planning. During each of the fiscal years ended December 31, 2003 and 2002, these services included the preparation and review of Avigen's income tax returns and general tax advice and planning. For the fiscal year ended December 31, 2003, these services also included consultations related to sales and use tax matters.

All Other Fees. Consists of fees for products and services other than the services described above. During each of the fiscal years ended December 31, 2003 and 2002, no fees were billed by Ernst & Young LLP other than as set forth under "Audit Fees" and "Tax Fees" above.

The Audit Committee has determined that the rendering of the services other than audit services by Ernst & Young LLP is compatible with maintaining the principal accountant's independence.

Pre-Approval of Audit and Non-Audit Services

Avigen's Audit Committee pre-approves all audit and permissible non-audit services provided by its independent auditors. These services may include audit services, audit-related services, tax services and other services. Prior to engaging Avigen's independent auditors to render an audit or permissible non-audit service, the Audit Committee specifically approves the engagement of Avigen's independent auditors to render that service. Accordingly, Avigen does not engage its independent auditors to render audit or permissible non-audit services pursuant to pre-approval policies or procedures or otherwise, unless the engagement to provide such services has been approved by the Audit Committee in advance. As such, the engagement of Ernst & Young LLP to render 100% of the services described in the categories above was approved by the Audit Committee in advance of the rendering of those services.

**THE BOARD OF DIRECTORS RECOMMENDS
A VOTE IN FAVOR OF PROPOSAL 3.**

**SECURITY OWNERSHIP OF
CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table sets forth certain information regarding the ownership of Avigen's common stock as of March 15, 2004 (except as noted): (i) each director and nominee for director; (ii) each of the executive officers named in the Summary Compensation Table presented later in this proxy statement; (iii) all executive officers and directors of Avigen as a group; and (iv) all those known by Avigen to be beneficial owners of more than five percent of its common stock.

Beneficial Owner	Beneficial Ownership (1)	
	Number of Shares	Percent of Total
Directors and Executive Officers		
Philip J. Whitcome, Ph.D.(2).....	707,745	3.36%
John Monahan, Ph.D.(3).....	575,798	2.78%
Thomas J. Paulson(4).....	301,445	1.46%
Kenneth G. Chahine, Ph.D., J.D.(5).....	247,966	1.20%
Glenn Pierce, Ph.D., M.D.(6).....	52,500	*
Yuichi Iwaki, M.D., Ph.D.(7).....	196,348	*
John K.A. Prendergast, Ph.D.(8).....	116,108	*
Zola Horovitz, Ph.D.(9).....	52,500	*
Daniel Vapnek, Ph.D.(10).....	10,836	*
All executive officers and directors as a group (9 persons)(11).....	1,692,948	7.76%
5% Stockholders		
Dimensional Fund Advisors Inc.(12)..... 1299 Ocean Avenue, 11 th Floor Santa Monica, CA 90401	1,556,472	7.65%
Federated Investors, Inc.(13)..... Federated Investors Tower 5800 Corporate Drive Pittsburgh, PA 15222-3779	1,134,800	5.58%
Apex Capital, LLC(14)..... 25 Orinda Way, Suite 300 Orinda, CA 94563	1,040,166	5.11%

* Less than one percent.

- (1) This table is based upon information supplied by officers, directors and principal stockholders and Schedules 13G filed with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, Avigen believes that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 20,353,387 shares outstanding on March 15, 2004, adjusted as required by rules promulgated by the SEC. Unless otherwise indicated, the address of each of the individuals and entities listed in this table is c/o Avigen at the address on the first page of this proxy statement.
- (2) Includes 690,558 shares issuable upon the exercise of options held by Dr. Whitcome that are exercisable within 60 days of the date of this table. Also includes 17,187 shares of common stock held by the Philip J. Whitcome Revocable Trust. Dr. Whitcome is a trustee of the Philip J. Whitcome Revocable Trust and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (3) Includes 355,624 shares issuable upon the exercise of options held by Dr. Monahan that are exercisable within 60 days of the date of this table. Also includes 104,522 shares held in the name of Dr. Monahan's former

spouse and for which Dr. Monahan has voting rights. Dr. Monahan served as President, Chief Executive Officer and as a director of Avigen since 1992 and resigned from Avigen in March 2004.

- (4) Includes 281,290 shares issuable upon the exercise of options held by Mr. Paulson that are exercisable within 60 days of the date of this table. Also includes 1,000 shares held in the name of Mr. Paulson's wife.
- (5) Consists solely of shares issuable upon the exercise of options held by Dr. Chahine that are exercisable within 60 days of the date of this table.
- (6) Consists solely of shares issuable upon the exercise of options held by Dr. Pierce that are exercisable within 60 days of the date of this table.
- (7) Includes 46,250 shares issuable upon the exercise of options held by Dr. Iwaki that are exercisable within 60 days of the date of this table, as well as 128,371 shares of common stock held by the Iwaki Family Limited Partnership. Dr. Iwaki is a partner of the Iwaki Family Limited Partnership and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Dr. Iwaki also holds 3,643 of such shares with his wife. Also includes warrants to purchase 18,084 shares of common stock held by Iwaki & Associates. Dr. Iwaki is a partner of Iwaki & Associates and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (8) Includes 57,500 shares issuable upon the exercise of options held by Dr. Prendergast that are exercisable within 60 days of the date of this table.
- (9) Consists solely of shares issuable upon the exercise of options held by Dr. Horovitz that are exercisable within 60 days of the date of this table.
- (10) Consists solely of shares issuable upon the exercise of options held by Dr. Vapnek that are exercisable within 60 days of the date of this table.
- (11) Includes an aggregate of 1,464,984 shares issuable upon exercise of options and warrants which executive officers and directors of Avigen have the right to acquire within 60 days of the date of this table. Due to Dr. Monahan's resignation from Avigen on March 12, 2004, such number does not include shares held by Dr. Monahan, nor does such number include any shares issuable upon the exercise of options held by Dr. Monahan that are exercisable within 60 days of the date of this table.
- (12) Based upon a Schedule 13G/A filed with the SEC on February 6, 2004 by Dimensional Fund Advisors Inc. ("DFA"). DFA, a registered investment advisor, furnishes investment advice to four investment companies registered under the Investment Company Act of 1940 and serves as investment manager to certain other commingled group trusts and separate accounts. In its role as investment advisor or manager, DFA possesses voting and/or investment power over such shares, and may be deemed to be the beneficial owner of such shares. DFA disclaims beneficial ownership of such shares. Schedule 13G provides information only as of December 31, 2003 and, consequently, DFA's beneficial ownership of Avigen's common stock may have changed between December 31, 2003 and March 15, 2004.
- (13) Based upon a Schedule 13G filed with the SEC on February 13, 2004 by Federated Investors, Inc. (the "FII") in its capacity as the parent holding company of Federated Investment Management Company, Federated Investment Counseling, and Federated Global Investment Management Corp. (collectively, the "Investment Advisers"), which act as investment advisers to registered investment companies and separate accounts that own such shares. The Investment Advisers are wholly owned subsidiaries of FII Holdings, Inc., which is wholly owned subsidiary of FII. All of FII's outstanding voting stock is held in a Voting Shares Irrevocable Trust (the "Trust") for which John F. Donahue, Rhodora J. Donahue and J. Christopher Donahue act as trustees (collectively, the "Trustees"). FII, the Trust, and each of the Trustees have shared voting and dispositive power over the shares but expressly disclaim beneficial ownership of the shares. Schedule 13G provides information only as of December 31, 2003 and, consequently, FII's beneficial ownership of Avigen's common stock may have changed between December 31, 2003 and March 15, 2004.

- (14) Information is as provided by Apex Capital, LLC ("Apex"). Apex is a registered investment adviser whose clients have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the shares. Sanford J. Colen is the manager of Apex and Daniel S. Katz is a portfolio manager for Apex. Each of Apex and Messrs. Katz and Colen have shared voting and dispositive power with respect to such shares. Such shares do not include 2,500 shares of Avigen's common stock that Mr. Colen has sole voting and dispositive power over, and does not include 43,432 shares of Avigen's common Stock which Mr. Katz has sole voting and dispositive power over.

SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's directors and executive officers, and persons who own more than ten percent of a registered class of the Company's equity securities, to file with the SEC initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish the Company with copies of all Section 16(a) forms they file.

To Avigen's knowledge, based solely on a review of the copies of such reports furnished to Avigen and written representations that no other reports were required, during the fiscal year ended December 31, 2003, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with.

EXECUTIVE COMPENSATION

Compensation of Directors

Each of Avigen's non-employee directors receives a quarterly retainer of \$3,000 (plus \$500 for each committee meeting attended by committee members). In the fiscal year ended December 31, 2003, the total compensation paid to non-employee directors was \$62,500. The members of the Board are also eligible for reimbursement for their expenses incurred in connection with attendance at Board and committee meetings in accordance with Avigen's policy.

Each of Avigen's non-employee directors also receives stock option grants under the Directors' Plan, as described under Proposal 2 above. Only non-employee directors of Avigen are eligible to receive options under the Directors' Plan. As described under Proposal 2 above, options to purchase 10,000 shares of Avigen's common stock are automatically granted at each annual meeting of Avigen's stockholders to each non-employee director who has served for the entire preceding year. An option to purchase a prorated number of shares is granted each non-employee director who has served for less than the full preceding year. In addition, each director who is elected for the first time to be a non-employee director of Avigen is automatically granted an option to purchase 15,000 shares under the Directors' Plan upon the date of initial election to the Board whether by the Board or stockholders of Avigen. No other options may be granted at any other time under the Directors' Plan.

During the last fiscal year, Avigen made four grants of options to the group of non-employee directors of Avigen then in office (Drs. Horovitz, Iwaki, Prendergast and Vapnek). Each of Drs. Horovitz, Iwaki, Prendergast and Vapnek received options covering 10,000 shares at an exercise price per share of \$3.94, the fair market value of such common stock on the date of grant. As of March 15, 2004, options to purchase 20,000 shares had been exercised under the Directors' Plan.

Compensation of Executive Officers

The following table shows for the calendar years ended December 31, 2001, 2002 and 2003, compensation awarded or paid to, or earned by, Avigen's Chief Executive Officer and its other four most highly compensated executive officers at December 31, 2003 (the "Named Executive Officers"). Commensurate with Avigen's practice prior to the change in Avigen's fiscal year end from June 30 to December 31, the salary and bonus components of the Named Executive Officers' compensation are determined based upon a twelve month period ended June 30 of each year. Salary and bonus information reflects salary and bonus actually earned during the year, treating the bonus as having been earned ratably over the twelve months ending with the applicable month of June. Stock option awards are reported in the calendar year in which granted.

SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Annual Compensation			Long-Term Compensation	All Other Compensation (\$)(1)
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Securities Underlying Options (#)	
John Monahan, Ph.D.(2)	2003	365,096	--	--	40,000	2,175
Former President and Chief Executive Officer	2002	344,850	--	--	50,000	2,175
	2001	315,000	100,000	--	150,000	2,165
Kenneth G. Chahine, Ph.D., J.D.(3)	2003	286,325	--	--	75,000	4,863(4)
President and Chief Executive Officer	2002	241,075	--	--	37,500	4,863(4)
	2001	197,750	50,000	--	100,000	3,378(5)
Thomas J. Paulson	2003	246,777	--	--	40,000	9,505(6)
Vice President, Finance, and Chief Financial Officer	2002	234,135	--	--	37,500	9,505(6)
	2001	217,560	50,000	--	100,000	7,914(7)
Glenn Pierce, M.D., Ph.D.	2003	228,375	--	189,577(9)	40,000	4,411(10)
Vice President, Research and Clinical Development	2002	35,913(8)	--	--	120,000	319
	2001	--	--	--	--	--
Philip J. Whitcome, Ph.D.	2003	170,007	--	--	40,000	5,599(11)
Chairman of the Board	2002	161,291	--	--	25,000	5,541(11)
	2001	149,544	50,000	--	75,000	5,429(11)

- (1) Except as otherwise indicated, represents insurance premiums paid by Avigen with respect to term life and disability insurance for the benefit of the Named Executive Officer.
- (2) Dr. Monahan resigned from Avigen in March 2004.
- (3) Dr. Chahine has held various positions with Avigen since joining Avigen in 1998 and was appointed President and Chief Executive Officer in March 2004.
- (4) \$452 represents insurance premiums paid by Avigen with respect to additional long term disability insurance for each of the calendar years ended December 31, 2002 and 2003, and \$2,500 represents matching contributions to Avigen's 401(k) savings plan.
- (5) \$452 represents insurance premiums paid by Avigen with respect to additional long term disability insurance for the calendar year ended December 31, 2001, and \$1,094 represents matching contributions to Avigen's 401(k) savings plan.
- (6) \$5,094 represents insurance premiums paid by Avigen with respect to additional long term disability insurance for each of the calendar years ended December 31, 2002 and 2003, and \$2,500 represents matching contributions to Avigen's 401(k) savings plan.
- (7) \$5,094 represents insurance premiums paid by Avigen with respect to additional long term disability insurance for the calendar year ended December 31, 2001, and \$919 represents matching contributions to Avigen's 401(k) savings plan.
- (8) Dr. Pierce joined Avigen in November 2002.
- (9) Represents relocation expenses reimbursed by Avigen to Dr. Pierce.
- (10) \$2,500 represents matching contributions to Avigen's 401(k) savings plan.
- (11) \$3,853 represents insurance premiums paid by Avigen with respect to additional long term disability insurance for each of the calendar years ended December 31, 2001, 2002 and 2003.

Stock Option Grants and Exercises

The following tables show for the fiscal year ended December 31, 2003, certain information regarding options granted to, exercised by, and held at year end by, each of the Named Executive Officers. All options were granted pursuant to the 2000 Plan.

OPTION GRANTS IN LAST FISCAL YEAR

Name	Individual Grants			Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (3)	
	Number of Securities Underlying Options Granted (#)(1)	Percentage of Total Options Granted to Employees in Fiscal Year (2)	Exercise or Base Price (\$/SH)		5% (\$)	10%(\$)
Dr. Monahan(4).....	40,000	6.19%	3.53	12/31/07	35,701	78,115
Dr. Chahine(5).....	75,000	11.61%	3.53	5/19/13	166,500	421,943
Mr. Paulson.....	40,000	6.19%	3.53	5/19/13	88,800	225,036
Dr. Pierce.....	40,000	6.19%	3.53	5/19/13	88,800	225,036
Dr. Whitcome.....	40,000	6.19%	3.53	5/19/13	88,800	225,036

- (1) Options granted become exercisable at the rate of 6.25% of the shares subject to the option each quarter for four years. The options expire 10 years from the date of grant, or earlier upon termination of employment. The exercise price per share was equal to the fair market value of Avigen's common stock on the date of grant.
- (2) Based upon options to purchase 645,800 shares granted to employees of Avigen during the fiscal year ended December 31, 2003.
- (3) The potential realizable value is calculated based on the term of the option at its time of grant, or ten years (other than with respect to Dr. Monahan, whose option term expires on December 31, 2007 in connection with his resignation from Avigen in March 2004), compounded annually. Assumed stock price appreciation of 5% and 10% is used pursuant to rules promulgated by the SEC. The potential realizable value is calculated by assuming that the stock price on the date of grant appreciates at the indicated rate for the entire term of the option and that the option is exercised and sold on the last day of its term at the appreciated price. No gain to the optionee is possible unless the stock price increases over the option term.
- (4) Dr. Monahan resigned from Avigen in March 2004.
- (5) Dr. Chahine has held various positions with Avigen since joining Avigen in 1998 and was appointed President and Chief Executive Officer in March 2004.

AGGREGATED OPTION EXERCISES IN LAST FISCAL YEAR AND FISCAL YEAR END OPTION VALUES

Name	Shares Acquired on Exercise (#)	Value Realized (\$)	Number of Securities Underlying Unexercised Options at December 31, 2003 (#)(1)		Value of Unexercised In-the-Money Options at December 31, 2003 (\$)(2)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Dr. Monahan(3).....	--	--	306,875	165,625	117,763	88,500
Dr. Chahine(4).....	--	--	208,904	158,596	20,636	165,939
Mr. Paulson.....	--	--	246,603	125,783	196,664	88,500
Dr. Pierce.....	--	--	32,500	127,500	5,900	88,500
Dr. Whitcome.....	--	--	663,684	101,564	2,815,705	88,500

- (1) Reflects shares vested and unvested at December 31, 2003.
- (2) Value is based on the fair market value of Avigen's Common Stock at December 31, 2003 (\$5.89) with respect to in-the-money options minus the exercise price of the options.
- (3) Dr. Monahan resigned from Avigen in March 2004.

- (4) Dr. Chahine has held various positions with Avigen since joining Avigen in 1998 and was appointed President and Chief Executive Officer in March 2004.

Employment, Severance and Change of Control Agreements

In August 1992, Avigen entered into an employment agreement with John Monahan, Avigen's former President and Chief Executive Officer. The employment agreement provides for, among other things, severance payments and benefits at the standard compensation rate for 12 months or until new employment in the gene therapy field is commenced, unless termination is for just cause. In connection with Dr. Monahan's resignation from Avigen in March 2004, Avigen entered into a severance agreement with Dr. Monahan which provides that Dr. Monahan will receive as severance the continuation of his salary and certain health benefits through December 2005, and that the term during which Dr. Monahan may exercise his outstanding stock options will be extended until the earlier of December 31, 2007 or the end of the original term of such options. These severance benefits are in lieu of any severance benefits Dr. Monahan would otherwise be entitled under the terms of his August 1992 employment agreement.

In August 1996, Avigen entered into an employment agreement with Thomas J. Paulson, Avigen's Vice President, Finance and Chief Financial Officer. The employment agreement provides for, among other items: (i) a minimum base salary of \$160,000 and (ii) an option to purchase 100,000 shares of Avigen's common stock at a price and vesting schedule to be determined by the Board.

Avigen has established a Management Transition Plan. Under this plan, all executive officers and certain non-officers of Avigen will receive salary and benefits under certain change of ownership situations. Officers will receive up to 18 months of salary and benefits continuation if terminated within 18 months following a "Change in Control" as defined in the Management Transition Plan.

Certain Relationships and Related Transactions

Avigen has entered into indemnity agreements with certain officers and directors which provide, among other things, that Avigen will indemnify such officer or director, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings to which he or she is or may be made a party by reason of his or her position as a director, officer or other agent of Avigen, and otherwise to the fullest extent permitted under Delaware law and Avigen's Bylaws.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS ON EXECUTIVE COMPENSATION(1)

Compensation Committee

The Compensation Committee of the Board of Directors is currently composed of Drs. Horovitz, Prendergast and Vapnek, all of whom are independent (as independence is currently defined in Rule 4200(a)(15) of the NASD listing standards. The Compensation Committee is responsible for establishing Avigen's compensation programs for all employees, including executives. For executive officers, the Compensation Committee evaluates performance and determines compensation policies and levels.

Compensation Philosophy

The primary goal of the compensation program is to align compensation with business objectives and performance. Avigen's aim is to attract, retain and reward executive officers and other key employees who contribute to the long-term success of Avigen and to motivate those individuals to enhance long-term stockholder value. To establish this relationship between executive compensation and creation of stockholder value, the Board of Directors has adopted a total compensation package comprised of base salary, bonus and stock option awards. Key elements of this philosophy are:

- Avigen pays competitively with biotechnology companies with which Avigen competes for talent.
- Avigen maintains annual incentive opportunities sufficient to provide motivation to achieve specific operating goals and to generate rewards that bring total compensation to competitive levels.
- Avigen provides significant equity-based incentives for executives and other key employees to ensure that they are motivated over the long-term to respond to Avigen's business challenges and opportunities as owners and not just as employees.

Base Salary. The Compensation Committee annually reviews each executive officer's base salary. Among the factors taken into consideration are (1) individual and corporate performance, (2) levels of responsibility, (3) prior experience, (4) breadth of knowledge of the industry and (5) competitive pay practices.

Bonus. Avigen believes that executive performance may be maximized via a system of annual incentive awards. The actual incentive awards earned depend on the extent to which Avigen and individual performance objectives are achieved. During the fiscal year, the Compensation Committee will review and approve the annual performance objectives for Avigen and the individual officers. Avigen's objectives consist of operating, strategic and financial goals that are considered to be critical to Avigen's overall goal: building stockholder value. For the next fiscal year the Board of Directors determined that the primary goals in building stockholder value were:

- understanding, identifying and developing products in the research pipeline as candidates for clinical testing;
- implementing strategies relating to the development of manufacturing capacity for clinical testing;
- establishing strategic corporate collaborations to facilitate product development and provide support for clinical testing; and
- identifying additional potential uses for products which are currently under development.

Long-Term Incentives. Avigen's long-term incentive program consists of the following plans (the "Plans") under which Avigen has granted stock options to its executive officers: 1993 Stock Option Plan, 1996 Equity Incentive Plan and 2000 Equity Incentive Plan. Avigen has also granted a "stand-alone" grant outside of the Plans to

(1) The material in this report is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

the Chairman of the Board of Directors of Avigen. The Plans utilize vesting periods (generally four years) to encourage key employees to continue in the employ of Avigen. Through option grants, executives receive significant equity incentives to build long-term stockholder value. The exercise price of options granted under the Plans generally is 100% of fair market value of the underlying stock on the date of grant. Employees receive value from these grants only if Avigen's common stock appreciates over the long-term. The size of option grants is determined based on competitive practices at leading companies in the biotechnology industry and Avigen's philosophy of significantly linking executive compensation with stockholder interests.

Chief Executive Officer Compensation

The base salary and stock option granted to John Monahan, Avigen's President and Chief Executive Officer during the 2003 fiscal year, were determined in accordance with the criteria described in the "Base Salary," "Bonus" and "Long Term Incentives" sections of this report.

The determination of Dr. Monahan's 2003 compensation was based on several key assessment criteria that had been established in consultation with Dr. Monahan. The Principal areas for evaluation were as follows:

- The progress of Avigen's therapeutic programs in general;
- The progress of Avigen's Factor IX clinical trial;
- The general strategic direction of Avigen including the October 2002 reduction-in-force; and
- The current return to stockholders based on the accomplishment of key corporate milestone events.

The Committee evaluated and discussed the performance of Avigen with Dr. Monahan with respect to each of these principal areas. In particular, the Committee noted that, while there had been certain difficulties associated with the Factor IX clinical trial that were out of Avigen's control, the Committee believed that the main performance measurement of Avigen in relation to Avigen's stockholders depended on the specific progress of this trial. Following its discussion and evaluation, the Committee determined that Avigen had not made substantial progress in any of these principal areas and had not met the Board of Director's expectations regarding the achievement of key corporate milestone events.

Based on these assessments, the Committee decided to recommend to the Board of Directors that the Company not award any bonus to Dr. Monahan for the period. However, it recommended that Dr. Monahan's base salary compensation was to be increased by 6% and that he was to be awarded 40,000 options. The salary increase and the option awards were identical to the rest of the officers of Avigen with the exception of Dr. Kenneth Chahine, who was promoted to Chief Operating Officer during the period.

In consultation with the Board, these recommendations for Dr. Monahan were discussed and duly passed by resolution.

Limitation on Deduction of Compensation Paid to Certain Named Executive Officers

Section 162(m) of the Internal Revenue Code limits Avigen to a deduction for federal income tax purposes of not more than \$1 million of compensation paid to certain Named Executive Officers (as defined in this proxy statement) in a taxable year. Compensation above \$1 million may be deducted if it is "performance-based compensation" within the meaning of the Internal Revenue Code.

The Compensation Committee believes that at the present time it is unlikely that the compensation paid to any Named Executive Officer in a taxable year will exceed \$1 million. Therefore, the Compensation Committee has not established a policy for determining which forms of incentive compensation awarded to its Named Executive Officers shall be designed to qualify as "performance-based compensation."

COMPENSATION COMMITTEE

John K.A. Prendergast, Ph.D.
Chairman Zola Horovitz, Ph.D.
Daniel Vapnek, Ph.D.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

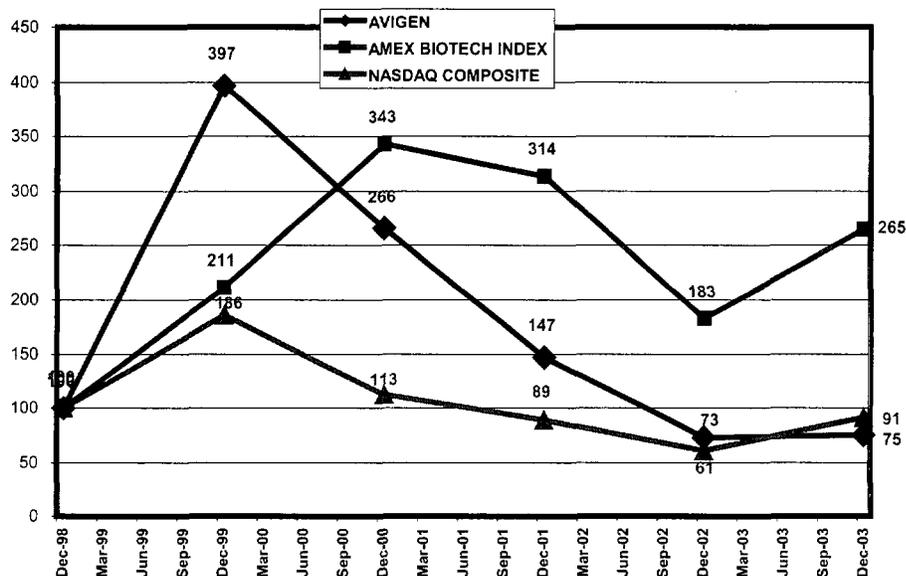
Drs. Horovitz, Prendergast and Vapnek served as members of the Compensation Committee during the fiscal year ended December 31, 2003. Dr. Prendergast was an executive officer of Avigen from December 1992 to 1995.

None of Avigen's executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of Avigen's Board or Compensation Committee.

PERFORMANCE MEASUREMENT COMPARISON(1)

The following graph shows the total stockholder return of an investment of \$100 in cash on December 31, 1998 for (i) Avigen's common stock, (ii) the NASDAQ National Market (U.S.) ("NASDAQ") and (iii) the American Stock Exchange Biotechnology Index (the "AMEX Biotech"). All values assume reinvestment of the full amount of all dividends and are calculated as of December 31 of each year:

Comparison of 5 year Cumulative Total Return on Investment(2)



	12/31/1998	12/31/1999	12/29/2000	12/31/2001	12/31/2002	12/31/2003
AVIGEN	100	397	266	147	73	75
AMEX BIOTECH INDEX	100	211	343	314	183	265
NASDAQ COMPOSITE	100	186	113	89	61	91

- (1) This Section is not "soliciting material," is not deemed "filed" with the SEC and is not to be incorporated by reference in any filing of the Company under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
- (2) The AMEX Biotechnology Index is calculated using an equal-dollar weighing methodology.

HOUSEHOLDING OF PROXY MATERIALS

The SEC has adopted rules that permit companies and intermediaries (e.g., brokers) to satisfy the delivery requirements for proxy statements and annual reports with respect to two or more stockholders sharing the same address by delivering a single proxy statement addressed to those stockholders. This process, which is commonly referred to as "householding," potentially means extra convenience for stockholders and cost savings for companies.

This year, a number of brokers with account holders who are Avigen stockholders will be "householding" our proxy materials. A single proxy statement may be delivered to multiple stockholders sharing an address unless contrary instructions have been received from the affected stockholders. Once you have received notice from your broker that it will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you notify your broker or Avigen that you no longer wish to participate in "householding." If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate proxy statement and annual report in the future you may (1) notify your broker, (2) direct your written request to: Investor Relations, Avigen, Inc., 1301 Harbor Bay Parkway, Alameda, California 94502, or (3) contact our Controller, Andrew Sauter, at (510) 748-7150. Stockholders who currently receive multiple copies of the proxy statement at their address and would like to request "householding" of their communications should contact their broker. In addition, Avigen will promptly deliver, upon written or oral request to the address or telephone number above, a separate copy of the annual report and proxy statement to a stockholder at a shared address to which a single copy of the documents was delivered.

OTHER MATTERS

The Board of Directors knows of no other matters that will be presented for consideration at the Annual Meeting. If any other matters are properly brought before the meeting, it is the intention of the persons named in the accompanying proxy to vote on such matters in accordance with their best judgment.

By Order of the Board of Directors

A handwritten signature in cursive script that reads "Thomas J. Paulson".

Thomas J. Paulson
Chief Financial Officer and Secretary

April 28, 2004

A copy of Avigen's Annual Report to the Securities and Exchange Commission on Form 10-K for the fiscal ended December 31, 2003 is available without charge upon written request to: Investor Relations, Avigen, Inc., 1301 Harbor Bay Parkway, Alameda, California 94502.

APPENDIX A
AVIGEN, INC.
CHARTER OF THE AUDIT COMMITTEE
OF THE BOARD OF DIRECTORS

ORGANIZATION

The Audit Committee of the Board of Directors of Avigen, Inc. (the "Company") shall consist of at least three members of the Board of Directors (the "Board"). The members of the Audit Committee shall meet the independence and financial sophistication requirements of The Nasdaq Stock Market ("Nasdaq") and the rules and regulations of the Securities and Exchange Commission ("SEC"); provided, however, that if permitted by the Nasdaq rules and the rules and regulations of the SEC, one member need not meet the independence requirements under the conditions specified by such requirements and rules and regulations.

STATEMENT OF PURPOSE AND POLICY

The primary purpose of the Audit Committee shall be to act on behalf of the Board in fulfilling its responsibility to the stockholders, potential stockholders, and investment community relating to corporate accounting and financial reporting processes of the Company, the audits of the Company's financial statements, and the quality and integrity of the financial reports of the Company. In so doing, it is the responsibility of the Audit Committee to maintain free and open means of communication between the directors, the independent auditors and the financial management of the Company. The Audit Committee shall also establish procedures, and maintain easy access to the Audit Committee, for all employees and consultants to the Company to voice concerns and report potential misconduct to the Audit Committee. The Audit Committee shall have a clear understanding with management and the independent auditors that the independent auditors are ultimately accountable to the Board and the Audit Committee, as representatives of the Company's shareholders.

AUTHORITY

The Audit Committee shall have authority to appoint, determine compensation for, at the expense of the Company, retain and oversee the independent auditors as set forth in Section 10A(m)(2) of the Securities Exchange Act of 1934, as amended, and the rules thereunder and otherwise to fulfill its responsibilities under this charter. The Audit Committee shall have authority to retain and determine compensation for, at the expense of the Company, special legal, accounting or other advisors or consultants as it deems necessary or appropriate in the performance of its duties. The Audit Committee shall also have authority to pay, at the expense of the Company, ordinary administrative expenses that, as determined by the Audit Committee, are necessary or appropriate in carrying out its duties. The Audit Committee shall have full access to all books, records, facilities and personnel of the Company as deemed necessary or appropriate by any member of the Audit Committee to discharge his or her responsibilities hereunder. The Audit Committee shall have authority to require that any of the Company's personnel, counsel, independent auditors or investment bankers, or any other consultant or advisor to the Company attend any meeting of the Audit Committee or meet with any member of the Audit Committee or any of its special legal, accounting or other advisors and consultants.

RESPONSIBILITIES

The Audit Committee shall oversee the Company's financial reporting process on behalf of the Board, and shall have direct responsibility for the appointment, compensation, retention and oversight of the work of the independent auditors, who shall report directly and be accountable to the Committee. In carrying out its responsibilities, the Audit Committee believes its policies and procedures should remain flexible in order to best react to changing conditions and to ensure to the directors and stockholders that the corporate accounting and reporting practices of the Company are in accordance with all requirements and are of the highest quality.

In carrying out these responsibilities, the Audit Committee shall:

- Have sole authority to hire and terminate the independent auditors.

- Negotiate, execute and deliver the engagement letter to be entered into between the Company and the independent auditors, and establish the compensation to be received by the independent auditors.
- Have the sole authority to approve all audit, review and attest services, as well as non-audit services (but only as permitted by the Nasdaq rules and the rules and regulations of the SEC, which authority the Audit Committee may delegate to one or more members of the Audit Committee), to be performed by the independent auditors.
- Evaluate on a periodic basis the independence and performance of the independent auditors to be engaged to audit the financial statements of the Company and its divisions and subsidiaries and, if determined by the Audit Committee that the independent auditors are not independent or for any other reason, replace the independent auditors.
- Receive written statements from the independent auditors delineating all relationships between the independent auditors and the Company consistent with Independence Standards Board Standard No. 1, and consider and discuss with the auditors any disclosed relationships or services that could affect the auditors' objectivity and independence, and if so determined by the Audit Committee, take appropriate action.
- Meet with the independent auditors and financial management of the Company to review the scope of the proposed audit for the current year and the audit procedures to be utilized, and at the conclusion thereof review such audit, including any comments or recommendations of the independent auditors.
- Resolve any disagreements between the independent auditors and management regarding financial reporting.
- Evaluate the cooperation received by the independent auditors during their audit examination, including their access to all requested records, data and information, and to elicit the comments of management regarding the responsiveness of the independent auditors to the Company's needs.
- Review with the independent auditors and the Company's financial and accounting personnel the adequacy and effectiveness of the accounting and financial controls of the Company, and elicit any recommendations for the improvement of such internal control procedures or particular areas where new or more detailed controls or procedures are desirable. Particular emphasis should be given to the adequacy of such internal controls to expose any payments, transactions, or procedures that might be deemed illegal or otherwise improper. Further, the Audit Committee periodically should review Company policy statements to determine their adherence to the code of conduct.
- Review the financial statements contained in the annual report to stockholders with management and the independent auditors, as well as all significant correcting adjustments identified by the independent auditors, to determine that the independent auditors are satisfied with the disclosure and content of the financial statements to be presented to the stockholders. Any changes in accounting principles should be reviewed.
- Meet with the independent auditors and senior management in separate executive sessions to discuss any matters that the Audit Committee, the independent auditors or senior management believe should be discussed privately with the Audit Committee.
- Have the sole authority to approve the hiring of any employee who is employed by the independent auditor, or has been employed by an independent auditor within the five years prior to the date of determination whether or not to hire such employee.
- Review accounting and financial human resources planning within the Company.
- Review the Management's Discussion and Analysis section of the Company's Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q for purpose of determining if this section of the Company's periodic reports adequately disclose any off-balance sheet transactions by the Company, which authority the Audit Committee may delegate to one or more members of the Audit Committee.
- Review the Company's press releases containing pro forma financial information for the purpose of ensuring that such press releases properly disclose financial information presented in accordance with generally accepted

accounting principles and adequately disclose how such pro forma information differs from financial information presented in accordance with generally accepted accounting principles.

- Review and approve all related party transactions as such term is used by SFAS No. 57 or as otherwise required to be disclosed in the corporation's financial statements or periodic filings with the SEC. It is management's responsibility to bring such related party transactions to the attention of the members of the Audit Committee.
- Establish and maintain procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters and the confidential and anonymous submission by employees of concerns regarding questionable accounting or auditing matters, and a policy of open access to the members of the Audit Committee by the employees and consultants to the Company, to enable the employees and consultants to bring to the attention of the Audit Committee concerns held by such employees and consultants regarding the financial reporting of the Company, and to report potential misconduct to the Audit Committee.
- Investigate any matter brought to its attention within the scope of its duties, with the power to retain outside counsel and separate accountants for this purpose if, in its judgment, such retention or investigation is appropriate.
- Prepare the report required by the rules of the Securities and Exchange Commission to be included in the Company's annual proxy statement.
- Submit the minutes of all meetings of the Audit Committee to, or discuss the matters discussed at each Audit Committee meeting with, the Board.
- Perform such other functions and to have such power as it may deem necessary or advisable in the efficient and lawful discharge of the foregoing.
- Review and assess the adequacy of this charter annually and recommend any proposed changes to the Board for approval.

The operation of the Audit Committee shall be subject to the By-laws as in effect from time to time and Section 141 of the Delaware General Corporation Law.

APPENDIX B

AVIGEN, INC. CHARTER OF THE CORPORATE GOVERNANCE AND NOMINATING COMMITTEE OF THE BOARD OF DIRECTORS

ORGANIZATION

The Corporate Governance and Nominating Committee (the "Committee") of the Board of Directors (the "Board") of Avigen, Inc., a Delaware corporation (the "Company"), shall consist of at least two (2) members of the Board. No Committee member shall be an employee of the Company and each member shall be free from any relationship that would interfere with the exercise of his or her independent judgment, as determined by the Board, in accordance with the applicable independence requirements of The Nasdaq Stock Market and the rules and regulations of the Securities and Exchange Commission ("SEC"). The members of the Committee and the Committee chairperson shall be appointed by the Board.

STATEMENT OF POLICY

The purpose of the Committee shall be to (i) oversee all aspects of the Company's corporate governance functions on behalf of the Board; (ii) make recommendations to the Board regarding corporate governance issues; (iii) identify, review and evaluate candidates to serve as directors of the Company; (iv) serve as a focal point for communication between such candidates, non-committee directors and the Company's management; (v) recommend such candidates to the Board; and (vi) make such other recommendations to the Board regarding affairs relating to the directors of the Company, including director compensation.

OPERATING PRINCIPLES AND PROCESSES

In fulfilling its function and responsibilities, the Committee should give due consideration to the following operating principles and processes:

- *Communication* – Regular and meaningful contact throughout the year with the Board, committee chairpersons, members of senior management and independent professional advisors to the Board and its various committees, as applicable, is viewed as important for strengthening the Committee's knowledge of relevant current and prospective corporate governance issues.
- *Committee Education/Orientation* – Developing with management and participating in a process for systematic review of important corporate governance issues and trends in corporate governance practices that could potentially impact the Company will enhance the effectiveness of the Committee.
- *Resources* – The Committee shall be authorized to access such internal and, in consultation with senior management, external resources as the Committee deems necessary or appropriate to fulfill its defined responsibilities, including engagement of independent counsel, consultants and other professional advisors, as well as executive search firms to help identify director candidates. The Committee shall have sole authority to approve fees, costs and other terms of engagement of such outside resources. The Committee shall have the authority to perform such other functions, and shall have such powers, as may be necessary or appropriate in the efficient and lawful discharge of its responsibilities hereunder.
- *Reporting to the Board* – The Committee, through the Committee chairperson, shall report all material activities of the Committee to the Board from time to time, or whenever so requested by the Board.

RESPONSIBILITIES

The operation of the Committee will be subject to the provisions of the Bylaws of the Company and the Delaware General Corporation Law, each as in effect from time to time. The Committee will have the full power and authority to carry out the following primary responsibilities or to delegate such power and authority to one (1) or more subcommittees of the Committee:

- *Director Nominations* – The Committee, in consultation with the Chief Executive Officer, has the primary responsibility for establishing criteria for Board membership and identifying, evaluating, reviewing and recommending qualified candidates to serve on the Board, including consideration of any potential conflicts of interest as well as applicable independence and experience requirements.

The Committee shall also have the primary responsibility for evaluating, reviewing and considering the recommendation for nomination of current directors for reelection to the Board as well as monitoring the size of the Board. The selection of nominees for director to be presented to the stockholders for election or reelection, and the selection of new Directors to fill vacancies and newly created directorships on the Board, shall be made by the full Board based on the recommendations of the Committee.

The Committee shall have the power and authority to consider board nominees and proposals submitted by the Company's stockholders and to establish any procedures, including procedures to facilitate stockholder communication with the Board of Directors, and to make any such disclosures required by applicable law in the course of exercising such authority.

- *Board Assessment* – The Committee shall periodically review, discuss and assess the performance of the Board, including Board committees, seeking input from senior management, the full Board and others. The assessment includes evaluation of the Board's contribution as a whole, specific areas in which the Board and/or management believe better contributions could be made, and overall Board composition and makeup, including the reelection of current Board members. The factors to be considered shall include whether the Directors, both individually and collectively, can and do provide the skills and expertise appropriate for the Company. The Committee shall also consider and assess the independence of Directors, including whether a majority of the Board continue to be independent from management in both fact and appearance, as well as within the meaning prescribed by The Nasdaq Stock Market. The results of such reviews shall be provided to the Board for further discussion as appropriate.
- *Board Committee Nominations* – The Committee, in consultation with the Chief Executive Officer, and after due consideration of the wishes, independence and experience of the individual directors and independence and experience requirements in accordance with The Nasdaq Stock Market, the rules and regulations of the Securities and Exchange Commission and applicable law, shall recommend to the entire Board annually the chairmanship and membership of each committee.
- *Continuing Education* – The Committee shall also consider instituting a plan or program for the continuing education of directors.
- *Corporate Governance Principles* – The Committee shall develop a set of corporate governance principles to be applicable to the Company, shall periodically review and assess these principles and their application, and shall recommend any changes deemed appropriate to the Board for its consideration. Further, the Committee shall periodically review Company policy statements to determine their adherence to the Company's Code of Conduct.
- *Code of Business Conduct and Ethics* – The Committee shall periodically review and assess the adequacy of the Company's Code of Business Conduct and Ethics (the "Code") and shall recommend proposed changes to the Board of Directors. The Committee shall ensure the Code addresses specific requirements applicable to senior financial officers and principal executive officers under the securities laws and other applicable regulations, as well as the reporting of any illegal or unethical behavior.
- *Code of Conduct Compliance* – The Committee shall oversee compliance with the Code insofar as it applies to the Company's directors and officers, including the handling of reports and investigations involving such individuals. The Committee shall report the findings of such investigations to the Board of Directors and advise the Board with respect to remedial actions taken or waivers granted.
- *Procedures for Information Dissemination* – The Committee shall oversee and review the processes and procedures used by the Company to provide information to the Board and its committees. The Committee should consider, among other factors, the reporting channels through which the Board and its committees

receive information and the level of access to outside advisors where necessary or appropriate, as well as the procedures for providing accurate, relevant and appropriately detailed information to the Board and its committees on a timely basis.

- *Director Compensation* – The Committee shall periodically review the compensation paid to non-employee Directors for their service on the Board and its committees and recommend any changes considered appropriate to the full Board for its approval.

MEETINGS

The Committee will hold at least one (1) regular meeting per year and additional meetings as the Committee deems appropriate. At the discretion of the Committee, the President, Chief Executive Officer, Chairman of the Board (if so designated) and Chief Financial Officer may attend any meeting of the Committee, except for portions of the meetings where his, her or their presence would be inappropriate, as determined by the Committee.

MINUTES AND REPORTS

Minutes of each meeting will be kept and distributed to each member of the Committee, members of the Board who are not members of the Committee and the Secretary of the Company. The Chairman of the Committee will report to the Board from time to time, or whenever so requested by the Board.

APPENDIX C

AVIGEN, INC.

1996 NON-EMPLOYEE DIRECTORS' STOCK OPTION PLAN

Adopted March 29, 1996

Approved By Stockholders April 30, 1996

Amended By the Board of Directors on September 24, 1999

Approved By Stockholders November 12, 1999

Amended By the Board of Directors on June 14, 2000

Approved By Stockholders November 17, 2000

Amended By the Board of Directors on August 14, 2001

Approved By the Stockholders on November 16, 2001

Amended By the Board of Directors on February 24, 2004 and April 21, 2004

[Approved By the Stockholders on May 26, 2004]

1. PURPOSE.

(a) The purpose of the Avigen, Inc. 1996 Non-Employee Directors' Stock Option Plan (the "Plan") is to provide a means by which each director of Avigen, Inc. a Delaware corporation (the "Company") who is not otherwise an employee of the Company or of any Affiliate of the Company (each such person being hereafter referred to as a "Non-Employee Director") will be given an opportunity to purchase stock of the Company.

(b) The word "Affiliate" as used in the Plan means any parent corporation or subsidiary corporation of the Company as those terms are defined in Sections 424(e) and (f), respectively, of the Internal Revenue Code of 1986, as amended from time to time (the "Code").

(c) The Company, by means of the Plan, seeks to retain the services of persons now serving as Non-Employee Directors of the Company, to secure and retain the services of persons capable of serving in such capacity, and to provide incentives for such persons to exert maximum efforts for the success of the Company.

2. ADMINISTRATION.

(a) The Plan shall be administered by the Board of Directors of the Company (the "Board") unless and until the Board delegates administration to a committee, as provided in subparagraph 2(b).

(b) The Board may delegate administration of the Plan to a committee composed of not fewer than two (2) members of the Board (the "Committee"). If administration is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board, subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revert in the Board the administration of the Plan.

3. SHARES SUBJECT TO THE PLAN.

(a) Subject to the provisions of paragraph 10 relating to adjustments upon changes in stock, the stock that may be sold pursuant to options granted under the Plan shall not exceed in the aggregate [five hundred fifty thousand (550,000)] shares of the Company's Common Stock. If any option granted under the Plan shall for any reason expire or otherwise terminate without having been exercised in full, the stock not purchased under such option shall again become available for the Plan.

(b) The stock subject to the Plan may be unissued shares or reacquired shares, bought on the market or otherwise.

4. ELIGIBILITY.

Options shall be granted only to Non-Employee Directors of the Company.

5. NON-DISCRETIONARY GRANTS.

(a) Each person who is, after the Effective Date, elected for the first time to be a Non-Employee Director automatically shall, upon the date of initial election to be a Non-Employee Director by the Board or stockholders of the Company, be granted an option to purchase fifteen thousand (15,000) shares of Common Stock of the Company on the terms and conditions set forth herein.

(b) At each annual meeting of the Company's stockholders after the Effective Date (i) each person who is then a Non-Employee Director and continuously has been a Non-Employee Director since the preceding annual meeting of the Company's stockholders automatically shall be granted an option to purchase ten thousand (10,000) shares of Common Stock of the Company on the terms and conditions set forth herein, and (ii) each other person who is then a Non-Employee Director automatically shall be granted an option to purchase, on the terms and conditions set forth herein, the number of shares of Common Stock of the Company (rounded up to the nearest whole share) determined by multiplying the ten thousand (10,000) shares by a fraction, the numerator of which is the number of days the person continuously has been a Non-Employee Director as of the date of such grant and the denominator of which is 365.

6. OPTION PROVISIONS.

Each option shall be subject to the following terms and conditions:

(a) The term of each option commences on the date it is granted and, unless sooner terminated as set forth herein, expires on the date ("Expiration Date") ten (10) years from the date of grant. If the optionee's service as a Non-Employee Director or employee of or consultant to the Company or any Affiliate terminates for any reason or for no reason, the option shall terminate on the earlier of the Expiration Date or the date twelve (12) months following the date of termination of all such service; *provided, however*, that if such termination of service is due to the optionee's death, the option shall terminate on the earlier of the Expiration Date or eighteen (18) months following the date of the optionee's death. In any and all circumstances, an option may be exercised following termination of the optionee's service as a Non-Employee Director or employee of or consultant to the Company or any Affiliate only as to that number of shares as to which it was exercisable on the date of termination of such service under the provisions of subparagraph 6(e).

(b) The exercise price of each option shall be one hundred percent (100%) of the fair market value of the stock subject to such option on the date such option is granted.

(c) Payment of the exercise price of each option is due in full in cash upon any exercise when the number of shares being purchased upon such exercise is fewer than 1,000 shares. However, when the number of shares being purchased upon an exercise is 1,000 or more shares, the optionee may elect to make payment of the exercise price under one of the following alternatives:

(i) Payment of the exercise price per share in cash or by check at the time of exercise; or

(ii) Provided that at the time of the exercise the Company's Common Stock is publicly traded and quoted regularly in the Wall Street Journal, payment by delivery of shares of Common Stock of the Company already owned by the optionee, held for the period required to avoid a charge to the Company's reported earnings, and owned free and clear of any liens, claims, encumbrances or security interest, which Common Stock shall be valued at its fair market value on the date preceding the date of exercise; or

(iii) Payment by a combination of the methods of payment specified in subparagraph 6(c)(i) and 6(c)(ii) above.

Notwithstanding the foregoing, this option may be exercised pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board which results in the receipt of cash (or check) by the Company prior to the issuance of shares of the Company's Common Stock.

(d) An option shall not be transferable except by will or by the laws of descent and distribution, or pursuant to a qualified domestic relations order satisfying the requirements of Rule 16b-3 under the Securities Exchange Act of 1934 ("Rule 16b-3") and shall be exercisable during the lifetime of the person to whom the option is granted only by such person (or by his guardian or legal representative) or transferee pursuant to such an order. Notwithstanding the foregoing, the optionee may, by delivering written notice to the Company in a form satisfactory to the Company, designate a third party who, in the event of the death of the optionee, shall thereafter be entitled to exercise the option.

(e) The option shall become exercisable in installments over a period of three (3) years from the date of grant commencing on the date one (1) year after the date of grant of the option, with thirty-three percent (33%) becoming exercisable one (1) year after the date of the grant, thirty-four percent (34%) becoming exercisable two (2) years after the date of grant and the remaining thirty-three percent (33%) becoming exercisable three (3) years after the date of grant; provided that the optionee has, during the entire period prior to such vesting date, continuously served as a Non-Employee Director or employee of or consultant to the Company or any Affiliate of the Company, whereupon such option shall become fully exercisable in accordance with its terms with respect to that portion of the shares represented by that installment.

(f) The Company may require any optionee, or any person to whom an option is transferred under subparagraph 6(d), as a condition of exercising any such option: (i) to give written assurances satisfactory to the Company as to the optionee's knowledge and experience in financial and business matters; and (ii) to give written assurances satisfactory to the Company stating that such person is acquiring the stock subject to the option for such person's own account and not with any present intention of selling or otherwise distributing the stock. These requirements, and any assurances given pursuant to such requirements, shall be inoperative if (i) the issuance of the shares upon the exercise of the option has been registered under a then-currently-effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), or (ii), as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then-applicable securities laws.

(g) Notwithstanding anything to the contrary contained herein, an option may not be exercised unless the shares issuable upon exercise of such option are then registered under the Securities Act or, if such shares are not then so registered, the Company has determined that such exercise and issuance would be exempt from the registration requirements of the Securities Act.

(h) The Company (or a representative of the underwriters) may, in connection with the first underwritten registration of the offering of any securities of the Company under the Securities Act, require that any optionee not sell or otherwise transfer or dispose of any shares of Common Stock or other securities of the Company during such period (not to exceed one hundred eighty (180) days) following the effective date of the registration statement of the Company filed under the Securities Act as may be requested by the Company or the representative of the underwriters.

7. COVENANTS OF THE COMPANY.

(a) During the terms of the options granted under the Plan, the Company shall keep available at all times the number of shares of stock required to satisfy such options.

(b) The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to issue and sell shares of stock upon exercise of the options granted under the Plan; *provided, however*, that this undertaking shall not require the Company to register under the Securities Act either the Plan, any option granted under the Plan, or any stock issued or issuable pursuant to any such option. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell stock upon exercise of such options.

8. USE OF PROCEEDS FROM STOCK.

Proceeds from the sale of stock pursuant to options granted under the Plan shall constitute general funds of the Company.

9. MISCELLANEOUS.

(a) Neither an optionee nor any person to whom an option is transferred under subparagraph 6(d) shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares subject to such option unless and until such person has satisfied all requirements for exercise of the option pursuant to its terms.

(b) Throughout the term of any option granted pursuant to the Plan, the Company shall make available to the holder of such option, not later than one hundred twenty (120) days after the close of each of the Company's fiscal years during the option term, upon request, such financial and other information regarding the Company as comprises the annual report to the stockholders of the Company provided for in the Bylaws of the Company and such other information regarding the Company as the holder of such option may reasonably request.

(c) Nothing in the Plan or in any instrument executed pursuant thereto shall confer upon any Non-Employee Director any right to continue in the service of the Company or any Affiliate or shall affect any right of the Company, its Board or stockholders or any Affiliate to terminate the service of any Non-Employee Director.

(d) No Non-Employee Director, individually or as a member of a group, and no beneficiary or other person claiming under or through him, shall have any right, title or interest in or to any option reserved for the purposes of the Plan except as to such shares of Common Stock, if any, as shall have been reserved for him pursuant to an option granted to him.

(e) In connection with each option made pursuant to the Plan, it shall be a condition precedent to the Company's obligation to issue or transfer shares to a Non-Employee Director, or to evidence the removal of any restrictions on transfer, that such Non-Employee Director make arrangements satisfactory to the Company to insure that the amount of any federal or other withholding tax required to be withheld with respect to such sale or transfer, or such removal or lapse, is made available to the Company for timely payment of such tax.

(f) As used in this Plan, "fair market value" means, as of any date, the value of the Common Stock of the Company determined as follows:

(i) If the Common Stock is listed on any established stock exchange or a national market system, including without limitation the National Market of The Nasdaq Stock Market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such system or exchange (or the exchange with the greatest volume of trading in Common Stock) on the last market trading day prior to the day of determination, as reported in the Wall Street Journal or such other source as the Board deems reliable;

(ii) If the Common Stock is quoted on The Nasdaq Stock Market (but not on the National Market thereof) or is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a share of Common Stock shall be the mean between the bid and asked prices for the Common Stock on the last market trading day prior to the day of determination, as reported in the Wall Street Journal or such other source as the Board deems reliable;

(iii) In the absence of an established market for the Common Stock, the Fair Market Value shall be determined in good faith by the Board.

Notwithstanding the foregoing, the Fair Market Value of the Common Stock for an option granted on the Effective Date shall be the price per share at which shares of Common Stock are first sold to the public in the Company's initial public offering.

10. ADJUSTMENTS UPON CHANGES IN STOCK.

(a) If any change is made in the stock subject to the Plan, or subject to any option granted under the Plan (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or otherwise), the Plan and outstanding options will be appropriately adjusted in the class(es) and maximum number of shares subject to the Plan and the class(es) and number of shares and price per share of stock subject to outstanding options.

(b) In the event of: (1) a dissolution, liquidation or sale of substantially all of the assets of the Company; (2) a merger or consolidation in which the Company is not the surviving corporation; (3) a reverse merger in which the Company is the surviving corporation but the shares of the Company's Common Stock outstanding immediately preceding the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise; or (4) any other capital reorganization (including a sale of stock of the Company to a single purchaser or single group of affiliated purchasers) after which less than fifty percent (50%) of the outstanding voting shares of the new or continuing corporation are owned by stockholders of the Company immediately before such transaction, the time during which options outstanding under the Plan may be exercised shall be accelerated to permit the optionee to exercise all such options in full prior to such event, and the options shall terminate if not exercised prior to such event.

11. AMENDMENT OF THE PLAN

(a) The Board at any time, and from time to time, may amend the Plan, *provided, however*, that the Board shall not amend the Plan more than once every six (6) months, with respect to the provisions of the Plan which relate to the amount, price and timing of grants, other than to comport with changes in the Code, or applicable regulations or rulings thereunder. Except as provided in paragraph 10 relating to adjustments upon changes in stock, no amendment shall be effective unless approved by the stockholders of the Company within twelve (12) months before or after the adoption of the amendment, where the amendment will modify the Plan in any way if such modification requires stockholder approval in order for the Plan to comply with the requirements of Rule 16b-3.

(b) Rights and obligations under any option granted before any amendment of the Plan shall not be impaired by such amendment unless (i) the Company requests the consent of the person to whom the option was granted and (ii) such person consents in writing.

12. TERMINATION OR SUSPENSION OF THE PLAN.

(a) The Board may suspend or terminate the Plan at any time. No options may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) Rights and obligations under any option granted while the Plan is in effect shall not be impaired by suspension or termination of the Plan, except with the consent of the person to whom the option was granted.

(c) The Plan shall terminate upon the occurrence of any of the events described in Section 10(b) above.

13. EFFECTIVE DATE OF PLAN; CONDITIONS OF EXERCISE.

(a) The Plan shall become effective on the same day that the Company's initial public offering of shares of Common Stock becomes effective (the "Effective Date"), subject to the condition that the Plan is approved by the stockholders of the Company.

(b) No option granted under the Plan shall be exercised or exercisable unless and until the condition of subparagraph 13(a) above has been met.

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

FORM 10-K

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 _____ to _____.

Commission file number 0-28272

AVIGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

13-3647113
(I.R.S. Employer
Identification No.)

**1301 Harbor Bay Parkway
Alameda, California 94502**
(Address of principal executive offices and zip code)

(510) 748-7150
(Registrant's telephone number,
including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.001 par value

(Title of class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Sections 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendments to this Form 10-K.

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

The aggregate market value of the Common Stock held by non-affiliates of the registrant as of June 30, 2003, was approximately \$60,080,000 based upon the closing sale price of the registrant's Common Stock as reported on the NASDAQ National Market on such date(1).

The number of outstanding shares of the registrant's Common Stock as of March 1, 2004, was 20,353,387 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2004 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K.

(1) Excludes approximately 3,900,000 shares of the registrant's Common Stock held by directors and executive officers of the registrant, and by each person known by the registrant to own 5% or more of the registrant's outstanding Common Stock at June 30, 2003. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, directly or indirectly, to direct or cause the direction of the management or policies of the registrant, or that such person is controlled by or under common control with the registrant.

**ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003**

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Coagulin-B® is a registered trademark of Avigen, Inc.

Coagulin-A™ is a trademark of Avigen, Inc.

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to:

- the potential of our product development programs, including Coagulin-B for hemophilia and AV201 for Parkinson's disease;
- our anticipation of receiving clearance to begin our AV201 trial;
- our intention to submit an IND to the FDA regarding our AV333 potential product;
- our expectations as to when we will file investigational new drug applications for our other product candidates currently in preclinical development;
- our expectations with respect to the clinical development of our product candidates, our clinical trials and the regulatory approval process;
- our expectations as to the various products that we are developing;
- our expectations relating to our selection of additional disease targets;
- our expectations with regard to our future operational and manufacturing capabilities;
- our estimates regarding our capital requirements, how long our current capital resources will last, and our needs for additional financing; and
- our expectations related to licensing opportunities for products and intellectual property.

We have identified these forward-looking statements by using terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "potential" and similar expressions which imply that the statements relate to future events or expectations. These statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors," in Item 1 below. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Form 10-K.

You should read this Form 10-K and the documents that we incorporate by reference completely and with the understanding that our actual future results may be materially different from what we currently expect. We may not update these forward-looking statements, even though our situation may change in the future. We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Business

Overview

Avigen focuses on the development of pharmaceutical products for the treatment of serious and chronic hematological and neurological diseases. We have developed proprietary DNA-based drug delivery technologies, including our proprietary gene-delivery platform based on adeno-associated virus (AAV) vectors. We are using our DNA-based drug delivery technologies to develop products designed to treat hematological and neurological diseases that are difficult to treat using conventional pharmaceutical drugs. Our most advanced product development programs are designed to utilize our AAV vector technology to deliver DNA into the cells of patients in order to generate the expression of therapeutic proteins to treat hemophilia and Parkinson's disease.

We are also applying our experience with hematological and neurological diseases in an effort to develop additional potential products. In 2003, we initiated a preclinical development program to treat neuropathic pain. The product candidate we are developing for the treatment of neuropathic pain is designed to utilize our non-viral DNA delivery system in order to deliver small amounts of therapeutic proteins to a localized part of the body for a short period of time.

Avigen, Inc. is a Delaware corporation that was incorporated on October 22, 1992 and is based in the San Francisco Bay Area.

Company Strategy and Highlights

Our strategy is to focus on hematological and neurological diseases that are not adequately addressed by current pharmaceutical and surgical treatments and to develop therapies with improved safety, convenience, and efficacy. We select our product development programs based on a combination of internal research and external collaborations. We select these product candidates from targets in medical fields we believe compliment our scientific expertise and offer us potential commercialization opportunities appropriate for a company of our size and financial resources. Some factors that impact our selection decisions include potential market size and the estimated population size, duration, and cost of anticipated clinical trials. In this manner, we may also evaluate opportunities for the acquisition of compounds to develop conventional pharmaceutical drugs within our areas of expertise that have previously undergone target optimization and preclinical development.

In 2003, we completed an internal reorganization in order to position ourselves to be able to transition promising research projects into viable preclinical candidates for human clinical trials more efficiently. In so doing, we advanced our potential product for the treatment of Parkinson's disease by filing an investigational new drug (IND) application with the Food and Drug Administration (FDA) and restarted our clinical trial of Coagulin-B for the treatment of hemophilia B, which had been suspended for much of the year while we modified our protocol to address an unexpected response observed in a trial participant in December 2002. In addition to the continued development of our core programs, we accelerated the development of a new preclinical candidate for the treatment of neuropathic pain, we strengthened our management team and our intellectual property portfolio, we continued to make significant advances in the development of our AAV vector and non-viral DNA-based drug delivery technologies, and we enhanced our understanding of how our product candidates that utilize these delivery technologies interact with the human immune system. Research and commercial collaborations are a key component to all of our current product development programs.

We are actively enrolling subjects in our ongoing clinical trial for Coagulin-B. In September 2003, this clinical trial for Coagulin-B for the treatment of hemophilia was approved to resume enrollment by both the FDA and the institutional review boards (IRBs) of our clinical sites. Coagulin-B is our first clinical candidate and is a DNA-based drug used to deliver the gene for factor IX, which is deficient in patients with this blood clotting disorder. Our preclinical studies, in which hemophilia B dogs were treated with the gene for factor IX, demonstrated that we could produce sustained levels of protein in dogs sufficient to completely reverse their bleeding disorder. Through December 2003, we had treated six subjects in our phase I clinical trial in which we delivered Coagulin-B directly to the liver. In late 2002, we achieved factor IX levels in a human subject that were similar to those observed in preclinical animal models and were sufficient to reverse the bleeding disorder. The trial was placed on hold when the subject experienced a temporary elevation in the levels of two liver enzymes, a result not observed in the animal

models, and simultaneously experienced a decrease in factor IX levels to below the expected beneficial threshold. During this time, all other liver function tests were normal and the subject reported no other symptoms and continued to feel healthy.

In November 2003, we filed an IND for our second clinical candidate AV201 for the treatment of advanced Parkinson's disease. Parkinson's disease is a devastating neurodegenerative condition characterized by compromised motor skills, uncontrolled movements, and tremors. AV201 is a DNA-based drug designed to deliver the gene for aromatic amino acid decarboxylase, or AADC. Primate models of Parkinson's disease have demonstrated a dose-dependent improvement of symptoms after treatment with AV201. There is no guarantee, however, that similar results will be obtained in humans. We have completed the manufacture of the drug needed for the trial and continue to move forward with other preparatory work in anticipation of receiving clearance to begin the trial.

In 2003, we expanded our development pipeline by initiating preclinical development of AV333 for the treatment of chronic neuropathic pain. AV333 is a DNA-based drug designed to deliver the gene for interleukin-10 (IL-10), an anti-inflammatory protein that has been shown to be effective in treating neuropathic pain in established animal models. There is no guarantee, however, that similar results will be obtained in humans. In 2003, we exclusively licensed intellectual property rights for the treatment of neuropathic pain with IL-10. Pending the results of additional efficacy and toxicology studies, we intend to submit an IND to the FDA in order to initiate a clinical trial.

In 2003, we expanded the use of our DNA-based drug delivery platform through the use of our non-viral DNA delivery technologies for our AV333 product candidate. Like our AAV vectors, our non-viral DNA delivery system is designed to transfer potentially therapeutic DNA to a patient's cells. However, non-viral DNA differs from our AAV vectors in that it is designed to deliver small amounts of protein to isolated and localized parts of the body. Our use of non-viral DNA is a natural extension of our core AAV technology, which requires the production of non-viral DNA as an intermediate step in the manufacture of AAV vectors.

Finally, in the last year, we supplemented the strong hematology experience of our management team, led by Dr. Glenn Pierce, with the addition of experienced senior members to our neurobiology team. Dr. Dawn McGuire, a board-certified neurologist with extensive experience in neurotherapeutic drug development, was hired as our Chief Medical Officer. Dr. Kirk Johnson also joined the management team as Associate Vice President to head our Preclinical Development department. We expect that Dr. Johnson's expertise in pharmacology and toxicology will significantly enhance our ability to transition drugs from preclinical to clinical development stages. Dr. Pierce has extensive experience with DNA-based drug delivery and has exhibited strong leadership skills with research and clinical development. We believe this diverse but complimentary senior management team will allow us to tackle a broader range of pharmaceutical product targets and improve the overall quality and speed of our drug development efforts. In March 2004, Kenneth Chahine was appointed as our Chief Executive Officer, President and a director following the resignation of John Monahan from these positions. Dr. Chahine previously served as our Chief Operating Officer since July 2002.

Product Development Programs

Our current product development programs, which have progressed beyond early research stages, are:

<u>Program</u>	<u>Disease</u>	<u>Protein/Enzyme</u>	<u>Target Cell</u>	<u>Status</u>
Hematology	Hemophilia B	Factor IX	Liver	Phase I
Neurology	Parkinson's disease	Aromatic amino acid decarboxylase	Brain	IND filed
Neurology	Neuropathic pain	Interleukin-10	Intrathecal space surrounding the spinal cord	Preclinical
Hematology	Hemophilia A	Factor VIII	Liver	Preclinical

Hemophilia

The Disease

Hemophilia is an inherited blood clotting disorder characterized by the reduction or absence of a clotting factor. There are two major forms of hemophilia: hemophilia B, in which patients are deficient in the factor IX protein, and hemophilia A, in which patients are deficient in the factor VIII protein.

Due to the inability to produce sustained levels of factor VIII or factor IX in the body, patients with hemophilia can experience frequent internal bleedings during the course of normal daily activities. Currently, patients in developed countries with a severe form of the disease, inject themselves with factor VIII or factor IX several times a week in response to these bleeding episodes.

Unmet Medical Need — hemophilia B

Over the last 25 years, researchers have established that sustained levels of circulating factor IX protein equivalent to only 1% of the normal level found in humans confers a significant benefit to patients diagnosed with hemophilia B by reducing the frequency of spontaneous bleeding episodes. Researchers have also shown that elevation of the levels of factor IX protein to 3% to 5% of the normal level found in humans will significantly reduce the patient's reliance on replacement injections of factor IX and greatly improve the patient's quality of life and decrease associated complications.

Current protein replacement therapy can be effective, but has significant limitations:

- Protein injections do not provide a constant and sustained level of circulating protein; rather, they provide only temporary relief and when protein breaks down after a few days, the bleeding recurs.
- Administration requires two to three intravenous injections per week for patients on prophylactic treatment.
- Recurring internal bleeding episodes typically take place in the joints and soft tissue, frequently resulting in crippling muscle, bone, and joint problems. Patients also are at risk for permanent disability or death from brain hemorrhage or other catastrophic bleeding.
- When blood-derived replacement therapy is used there is a small risk of blood-transmitted viral infection.

Coagulin-B

Our Coagulin-B product candidate was designed to address the shortcomings of protein replacement therapy. Coagulin-B is a DNA-based drug designed to deliver the gene for factor IX via a catheter into the patient's liver, the organ normally responsible for producing factor IX in the body. Once in the liver cells, Coagulin-B is designed to cause the gene for factor IX to be used by those cells to continuously produce quantities of factor IX protein sufficient for clotting blood.

If effective, this treatment would:

- Deliver therapeutic levels of factor IX protein into the blood of treated patients over a prolonged period.
- Reduce or eliminate weekly injections.
- Produce stable levels of factor IX that are intended to reduce or eliminate bleeding in the joints and soft tissue. This would reduce the crippling effects of the disease and prevent the fatal bleeds that can occur in the central nervous system.
- Reduce the indirect costs associated with joint replacement and care.

Market for Hemophilia Treatment

According to data published by the National Hemophilia Foundation, hemophilia B affects approximately one in every 30,000 males worldwide, afflicting an estimated 10,000 to 15,000 individuals in developed countries. It is estimated that 40% to 50% of those affected with either form of hemophilia have a severe form of the disease. According to this data, the average annual amount spent for currently available factor IX protein by patients suffering from hemophilia B, exceeds \$100,000 per year. Based on this information, we believe that the current market for providing recombinant protein factor IX to patients in developed countries, who have a severe form of the disease, exceeds \$400 million per year. In addition, because protein therapy is often ineffective in preventing muscle, bone, or joint damage, patients may also require an additional \$100,000 to \$150,000 in indirect medical care each time surgery is required.

This same published data estimates that hemophilia A affects approximately one in every 10,000 males worldwide, afflicting approximately 40,000 to 50,000 individuals in developed countries. Like factor IX, the estimated average cost of currently available replacement protein factor VIII exceeds \$100,000 per year per patient. Based on this information, we believe the current market for providing protein factor VIII to patients in developed countries, who have a severe form of the disease exceeds \$2 billion per year. Because the protein therapy has not proven effective in preventing musculoskeletal damage, indirect costs of medical care are also estimated to cost hemophilia A patients an additional \$100,000 to \$150,000 each time surgery is required.

Preclinical Studies

We have demonstrated long-term expression of the clotting factors in dog models with a single injection of our AAV vectors containing the gene for either factor IX or VIII. In studies with hemophilic dogs, we have achieved levels of factor IX from 5% to 15% and levels of factor VIII of between 1.5% and 2.5% of normal. Hemophilic dogs treated with AAV, including the first dog treated more than 5 years ago, continue to express therapeutic and stable levels of factor IX and factor VIII. Additional species, including mice, rats, rabbits and non-human primates have also exhibited long term and stable expression of therapeutic levels of factor IX protein over periods ranging from months to years.

The success of our technology in animal models, however, does not mean that we will be able to obtain the same results in humans. Animals are different than humans and we have encountered difficulties in our clinical trials with humans that we did not encounter in our dog models. For example, the one human subject who demonstrated therapeutic levels of circulating factor IX when given a comparable dose size to that used in the successful dog studies was not able to sustain steady factor IX expression beyond five weeks and developed other complications not experienced by the dogs. See "Clinical Trial Update" and "Risk Factors—The success of our technology in animal models does not guarantee that the same results will be replicated in humans" below.

Clinical Trial Update

We have been actively enrolling subjects in our Coagulin-B phase I study since receiving approval from both the FDA and the IRBs of our clinical sites to resume treating patients in September 2003. In December 2002, our Coagulin-B phase I study was put on hold due to an unexpected response observed in a trial participant. Prior to December 2002, six subjects with severe hemophilia B were treated in our phase I study with administration of Coagulin-B directly into the liver. The first four subjects had received relatively lower doses of the DNA drug. All of these subjects tolerated the procedures well and showed no side effects or drug-related toxicity. None of the first four subjects exhibited consistent levels of factor IX above 1.0% of normal, however. Subjects five and six received a higher dose, which was predicted to have a therapeutic effect based on the results of our preclinical animal studies. Both of these subjects tolerated the procedures well, with subject five exhibiting measurable levels of circulating factor IX in excess of 10% of the normal level found in humans for approximately four weeks after gene transfer. In week four, subject five experienced a temporary elevation in the levels of two liver enzymes, at which point the circulating levels of factor IX began to decline rapidly. During this time, all other liver function tests were normal and the subject reported no other symptoms and reported feeling healthy. The temporary elevation of liver enzymes reversed naturally without further medical intervention. Subject six exhibited much lower levels of circulating factor IX for a few weeks. Subject six did not experience an elevation in the levels of his liver enzymes.

In December 2002, we suspended enrollment of additional subjects in our phase I study in order to gather additional data from the current study participants and to evaluate the cause of the temporary elevation of liver enzymes, its potential connection to the decline in effectiveness of our proposed Coagulin-B treatment, and any potential health risks to future subjects. Relying on four years of safety data, covering multiple nonclinical studies in mice, rats, rabbits, dogs, and non-human primates, and 13 human subjects in two phase I clinical trials using our AAV vector gene delivery technology, we submitted modifications to our clinical trial protocol to the FDA in early 2003.

In September 2003, we were approved to resume enrollment of subjects by the FDA and the IRBs of our clinical sites, at a dose that, while still predicted to be therapeutic based on our preclinical studies, is lower than the dose at which the elevated liver enzymes were observed. If subjects at this dose do not exhibit an elevation of liver enzymes or other side effects, we will resume treatment of subjects at the previous higher dose.

Challenges

Although Coagulin-B is in clinical trials, it is still in a development stage. As a result, we continue to face challenges in the development of our Coagulin-B product candidate, including unexpected responses that have caused the performance of Coagulin-B in humans to differ from that which we observed in preclinical animal models. While these unexpected responses have not threatened the health of the subjects participating in our clinical trial, they have raised issues regarding the effectiveness and expected performance of Coagulin-B in humans. Since these responses have proven difficult to replicate in animal models, we do not fully understand why we have observed these unexpected responses. In order to improve our understanding of the factors that have led to these responses, we will need to treat additional subjects. We continue to evaluate data from all subjects treated in this clinical trial with regard to the impact of the human immune system on the effectiveness of the Coagulin-B treatment. The results of this evaluation may require us to make additional modifications to our Coagulin-B clinical trial protocol, which would require additional regulatory reviews and approvals by the FDA and the IRBs of our clinical sites. In addition, the challenges and delays we have experienced to date have impacted subject recruitment and our ability to schedule subject treatments in a timely manner. We expect this clinical trial to continue to be impacted by these challenges, as well as other challenges we face discussed in "Risk Factors" below.

Parkinson's Disease

The Disease

Parkinson's disease is the second most common neurodegenerative disease after Alzheimer's disease. Parkinson's disease affects an estimated 2.5 million people in developed countries worldwide. Primary features of Parkinson's disease include tremor, gait difficulty, postural instability, and rigidity. Parkinson's disease results from a decrease in the levels of dopamine, a neurotransmitter, required in the brain for normal voluntary movement.

Dopamine, produced in a region of the brain called the substantia nigra and released to another region of the brain called the striatum, is required for normal movement. In patients who suffer from Parkinson's disease, by the time the disease becomes clinically apparent, about 80% of the cells in the substantia nigra are estimated to have died or have degenerated by a mechanism that is not yet understood. As these cells continue to die, the signs and symptoms of the disease become more difficult to manage with current drug therapies, and the quality of life becomes severely compromised.

Unmet Medical Need

The primary treatment for Parkinson's disease is an oral administration of L-dopa, a dopamine precursor, which can be converted into dopamine in the substantia nigra by the enzyme aromatic amino acid decarboxylase, or AADC. Dopamine itself cannot be used to treat Parkinson's disease because it cannot pass through the blood brain barrier. Early in the development of the disease, orally-administered L-dopa/carbidopa is able to restore dopamine levels required for normal movement.

However, as the disease progresses, the remaining cells of the substantia nigra continue to die. This continued neurodegeneration results in a deficiency of AADC which is required to convert the orally administered L-dopa to dopamine to achieve therapeutic benefit. Over a period of approximately 5 to 10 years from the onset of Parkinson's disease, the required doses of L-dopa must be regularly increased from about 0.3 gram per day to about 1 gram per day in order to achieve a therapeutic benefit. Higher doses of L-dopa increase the risk of debilitating side-effects, including severe uncontrolled movements, or dyskinesias. In later stages, Parkinson's disease becomes a condition without any satisfactory treatment for the majority of people afflicted.

AV201

We designed our AV201 product candidate to restore the effectiveness of L-dopa as a therapy for Parkinson's disease. AV201 is a DNA-based drug that encodes the gene for human AADC. AV201 is surgically delivered using a proprietary delivery method to the healthy striatum in the brain where dopamine is needed. By restoring the levels of the enzyme AADC, AV201 restores the effectiveness of L-dopa. Since AADC cannot make dopamine in the absence of orally-administered L-dopa, the activity and therapeutic effect of AV201 can potentially be manipulated by a patient and physician by regulating the amount of oral L-dopa administered.

Another appealing characteristic of AV201 is the ability of physicians to non-invasively monitor a patient's production of AADC after surgery. We have demonstrated that using a technique known as positron emission tomography (PET), the production of AADC can be measured by the strength of a fluorescent signal that it emitted when AADC interacts with an L-dopa analog.

Market for Parkinson's Disease Treatment

Parkinson's disease affects an estimated 2.5 million people in developed countries according to prevalence rates from epidemiologic studies and World Health Organization population data. Based on information obtained from industry reports, we believe that the current amount spent on drugs to treat Parkinson's disease worldwide is approximately \$1 billion per year. Approximately 50% of this market represents sales of L-dopa in various formulations. The cost of the disease increases as it progresses, both due to the need for increasing doses of therapeutic drugs, and because of an increasing need for assistance in performing activities of daily living. In 1999, a French study reported that drug costs were estimated to represent only 22% of the total costs for patients with Parkinson's disease, and that half of the patients in the study reported requiring help to perform daily living activities.

Preclinical Studies

Our preclinical rodent and primate data suggest that AV201 is a promising treatment for advanced Parkinson's disease. Like human patients, rodent and primate models of advanced Parkinson's disease have few functional cells in the substantia nigra and fail to respond to L-dopa therapy.

When treated with AV201, rodent and primate models have displayed:

- a dose dependent increase in AADC activity as measured by PET,
- a decrease in the requirement for oral L-dopa, and
- a significant improvement in motor skills and Parkinson's symptoms.

Several primates treated more than three years ago continue to show constant levels of AADC production as measured by PET and a decrease in Parkinsonian disease characteristics. The success of our technology in animal models, however, does not mean that we will be able to obtain the same results in humans. See "Risk Factors—The success of our technology in animal models does not guarantee that the same results will be replicated in humans" below.

Clinical Trial

On November 5, 2003 we filed an IND with the FDA seeking approval to initiate a phase I dose-escalating clinical trial to assess the safety of AV201. We are currently responding to a request for more information from the FDA. Drug manufacture for the trial has been completed, and other preparatory work continues to move forward in anticipation of receiving clearance to begin the trial.

Chronic Neuropathic Pain

The Disease

Pain is generally classified into two categories: nociceptive pain and neuropathic pain. Nociceptive pain describes a normal pain in response to an injury to the body. Nociceptive pain is acute, usually localized, and warns of existing or impending tissue injury. Neuropathic pain, in contrast, is pain that is initiated or caused by direct damage or other insult to a nerve, often spreads to other areas of the body, and persists long after the time of the initial injury.

Neuropathic pain can be caused by many different insults and diseases including cancer, nerve damage caused by diabetes or chemotherapeutic agents, amputation, and viral infections such as herpes zoster (which causes shingles) and HIV. Many of the diseases that can lead to neuropathic pain are long lasting, thereby resulting in a chronic pain condition.

Neuropathic pain can present an aching, burning or sharply cutting sensation. Patients have reported that simple tasks, such as putting on socks, can be excruciatingly painful and that normal tactile sensations, like a light breath, can cause a skin burning sensation. Severe, spontaneous pain, in the absence of any stimulus, is also commonly reported.

Unmet Medical Need

Patients with neuropathic pain are under-served, despite a common understanding among researchers in the field of the pathophysiology and molecular biology of the condition. Drugs including gabapentin (Neurontin), lidocaine patch (Lidoderm), tramadol (Ultram), antiepileptics, and tricyclic antidepressants are generally successful in approximately one-third of patients, about one-third of the time. Other patients, with severe neuropathic pain, rely on oral or injected opioids for pain relief, such as morphine, but these opioid therapies typically require substantial dose increases over time, and patients endure side effects such as sedation, cognitive impairment, severe constipation, itching and edema. Addiction is also a major concern for both the patient and the treating physician, as is the stigma of using narcotics.

AV333

Traditionally, development of treatments for neuropathic pain have focused on drugs that interact directly with neural cells. However, the theory that neurons are solely responsible for promoting and maintaining the pain state cannot adequately explain several types of pain states such as:

- pain in the absence of direct nerve injury such as a viral infection;
- extra-territorial pain or pain distant from any insult to a nerve;
- mirror-image pain or pain that is perceived not only in the affected tissue, but also in the corresponding part of the healthy side of the body; and
- phantom limb pain or pain located in an appendage that no longer exists due to amputation.

Mounting evidence supports the theory that other cells in the nervous system called glia cells may hold the key to neuropathic pain. Glia cells make up 70% to 80% of the cells in the nervous system and play numerous roles in maintaining the stability of the normal functions of the nervous system.

Data from our collaborators demonstrate that glia cells release proteins that promote and maintain an inflammatory state following nerve insult. Such an inflammatory state can cause adjacent neurons to send pain signals to the brain in the absence of any actual or ongoing injury.

AV333 is a DNA-based drug that may address shortcomings of current neuropathic pain treatments. AV333 is based on our non-viral DNA delivery system and carries the gene for interleukin-10 (IL-10). IL-10 is a naturally occurring protein with powerful *anti-inflammatory* properties.

Clinically, AV333 is designed to be delivered intrathecally (into the fluid surrounding the spinal cord) near the glial and nerve cells responsible for transmitting the pain signal. Potentially, IL-10 would be produced by these or by neighboring cells and shut down the inflammatory process that is promoting or maintaining the pain state.

Market for Neuropathic Pain Treatment

According to the International Association for the Study of Pain and other sources, pain accounts for over 70 million office visits per year in the United States. An American Pain Society study in 1999 found that over 50% of individuals with chronic, non-cancer-related pain classify their pain as severe or very severe, and that fewer than half of these feel that their pain is adequately controlled by currently available medication. Over 600,000 patients with diabetic neuropathy, 500,000 patients with post-herpetic neuralgia (shingles), 300,000 cancer patients, 100,000 patients with spinal cord injuries and another 200,000 with complex regional pain syndrome, multiple sclerosis, phantom pain, stroke and HIV suffer neuropathic pain. In 2002, sales of oral opioids were estimated to exceed \$2 billion and in 2003, sales of Gabapentin, prescribed for both moderate neuropathic pain and for epilepsy, were estimated to exceed \$2.7 billion.

Preclinical Data

In a commonly used rat model of neuropathic pain, intrathecal administration of IL-10-encoding plasmid DNA exhibited good reversal of chronic neuropathic pain for over a month. The unique profile observed represents both the impetus and foundation for seriously considering AV333 as a pharmaceutical for neuropathic pain. The success of our technology in animal models, however, does not mean that we will be able to obtain the same results in humans. See “Risk Factors—The success of our technology in animal models does not guarantee that the same results will be replicated in humans” below.

Research Programs

We believe our AAV gene therapy technology can be used to treat a broad array of other diseases that could benefit from long-term gene expression of therapeutic proteins. To this end, we have taken steps to promote the use of our technology within the larger research community. We have allowed a third-party licensor to distribute reagent kits that make it possible for researchers to make limited amounts of AAV vectors using our proprietary technology. We have also chosen to participate directly with selective collaborators to employ our manufacturing expertise by supplying AAV vectors for collaborative studies.

Research and Development Expenses

We incurred research and development expenses of approximately \$21.8 million and \$24.8 million in fiscal 2003 and 2002, respectively, and \$11.5 million for the six months ended December 31, 2001, and \$17.0 million for the fiscal year ended June 30, 2001. Of these amounts, we received \$86,000 in reimbursements from a research grant for the fiscal year ended June 30, 2001, and reported such receipts as revenue on our statements of operations. No reimbursements by third parties were received for the years ended December 31, 2003 and 2002, or the six months ended December 31, 2001, and we are not currently a party to any collaborative agreements that would reimburse any future research and development expenses by a third party.

DNA-Based Drugs

Many serious human diseases are caused by the absence or malfunction of proteins. Genes control the production of these proteins. There are generally two approaches for making proteins: protein-based drugs and DNA-based drugs.

Protein-based drugs are administered to patients by intravenous or subcutaneous injection. While protein-based drugs are in many cases extremely effective, they have several shortcomings. Diseases caused by chronic protein deficiencies, such as anemia, hemophilia, diabetes and most metabolic conditions, require prolonged and steady maintenance of protein levels, which in turn requires frequent injections. Even then the proteins are not usually present at their optimal level, but rather fluctuate considerably above and below their ideal therapeutic levels. In addition, proteins injected intravenously cannot access the central nervous system and therefore have limited use in treating diseases such as Parkinson’s disease and neuropathic pain.

DNA-based drugs deliver the gene, not the protein. As a result, the patient’s own cells make the protein. This affords the ability to produce an appropriate level of a therapeutic protein over a prolonged period, which would free patients from frequent injections as well as address diseases currently untreatable with protein replacement therapies such as many neurological disorders. In addition, by producing steady protein expression, DNA-based drugs would modulate the fluctuations in protein levels. We are not aware of any DNA-based drugs that have received regulatory approval for commercial sale in the United States.

Adeno-Associated Virus Vectors

AAV comprises DNA encapsulated or packaged in a protein shell. To convert AAV into a pharmaceutical drug, we take advantage of the virus’ protein shell which has evolved to efficiently deliver genes to cells, but replace the virus’ normal DNA with a therapeutic gene of interest. This altered or recombinant virus is called a vector. The AAV vector is now designed to be used to efficiently transfer the therapeutic DNA to the patient’s own cells where it can be used as a template to make continuous levels of therapeutic protein.

AAV is unique from other viral vector-based systems in several regards:

- Safety—The AAV virus has never been associated with any human disease. More than 80% of the population has been exposed to AAV.
- Efficiency—AAV is very efficient at getting into cells.
- Potential for prolonged, high-level gene expression — Genes delivered in AAV vectors have demonstrated stable, high-level expression for months to years in many animal models.
- Versatility—AAV is designed to deliver many different genes (more than 30 to date in animal studies) to a wide range of cell types including muscle, liver, central nervous system, and skin.
- Stability—AAV vector is stable under a wide range of conditions which should simplify manufacturing, storage and handling of the final product.

Non-Viral DNA

Non-viral DNA is DNA that is not encapsulated or packaged in a protein shell. Non-viral DNA is very safe and stable, but is less efficient than AAV at entering cells, produces smaller amounts of protein and results in short-lived expression of the therapeutic gene. These differences make non-viral DNA useful when only a small amount of protein is required for a period of weeks or months. Non-viral vectors can typically be readministered if longer expression is required.

AAV Vector Manufacturing

We believe our current manufacturing facility has the capacity to manufacture sufficient quantities of our AAV vectors, in compliance with current good manufacturing practices (cGMP), to support our research efforts, our clinical trials and the commercial launch of Coagulin-B.

In 2003, we made significant progress towards improving our AAV vector manufacturing capabilities. In addition to successfully manufacturing clinical grade drug for our Parkinson's disease clinical trial, we improved our vector manufacturing productivity, large-scale manufacturing and purification technology and sterile-fill capability.

We currently produce our AAV vectors with a proprietary process called DNA transfection. In DNA transfection, the DNA templates necessary to produce a functional AAV vector are transiently transferred to a cell in culture.

We believe that transfection offers many advantages over other methods of making AAV:

- Helper virus free—no live human pathogenic virus (e.g., adenovirus or herpes virus) is used in the manufacturing process.
- High-titer—more vector production per cell than that of other manufacturing methods.
- Flexibility—also allows us to develop new vectors quickly and easily.
- Scaleable—other helper viruses need not be produced for large scale manufacturing.

AAV Purification

We currently have the capability to purify AAV vectors using either density centrifugation or chromatographic means.

Density centrifugation separates the virus by its density compared to other impurities such as cell debris. While the scalability of this purification method is limited, compared to classic column chromatographic techniques, it offers several advantages to early product development. Most significantly, it allows us to purify multiple AAVs or serotypes which are closely related, but not identical, to our clinical product.

Chromatographic purification separates the virus by its ability to bind to certain chemicals versus other impurities including cell debris and unpackaged DNA. Once a product has progressed through preclinical

development and initial phase I clinical testing, using chromatographic techniques is preferred. Avigen has developed chromatographic purification methods which allow us to purify commercial quantities of AAV vector.

We have designed and constructed our manufacturing facilities to accommodate large-scale vector production, as well as to meet the requirements of government mandated policies for pharmaceutical manufacturing, known as current good manufacturing practices (cGMPs). All of our facilities and long-lived assets are located in the United States. Our production process is inherently scalable by increasing the number of roller bottles per production run. We use automated robotic equipment to manipulate the roller bottles in a clean environment to maintain the purity and consistency of the vector product.

We obtain materials used in the manufacture of our clinical vector products from a number of suppliers, some of whom are our sole qualified source of these materials. We qualify the suppliers of our clinical materials according to cGMP regulations. If we were to lose access to critical materials from any of these sole-source suppliers, we would be required to obtain a new source of the materials. It could take us several months to qualify new suppliers before we would be able to use their materials in the manufacture of our clinical vector products; however, we believe that we would eventually be able to find a secondary source for all materials critical to our manufacturing process.

We also use certain hazardous materials, chemicals, biological materials, and various radioactive compounds in our research and development activities, which make us subject to a number of environmental laws and regulations, including the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, and the Resource Conservation and Recovery Act. We do not believe that our current level of use of these controlled substances will require any material capital expenditures for environmental control facilities for the next few years. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we could be held liable for any damages that result from accidental contamination or injury.

Collaboration Agreements

Research and commercial collaborations are a key element of our strategy. We consider entering into collaboration agreements when we feel they will enhance our potential success to commercialize our products in the future. Our strategy is to partner our products after they have entered the clinical trial phase in order to retain a larger interest in their potential commercial value. We look for the opportunity to partner with other leaders in the field that we feel could help enhance our chances of success in clinical trials or product distribution. An example of such a collaboration is our partnership with Bayer Corporation for Coagulin-B, our AAV gene therapy product for hemophilia B.

Bayer Corporation. In November 2000, we announced a collaboration agreement with Bayer Corporation, a worldwide health care and life sciences company and leader in the development, manufacture, and distribution of hemophilia treatments. Under the terms of the agreement, Bayer, in collaboration with Avigen, will conduct any Phase II/III clinical trials for Coagulin-B and Bayer will receive exclusive worldwide marketing and distribution rights to any resulting products. We will file for any regulatory approvals and will be the holder of such regulatory licenses worldwide, including the United States, the European Union, Canada, and Japan. We will manufacture any products developed and will receive a substantial share of the gross revenues from potential future Coagulin-B sales, as well as royalties on the net sales of the product. The agreement also calls for Bayer to make milestone payments to us, pay for third-party costs of the clinical trials, and pay our costs of manufacturing AAV vector used in the clinical trials. Under the terms of the agreement, in November 2000, Bayer purchased shares of our common stock for \$15 million, or \$47.82 per share, which was set at a premium to the market price at the time the agreement was announced. The sale of the common stock to Bayer was completed in February 2001. In March 2003, we received an additional \$2.5 million payment from Bayer under the terms of this agreement.

Patents and Intellectual Property

Patents and other proprietary rights are important to our business. Our intellectual property strategy is to file patent applications that protect our technology, inventions and improvements to our inventions that we consider commercially important to the development of our business. We also rely on a combination of trade secrets, know-how and licensing opportunities to develop and protect intellectual property rights pertaining to our products and technology. As of March 1, 2004, we owned, co-owned, or held licenses to 37 issued U.S. patents and 41 pending

U.S. patent applications, as well as 13 issued non-U.S. patents and 70 pending non-U.S. patent applications. The patents in which we own or hold as licensees protect rights that relate to the formulation of specific AAV vectors, methods of vector production, methods of tissue administration, and treatment of specific disease indications using AAV vectors. All issued patents within our current portfolio are scheduled to expire in the U.S. between 2008 and 2020.

The intellectual property rights these patents cover that are important to us are:

- specific AAV vectors, including AAV vectors containing any type of cytokine, tumor suppressor or suicide gene, which may have important applications in cancer and neuropathic pain applications, as well as vectors containing enzymes associated with lysosomal storage diseases;
- high-yield methods of producing AAV vectors free from contamination from wild-type AAV or adenovirus, and large-scale manufacturing and purification processes;
- methods of administering AAV vectors, including to skeletal muscle, cardiac muscle, and smooth muscle, as well as delivery to the bloodstream, including intravenous (IV) and intra-arterial (IA) injection and delivery to the nervous system; and
- the use of AAV vectors for treating certain diseases such as hemophilia A, hemophilia B, Parkinson's disease, cancer, anemia, cardiomyopathies, and lysosomal storage diseases.

When we identify previously patented technologies that we believe are critical to the development and commercialization of our gene therapy products, we seek to in-license such rights under the most favorable terms. Such licenses normally last for the life of the underlying patent. Licenses typically require us to pay license fees and royalties based on the net sales of products that fall within the scope of the license. Some licenses require us to exercise our best efforts to achieve research, clinical, and commercial milestones and may require us to make additional payments upon the completion of such milestones. In some cases, we were required to issue shares of our common stock, or warrants to purchase shares of our common stock at some future period, as partial consideration upon initiation of the license. Our failure to achieve any required development milestones or to negotiate appropriate extensions of any of our license agreements or to make all required milestone and royalty payments when due, and the subsequent decision of any such institution to terminate such license, could have a material adverse effect on our financial position.

The exclusive and non-exclusive licenses that we feel are important to our future commercial interests are:

University of Florida. In November 1992, we entered into an agreement with the University of Florida for rights to certain patents related to AAV transduction vectors. The license is non-exclusive for the duration of the patent, or until approximately 2009.

The Children's Hospital of Philadelphia (CHOP). In May 1999, we entered into an agreement with CHOP for rights to certain patents related to vectors and methods for treating hemophilia B using recombinant AAV vectors. The license is exclusive for the duration of the patent, or until approximately 2017.

BTG International Ltd. In March of 2000, we entered into an agreement with BTG International for rights to certain patents related to the factor IX gene. The license is non-exclusive for the duration of the last to expire patent, or until approximately 2008.

The Rockefeller University and Yale University. In September of 2002, we entered into an agreement with The Rockefeller University and Yale University for rights to certain patents related to the delivery of recombinant AAV vectors to the nervous system, and to the use of such vectors for ameliorating symptoms of central nervous system disorders. The license is non-exclusive for the duration of the last to expire patent, or until approximately 2018.

University of Colorado. In November, 2003, we entered into an agreement with the University of Colorado for rights to certain intellectual property related to the treatment of chronic pain. The license is exclusive for the duration of any issued patents embodying the licensed intellectual property, or until approximately 2023.

When we are party to co-owned technologies, we often seek to acquire exclusive licenses to the shared rights of our co-owner to the technologies. Licenses to co-owned technologies include:

Johns Hopkins University (JHU). In September 1999, we entered into an agreement with JHU granting Avigen an exclusive license to JHU's rights in co-owned patents related to administration methods using AAV vectors and delivery methods for providing a therapeutic effect in any cardiomyopathy. The methods covered by this license include skeletal, smooth, and cardiac muscle, as well as delivery to the bloodstream, including intravenous and intraarterial injection. This license excludes use to such methods to treat Pompe disease and alpha-1-antitrypsin. The license is for the duration of the underlying patents, or until approximately 2016.

Lawrence Berkeley National Laboratory (LBL). In July 2001, we entered into an agreement with LBL granting Avigen an exclusive license to LBL's rights in co-owned patents related to the treatment of Parkinson's disease. The license is for the duration of the last to expire patent, or until approximately 2018.

In consideration for each of the seven licenses listed above, we paid an initial license fee and are required to pay the licensor royalties based on net sales of future products that utilize the licensed technology. In connection with the licenses to BTG International and the University of Colorado, we also issued warrants to purchase shares of our common stock at strike prices equal to the fair market value of our common stock on the respective effective date of each license agreement.

We currently investigate and use certain gene sequences or proteins encoded by those sequences, including certain forms of the factor VIII gene, IL-10 gene, and manufacturing processes that may be or become patented by others, for which we do not currently own patent rights. As a result, we may be required to obtain licenses to these known gene sequences or proteins or other technology in order to continue to test, use or market products. However, we may not be able to obtain these licenses on terms favorable to us, if at all.

Legal standards relating to the validity and scope of claims in the biotechnology and biopharmaceutical fields are still evolving. As a result, our patent position is generally uncertain and involves complex legal and factual questions. Accordingly, the degree of future protection for our patent rights is uncertain. The risks and uncertainties we face with respect to the commercial benefits we hope to gain through our patents and the patents licensed to us include, but are not limited to, the following:

- we may be unable to develop additional proprietary technologies that are patentable;
- the claims of any patents that are issued may not provide meaningful protection;
- the pending patent applications that we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- we cannot be certain that others have not filed applications for technology covered by our patent applications;
- we may not be able to negotiate exclusive rights to co-owned technology from our co-owners;
- the patents licensed or issued to us may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us;
- others may assert that our products and technologies infringe their patents;
- disputes may arise regarding the invention and corresponding ownership rights in inventions and know-how resulting from the joint creation or use of intellectual property by us, our licensors, corporate partners and other scientific collaborators; and
- other companies may design around our patented technologies.

We also rely on a combination of trade secret and copyright laws, employee and third-party nondisclosure agreements, and other protective measures to protect intellectual property rights pertaining to our products and technology. We cannot ensure that these agreements will provide meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use, misappropriation or disclosure. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States. We cannot ensure that we will be able to protect our intellectual property successfully.

Competition

Pharmaceutical drug development is a highly competitive arena. Within this arena, gene therapy drug development is a new and rapidly evolving field that is expected to continue to undergo significant and rapid technological change. We expect that we will experience intense competition both from other companies in the gene therapy field and from companies that have other forms of treatment for the diseases currently being targeted. Ultimately, we believe that if we do develop products that receive regulatory approval for commercialization, we will compete primarily on the basis of the efficacy of the treatment with the products.

We are aware of several development-stage and established enterprises, including major pharmaceutical and biotechnology firms that are exploring gene-based drugs or are actively engaged in gene delivery research and development. These include companies making protein therapies for hemophilia, such as Aventis S.A., Bayer Corporation, which produces factor VIII for the treatment of hemophilia A that is outside of the scope of our collaboration agreement, Baxter Healthcare Corporation, CSL Therapeutics, and Wyeth. We are also aware of other companies actively engaged in other types of gene therapy product development programs, including Cell Genesys, Inc., Corautus Genetics, Inc., GenVec, Inc., and Targeted Genetics Corporation.

Our products for neurologic diseases will face competition from both branded pharmaceuticals and generic compounds. Therapies for advanced Parkinson's disease are marketed by companies including GlaxoSmithKline plc, Pfizer Inc., Boehringer-Ingelheim GmbH, and Medtronic Inc.. We are also aware of products for Parkinson's disease currently in development at both pharmaceutical and biotechnology firms including Schering-Plough Corporation, Schwartz Pharma AG, NeuroSearch A/S, Ceregene Inc., and Juvantia Pharma Ltd. Therapies for chronic pain range from over-the-counter compounds, such as aspirin, to opioids, such as morphine. Off-label use of compounds such as the anti-epileptic Neurontin (gabapentin, Pfizer), also represent significant competition for this indication. We are aware of additional compounds for chronic pain that are currently in development at numerous companies including Bayer, GlaxoSmithKline, Merck & Co., Inc., Novartis AG, Pfizer, Cogentix, Inc., GW Pharmaceuticals plc, Indevus Pharmaceuticals, Inc., Nastech Pharmaceutical Company Inc., Renovis, Inc., and Pain Therapeutics, Inc.

Some of our potential competitors have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations, than we do. In addition, some of them have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. They may also market commercial products, either on their own or through collaborative efforts.

Companies that complete clinical trials, obtain required regulatory approvals, and commence commercial sales of their products before their competitors, may achieve a significant competitive advantage. In order to compete successfully, we must develop proprietary positions in patented products for therapeutic markets that have not been satisfactorily addressed by conventional research strategies and, in the process, expand our expertise in our AAV vector gene therapy products. Our products, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies.

Government Regulation

The production and marketing of our proposed products and our research and development activities are subject to regulation for safety, efficacy, and quality by numerous governmental authorities in the United States and other countries. In the United States, pharmaceutical products and personnel are subject to rigorous regulation by the FDA and the National Institutes of Health (NIH). The Federal Food, Drug, and Cosmetic Act, as amended, the regulations promulgated under such Act, and other federal and state statutes and regulations govern, among other things, the testing, manufacture, safety, efficacy, labeling, storage, record keeping, advertising and promotional practices, and import and export of drugs and biological products. We believe that our current proposed products will be regulated as biologics by the FDA and comparable foreign regulatory bodies.

Gene therapy is, however, a relatively new technology and has not been extensively tested in humans. The regulatory requirements governing gene therapy products are uncertain and are subject to change. No gene therapy products have been approved to date in the United States. Product development and approval within this regulatory framework can be unpredictable and may result in considerable time and expense to us.

The Drug Approval Process

The steps required before our proposed products may be marketed in the United States generally include:

- preclinical laboratory testing and preclinical animal studies;
- the submission to the FDA of an investigational new drug application for review before the commencement of any human clinical trials;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the product;
- the submission to the FDA of a Biologics License Application (BLA), or New Drug Application (NDA), for a biological product;
- successful inspection of manufacturing facilities by the FDA as part of the BLA or NDA approval process; and
- FDA approval of the BLA or NDA prior to any commercial sale or shipment of the biological product.

Domestic drug and biological manufacturing establishments are subject to inspections at any time by the FDA and must comply with good manufacturing practices regulations enforced by the FDA, even at the clinical testing phase, through its facilities inspection program. Manufacturers of biological products also must comply with FDA general biological product standards. Because our manufacturing facilities are located in California, we are also required to obtain a drug manufacturing license from the State of California for any of our products administered to humans, including products used in clinical trials.

Preclinical Testing

Preclinical studies include laboratory evaluation of the product chemistry and formulation as well as animal studies to assess the potential safety and efficacy of the product. Preclinical safety studies must be conducted in compliance with FDA regulations regarding good laboratory practices. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND application to be reviewed by the FDA prior to the commencement of human clinical trials. Submission of an IND application may not result in FDA authorization to commence clinical trials, however, if not rejected by the FDA within 30 days after its receipt, an IND will become automatically effective. The IND application must include the following information:

- the results of previous testing;
- how, where and by whom the clinical studies will be conducted;
- the chemical structure of the product;
- the method by which the product is believed to work in the human body;
- any toxic effects of the product found in the animal studies;
- how the product is manufactured; and
- what patients will be notified of through the informed consent form.

Clinical Trials

Clinical trials must be conducted under the supervision of qualified principal investigators in accordance with the FDA's good clinical practice guidelines, under protocols that detail the objectives of the study, the parameters to be used to monitor safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA for review as part of the IND application prior to commencing the study. Each clinical trial must also be approved by an institutional review board ethics committee, or IRB, at each respective institution participating in the study. The IRB will consider, among other things, safety risk, ethical issues, informed consent of the human subjects, possible issues relating to health care costs and potential liability of the institution. An IRB may require changes in a protocol, and we cannot assure you that any IRB will permit any given study to be initiated or completed. Gene therapy clinical trials must also be approved by an institutional biosafety committee, or IBC, at

each respective institution participating in the study. The IBC will consider, among other things, safety risks to institutional personnel, community ethical issues, and potential liability of the institution. An IBC may require changes in a protocol, and we cannot assure you that any IBC will permit any given study to be initiated or completed.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. Phase I typically involves the initial introduction of the drug into patients primarily to test for safety or adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology. Phase II typically involves studies in a limited patient population to further identify possible adverse effects and safety risks, determine the efficacy of the drug for specific targeted indications, and determine dosage tolerance and optimal dosage.

When a drug appears to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials can be undertaken to further evaluate clinical efficacy and to further test for safety within an expanded patient population, typically at geographically dispersed clinical study sites. Phase III studies conducted to seek marketing approval by the FDA are generally referred to as pivotal studies.

The FDA is known to view gene therapy as a relatively new technology, with little data regarding long-term safety. As a result, the FDA may require long-term monitoring of all patients that participate in each phase of our clinical trials. The FDA may also require us to undertake post-marketing clinical studies, sometimes referred to as phase IV clinical trials, which could require extensive patient monitoring and record keeping and may result in restricted marketing of our products for an extended period of time.

Marketing Applications

After the completion of all three clinical trial phases, if the data indicate that the product is safe and effective, a BLA or NDA is filed with the FDA for approval of the manufacture, marketing, sale, and commercial shipment and distribution of the tested product. The marketing application must contain all of the information on the product gathered to date, including data from the clinical trials, and must be in the appropriate format.

Once a BLA or NDA submission is accepted for review by the FDA, the Federal Food, Drug and Cosmetic Act allows the FDA 180 days in which to review it and respond to the applicant. The review process can be significantly extended by FDA requests for additional information or clarification of information already provided in the submission, or the FDA may refuse to file the application. The FDA may also choose to refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. However, the FDA is not bound by the recommendations of any advisory committee.

If the FDA is satisfied that all regulatory criteria are met, it will issue an approval letter, authorizing commercial marketing for the product for certain indications. Such product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. If the FDA is not satisfied that all regulatory criteria are met, it may refuse to accept a BLA submission or issue a refusal to file letter, it may refuse to approve a BLA submission, or it may issue a not-approvable letter.

For clinical investigation and marketing outside the United States, we are also subject to foreign regulatory requirements governing clinical trials and marketing approval for pharmaceutical products. In Europe, for instance, the approval process for the commencement of clinical trials varies from country to country, and Canada has its own set of requirements as well. The foreign regulatory approval process includes all of the risks associated with FDA approval set forth above.

Other Regulations

In addition to regulations enforced by the FDA, in the U.S. we are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other federal, state and local regulations. Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials, and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by state and federal regulations, we could be held liable for any damages that result from accidental contamination or injury and this liability could exceed our resources.

Our clinical trials may also involve subjects that reside outside of the U.S. which can involve subsequent monitoring of the subjects' responses at clinical sites outside the U.S. where other regulations apply.

Orphan Drug Status

In accordance with the Orphan Drug Act, the FDA may grant Orphan Drug status to certain drugs intended to treat a "rare disease or condition" defined as a disease or condition which affects fewer than 200,000 people in the United States, or which affects more than 200,000 people for which the cost of developing and marketing the drug will not be recovered from sales of the drug in the United States. An approved Orphan Drug may provide certain benefits including exclusive marketing rights in the United States to the first drug approved for the disease for seven years following marketing approval and federal income tax credits for certain clinical trial expenses.

In July 2001, we announced that we were notified by the FDA that Coagulin-B, our AAV vector product for treating hemophilia B, whether delivered via intramuscular injection or intravenously to the liver, qualified for Orphan Drug designation. We also believe that some of our other potential products may qualify for Orphan Drug status as well, but we cannot assure you that these products will receive FDA approval or that Coagulin-B or our other potential products will receive any benefit under the Orphan Drug Act. In addition, there is no assurance that potential benefits provided by the Orphan Drug Act will not be significantly limited by future amendment by the United States Congress and/or reinterpretation by the FDA.

Employees

As of March 1, 2004, Avigen had 95 full-time employees, including 26 with Ph.D. degrees and 5 with M.D. degrees. Approximately 76 employees are involved in our research and development activities, including research, preclinical development, process development, clinical affairs, regulatory affairs, clinical manufacturing, and quality assurance and quality control, and 19 employees are involved in general administration, finance, legal, and business development activities. We also rely on a number of temporary staff positions and third-party consultants to supplement our workforce. None of our employees are represented by a collective bargaining agreement nor have we ever experienced a work stoppage. We believe that our relationship with our employees is good.

Available Information and Website Address

Our website address is www.avigen.com; however, information found on our website is not incorporated by reference into this Annual Report on Form 10-K. We file electronically with the Securities and Exchange Commission our annual reports on Form 10-K, quarterly interim reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on or through our website, free of charge, copies of these reports as soon as reasonably practicable after we electronically file or furnish it to the SEC. You can also request copies of such documents by contacting our Investor Relations Department at (510) 748-7150 or sending an email to ir@avigen.com.

RISK FACTORS

This section briefly discusses certain risks that should be considered by stockholders and prospective investors in Avigen. Many of these risks are discussed in other contexts in other sections of this report.

We expect to continue to operate at a loss and we may never achieve profitability

Since our inception in 1992, we have not been profitable, and we cannot be certain that we will ever achieve or sustain profitability. To date, we have been engaged in research and development activities and have not generated any revenues from product sales. As of December 31, 2003, we had an accumulated deficit of \$132.7 million. Developing our products will require significant additional research and development, preclinical testing and clinical trials, as well as regulatory approval. We expect these activities, together with our general and administrative expenses, to result in operating losses for the foreseeable future. Our ability to achieve profitability will depend, in part, on our ability to successfully complete development of our proposed products, obtain required regulatory approvals and manufacture and market our approved products directly or through business partners.

Our clinical trials to date for Coagulin-B for the treatment of hemophilia B have been conducted with a small number of patients over a short period of time, and the results reported may not be indicative of future results in a larger number of patients or have lasting effects

Our current Coagulin-B clinical trial studies are based upon the evaluations of very small groups of patients and any reported progress or results may not be indicative of subsequent progress or results achieved from larger populations. As our Coagulin-B clinical trial is still in a very early stage, we do not yet know if any favorable results

achieved will have a lasting effect. Further, we have experienced difficulties in obtaining positive results in humans reflective of the positive results we obtained in animal models. If a larger population of patients does not experience positive results, or any favorable results do not demonstrate a lasting effect, this product candidate may not receive approval from the FDA for further studies or commercialization. If we are not able to proceed with, or decide to abandon our Coagulin-B development program, our business prospects may be substantially impaired.

The success of our technology in animal models does not guarantee that the same results will be replicated in humans

Even though our product candidates have shown successful results in mouse, dog, and non-human primate models, animals are different than humans and results in animal models may not be replicated in our clinical trials with humans. For example, while the results of our gene therapy treatment for hemophilia B were favorable and demonstrated sustained long-term expression in both dogs and mice for multiple years, one human subject who demonstrated therapeutic levels of circulating factor IX when given a comparable dose size to that used in the successful animal studies was not able to sustain steady factor IX expression beyond five weeks. In addition, this human subject experienced a mild, temporary elevation of two liver enzymes, which was not seen in any of the animal models. Further, we have experienced an immune system response to Coagulin-B that we did not observe in the animal models, which we have not yet been able to, and may not be able to, adequately address. Consequently, you should not rely on the results in any of our animal models as being predictive of the results that we will see in our clinical trials with humans.

Adverse events in the field of gene therapy may negatively impact regulatory approval or public perception of our potential products

The commercial success of our potential products will depend in part on public acceptance of the use of gene therapy for the prevention or treatment of human diseases. Public attitudes may be influenced by claims that gene therapy is unsafe, and consequently our products may not gain the acceptance of the public or the medical community. Negative public reaction to gene therapy in general could result in greater government regulation and stricter labeling requirements of gene therapy products, including any of our products, and could cause a decrease in the demand for any products we may develop.

Our stock price is also influenced by public perception. For example, in January 2003, a report of serious adverse events in a retroviral trial for infants diagnosed with severe combined immunodeficiency (SCID) in France and subsequent FDA actions putting related trials on hold in the United States had a significant impact on the public perception and stock price of all companies involved in gene therapy. Avigen's stock declined despite the fact that we do not work with retroviruses or with infants diagnosed with SCID and our clinical trial was not affected by the FDA's actions in this case.

Other potential adverse events in the field of gene therapy may occur in the future that could result in greater governmental regulation of our potential products and potential regulatory delays relating to the testing or approval of our potential products.

AAV technology is new and developing rapidly; there is limited clinical data and new information may arise which may cause delays in designing our protocols, submitting applications that satisfy all necessary regulatory review requirements, and ultimately completing the clinical trials of our products

Clinical trials are governed by regulations enforced by the FDA. Our technology is fairly new, and we have limited historical data from preclinical studies or clinical trials that are often necessary to satisfy the FDA's regulatory review process. In addition, as new information about the technology becomes available, it may change perceptions of previously accepted data, which could require additional periods of time to review and interpret these data. For example, while animals in preclinical studies do not appear to develop antibodies to AAV vectors or any expressed protein, further clinical testing is required to confirm to what extent our product candidates might cause human patients to develop antibodies to these potential products or the proteins produced by these potential products. Such antibodies could make our product ineffective or lead to unwanted side effects. In addition, as previously discussed, one human subject in our clinical trial experienced a mild, temporary elevation of two liver enzymes, which was not seen in any of the animal models, and was not able to sustain steady factor IX expression beyond

five weeks. Consequently, we may encounter deficiencies in the design or application stages while developing our clinical trial studies, or in the subsequent implementation stages of such studies, which could cause us or the FDA to delay, suspend or terminate our trials at any time.

Because our product candidates are in an early state of development, there is a high risk that they may never be commercialized

All of our product candidates are in early stages of development. We do not have any product candidates that have received regulatory approval for commercial sale, and we face the risk that none of our product candidates will ever receive regulatory approval. We have one product candidate in clinical trials, Coagulin-B for the treatment of hemophilia B. This product candidate is only in phase I of the clinical trial process. We have applied for an IND for our second product candidate, AV201 for the treatment of Parkinson's disease, and are currently responding to requests from the FDA for additional information. We are not aware of any other gene therapy products of other companies that have received regulatory approval for commercial sale in the United States, and do not expect any of our prospective products, including Coagulin-B and AV201, to be commercially available for at least several years. As results of future stages of our clinical trials become available and are evaluated, we may decide at any time to discontinue any further development of one or more of our product candidates.

The testing of our potential products relies heavily on the voluntary participation of patients in our clinical trials, which is not within our control, and could substantially delay or prevent us from completing development of such products

The development of our potential products is dependent upon collecting sufficient data from human clinical trials to demonstrate safe and effective results. We have experienced delays in enrolling patients in our clinical trials for Coagulin-B, and we may experience similar difficulties in the future. Any delay or failure to recruit sufficient numbers of patients to satisfy the level of data required to be collected under our clinical trial protocols could prevent us from developing any products we may target.

Our potential products must undergo rigorous clinical testing and regulatory approvals, which could substantially delay or prevent us from marketing any products

Prior to marketing in the United States, any product developed by us must undergo rigorous preclinical testing and clinical trials as well as an extensive regulatory approval process implemented by the FDA. This process is lengthy, complex and expensive, and approval is never certain. Positive results from preclinical studies and early clinical trials do not ensure positive results will be demonstrated in clinical trials designed to permit application for regulatory approval.

Potential problems we may encounter in the implementation stages of our studies include the chance that we may not be able to conduct clinical trials at preferred sites, obtain sufficient test subjects or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, the FDA may temporarily suspend clinical trials at any time if it believes the subjects participating in trials are being exposed to unacceptable health risks, if it finds deficiencies in the clinical trial process or conduct of the investigation, or to better analyze data surrounding any unexpected developments. For example, progress in our current Coagulin-B clinical trial has been interrupted twice to better analyze data from unexpected observations. These included the identification of vector fragments in the seminal fluid of two early patients beyond an expected timeframe and the development reported in December 2002 of a temporary elevation in the levels of two liver enzymes in one patient treated with a higher dose.

Because of the risks and uncertainties in biopharmaceutical development, our products could take a significantly longer time to gain regulatory approval than we expect or may never gain FDA approval. If we do not receive these necessary approvals from the FDA, we will not be able to generate substantial revenues that would be necessary to become profitable.

We may not be successful in obtaining required foreign regulatory approvals, which would prevent us from marketing our products internationally

We cannot be certain that we will obtain any regulatory approvals in other countries. In order to market our products outside of the United States, we must comply with numerous and varying foreign regulatory requirements implemented by foreign regulatory authorities. The approval procedure varies among countries and can involve

additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process includes all of the risks associated with obtaining FDA approval set forth above, and approval by the FDA does not ensure approval by the regulatory authorities of any other country.

Our success is dependent upon our ability to effectively protect our patents and proprietary rights, which we may not be able to do

Our success will depend to a significant degree on our ability to obtain patents and licenses to patent rights, preserve trade secrets, and to operate without infringing on the proprietary rights of others. If we are not successful in these endeavors, our business will be substantially impaired.

To date, we have filed a number of patent applications in the United States relating to technologies we have developed or co-developed. In addition, we have acquired exclusive and non-exclusive licenses to certain issued patents and pending patent applications. We cannot guarantee that patents will issue from these applications or that any patent will issue on technology arising from additional research or, if patents do issue, that claims allowed will be sufficient to protect our technologies.

The patent application process takes several years and entails considerable expense. The failure to obtain patent protection on the technologies underlying our proposed products may have a material adverse effect on our competitive position and business prospects. Important legal issues remain to be resolved as to the scope of patent protection for biotechnology products, and we expect that administrative proceedings, litigation or both may be necessary to determine the validity and scope of our and others' biotechnology patents. These proceedings or litigation may require a significant commitment of our resources in the future.

If patents can be obtained, we cannot assure you that any of these patents will provide us with any competitive advantage. For example, others may independently develop similar technologies or duplicate any technology developed by us, and patents may be invalidated or held unenforceable in litigation.

In addition, several of our patents and patent applications are co-owned with co-inventors or institutions. To date, we have negotiated exclusive licenses for many of our co-owned technologies. However, if we cannot negotiate exclusive rights to other co-owned technology, each co-inventor may have rights to independently make, use, offer to sell or sell the patented technology. Commercialization, assignment or licensing of the technology by a co-owner could harm our business.

We also rely on a combination of trade secret and copyright laws, employee and third-party nondisclosure agreements and other protective measures to protect intellectual property rights pertaining to our products and technologies. We cannot be certain that these measures will provide meaningful protection of our trade secrets, know-how or other proprietary information. In addition, the laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States. We cannot assure you that we will be able to protect our intellectual property successfully.

Other persons may assert rights to our proprietary technology, which could be costly to contest or settle

Third parties may assert patent or other intellectual property infringement claims against us with respect to our products, technologies, or other matters. Any claims against us, with or without merit, as well as claims initiated by us against third parties, can be time-consuming and expensive to defend or prosecute and resolve. There may be third-party patents and other intellectual property relevant to our products and technology which are not known to us. We have not been accused of infringing any third party's patent rights or other intellectual property, but we cannot assure you that litigation asserting claims will not be initiated, that we would prevail in any litigation, or that we would be able to obtain any necessary licenses on reasonable terms, if at all. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings declared by the Patent and Trademark Office to determine priority of invention, which could result in substantial cost to us, even if the outcome is favorable to us. In addition, to the extent outside collaborators apply technological information developed independently by them or by others to our product development programs or apply our technologies to other projects, disputes may arise as to the ownership of proprietary rights to these technologies.

We may be required to obtain rights to proprietary genes and other technologies to further develop our business, which may not be available or may be costly

We currently investigate and use certain gene sequences or proteins encoded by those sequences, including the factor VIII and IL-10 genes, and manufacturing processes that are or may become patented by others. As a result, we may be required to obtain licenses to these gene sequences or proteins or other technology in order to test, use or market products. We may not be able to obtain these licenses on terms favorable to us, if at all. In connection with our efforts to obtain rights to these gene sequences or proteins or other technology, we may find it necessary to convey rights to our technology to others. Some of our products may require the use of multiple proprietary technologies. Consequently, we may be required to make cumulative royalty payments to several third parties. These cumulative royalties could become commercially prohibitive. We may not be able to successfully negotiate these royalty adjustments to a cost effective level, if at all.

If we do not achieve certain milestones, we may not be able to retain certain licenses to our intellectual property

We have entered into license agreements with third parties for technologies related to our gene therapy product development programs. Some of these license agreements provide for the achievement of development milestones. If we fail to achieve these milestones or to obtain extensions, the licensor may terminate these license agreements with relatively short notice to us. Termination of any of our license agreements could harm our business.

If we are able to bring our potential products to market, we continue to face a number of risks including our inexperience in marketing or selling our potential products, the acceptance of our products by physicians and insurers, our ability to price our products effectively and to obtain adequate reimbursement for sales of our products.

Even if we are able to develop our potential products and obtain necessary regulatory approvals, we have no experience in marketing or selling any of our proposed products. We intend to enter into distribution and marketing agreements with other companies for our products and do not anticipate establishing our own sales and marketing capabilities for any of our potential products in the foreseeable future. For example, we have entered into an exclusive worldwide marketing and distribution agreement with Bayer Corporation for our Coagulin-B proposed product. However, if Bayer Corporation does not perform under this agreement, we would need to identify an alternative marketing and distribution partner, or market this product ourselves, and we may not be able to establish adequate marketing capabilities for this product. Similarly, we may not be able to develop adequate marketing capabilities for our other potential products, either on our own or through other third parties.

Our success is dependent on acceptance of our products. We cannot assure you that our products will achieve significant market acceptance among patients, physicians or third-party payors, even if we obtain necessary regulatory and reimbursement approvals. Failure to achieve significant market acceptance will harm our business. In addition, we cannot assure you that these products will be considered cost-effective and that reimbursement to the consumer will be available or will be sufficient to allow us to sell our products on a profitable basis. In both the United States and elsewhere, sales of medical products and treatments are dependent, in part, on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect that such potential proposals or managed care efforts may have on our business.

We expect that we will face intense competition, which may limit our ability to become profitable

Our competitors may develop more effective or more affordable products, or commercialize products earlier than we do, which would limit the prices that we could charge for the products that we are able to market, and prevent us from becoming profitable. We expect increased competition from fully integrated pharmaceutical companies and more established biotechnology companies. Most of these companies have significantly greater financial resources and expertise than we do in research and development, preclinical studies, clinical trials, obtaining regulatory approvals, manufacturing, and marketing and distribution.

Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical companies. Academic institutions, government agencies and other public

and private research organizations also conduct research, seek patent protection and establish collaborative arrangements for product development and marketing. In addition, these companies and institutions compete with us in recruiting and retaining highly qualified scientific and management personnel.

We are aware that other companies are conducting preclinical studies and clinical trials for viral and non-viral gene therapy products that could compete with products we are developing. See "Item 1. Business—Competition" for a more detailed discussion of the competition we face.

We have limited experience in manufacturing our potential products at a commercial scale, which raises uncertainty about our ability to manufacture our potential products cost-effectively

Even if we are able to develop our potential products and obtain necessary regulatory approvals, we have limited experience in manufacturing any of our proposed products on a commercial basis. If we are unable to manufacture our products in a cost-effective manner, we are not likely to become profitable. We have not yet received a license from the FDA for our manufacturing facilities, and cannot apply for one until we submit our product for commercial approval. Even if we do receive a manufacturing license, we may fail to maintain adequate compliance with the FDA's regulations concerning current good manufacturing practices (cGMP), in which case the license, and our authorization to manufacture product, could be revoked.

We may lose access to critical materials from single source suppliers, which is not within our control and could delay us from manufacturing materials needed to support our clinical trials or future commercialization

We obtain materials used in the manufacture of our clinical products from a number of suppliers, some of whom are our sole qualified source of these materials. We qualify the suppliers of our clinical materials according to cGMP regulations. If we were to lose access to critical materials from any of these sole-source suppliers, we would be required to obtain a new source of the materials. It could take us several months to qualify new suppliers before we could use their materials in the manufacture of our clinical products.

We may be unable to attract and retain the qualified employees, consultants and advisors we need to be successful

We are highly dependent on key members of our senior management and scientific staff. The loss of any of these persons could substantially impair our research and development efforts and impede our ability to develop and commercialize any of our products. Recruiting and retaining qualified scientific, technical and managerial personnel will also be critical to our success. Biotechnology personnel with these skills are in high demand. As a result, competition for and retention of personnel, particularly for employees with technical expertise, is intense and the turnover rate for these people can be high.

In addition, we rely on consultants and advisors to assist us in formulating our research and development strategy. A majority of our scientific advisors are engaged by us on a consulting basis and are employed on a full-time basis by others. We have limited control over the activities of these scientific collaborators which often limit their availability to us. Failure of any of these persons to devote sufficient time and resources to our programs could delay our progress and harm our business. In addition, some of these collaborators may have consulting or other advisory arrangements with other entities that may conflict or compete with their obligations to us.

We may need to secure additional financing to complete the development and commercialization of our products

We anticipate that our existing capital resources as of December 31, 2003, will be adequate to fund our needs for at least the next three to four years. However, we may require additional funding to complete the research and development activities currently contemplated and to commercialize our products. Our future capital requirements will depend on many factors, including:

- continued scientific progress in research and development programs;
- the scope and results of preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting and enforcing patent claims;

- the costs involved in obtaining licenses to patented technologies from third-parties that may be needed to commercialize our products;
- the cost of manufacturing scale-up;
- the cost of commercialization activities; and
- other factors which may not be within our control.

We intend to continue to seek additional funding through public or private equity or debt financing, when market conditions allow, or through additional collaborative arrangements with corporate partners. If we raise additional funds by issuing equity securities, there may be further dilution to existing stockholders. We cannot assure our investors that we will be able to enter into such financing arrangements on acceptable terms or at all. Without such additional funding, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs.

We face the risk of liability claims which may exceed the scope or amount of our insurance coverage

The manufacture and sale of medical products entail significant risk of liability claims. We currently carry liability insurance; however, we cannot assure you that this coverage will remain in place or that this coverage will be adequate to protect us from all liabilities which we might incur in connection with the use of our products in clinical trials or the future use or sale of our products upon commercialization. In addition, we may require increased liability coverage as additional products are used in clinical trials and commercialized. This insurance is expensive and may not be available on acceptable terms in the future, if at all. A successful liability claim or series of claims brought against us in excess of our insurance coverage could harm our business. We must indemnify certain of our licensors against any liability claims brought against them arising out of products developed by us under these licenses.

Our use of hazardous materials exposes us to the risk of environmental liabilities, and we may incur substantial additional costs to comply with environmental laws in connection with the operation of our research and manufacturing facilities

We use radioactive materials and other hazardous substances in our research and development and manufacturing operations. As a result, we are potentially subject to substantial liabilities related to personal injuries or property damages they may cause. In addition, clean up costs associated with radioactivity or other hazardous substances, and related damages or liabilities could be significant and could harm our business. We are required to comply with increasingly stringent laws and regulations governing environmental protection and workplace safety which could impose substantial fines and criminal sanctions for violations. Maintaining compliance with these laws and regulations could require substantial additional capital.

Risks Related to Our Stock

Anti-takeover effects of certain charter provisions and Delaware law may negatively affect the ability of a potential buyer to purchase some or all of our stock at an otherwise advantageous price, which may limit the price investors are willing to pay for our common stock

Certain provisions of our charter and Delaware law may negatively affect the ability of a potential buyer to attempt a takeover of Avigen, which may have a negative effect on the price investors are willing to pay for our common stock. For example, our board of directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences, and privileges of those shares without any further vote or action by the stockholders. This would enable the Board of Directors to establish a shareholder rights plan, commonly referred to as a “poison pill,” which would have the effect of making it more difficult for a third party to acquire a majority of the outstanding voting stock of Avigen. In addition, our board of directors is divided into three classes, and each year on a rotating basis the directors of one class are elected for a three-year term. This provision could have the effect of making it less likely that a third party would attempt to obtain control of Avigen through Board representation. Furthermore, certain other provisions of our restated certificate of incorporation may have the effect of delaying or preventing changes in control or management, which could adversely affect the market price of our common stock. In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law, an anti-takeover law.

Our stock price is volatile, and as a result investing in our common stock is very risky

From January 1, 2002 to March 1, 2004, our stock price has fluctuated between a range of \$11.58 and \$2.75 per share. We believe that various factors may cause the market price of our common stock to continue to fluctuate, perhaps substantially, including announcements of:

- technological innovations or regulatory approvals;
- results of clinical trials;
- new products by us or our competitors;
- developments or disputes concerning patents or proprietary rights;
- achieving or failing to achieve certain developmental milestones;
- public concern as to the safety of gene therapy, recombinant biotechnology or traditional pharmaceutical products;
- health care or reimbursement policy changes by governments or insurance companies;
- developments in relationships with corporate partners; or
- a change in financial estimates or securities analysts' recommendations.

In addition, in recent years, the stock market in general, and the shares of biotechnology and health care companies in particular, have experienced extreme price fluctuations. These broad market and industry fluctuations may cause the market price of our common stock to decline dramatically.

Item 2. Properties

We lease approximately 112,500 square feet in two adjacent buildings of manufacturing, research laboratory and office space in an established commercial neighborhood in Alameda, California. In June 2003, a lease and sublease that accounted for approximately 45,000 square feet in one building expired; however, we had previously negotiated an extension for the combined space that went into effect in July 2003 and runs for five more years and expires in 2008. We also have a 10-year lease for 67,500 square feet in a second building adjacent to the original facility that was entered into in December 2000. The lease of this second building will expire in November 2010. We believe that these facilities will be adequate to meet our property needs for at least the next two years.

Item 3. Legal Proceedings

As of March 1, 2004, we were not involved in any legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Executive Officers of the Registrant

Our executive officers and their respective ages and positions as of March 12, 2004, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Philip J. Whitcome, Ph.D.	55	Chairman of the Board
Kenneth G. Chahine, Ph.D.	39	President, Chief Executive Officer and Director
Thomas J. Paulson	57	Vice President, Finance, Chief Financial Officer and Secretary
Glenn Pierce, Ph.D., M.D.	48	Vice President, Research and Clinical Development
Dawn McGuire, M.D.	50	Chief Medical Officer

All of our officers are elected annually by the Board of Directors. There is no family relationship between or among any of the officers or directors.

Philip J. Whitcome, Ph.D., has served as a director of Avigen since December 1992. In April 1995, Dr. Whitcome was elected Chairman of the Board and from March 1996 to December 1996 he served as acting Chief Financial Officer. From 1988 to 1994, Dr. Whitcome was President and Chief Executive Officer of Neurogen

Corporation, a biopharmaceutical company. From 1981 to 1988, Dr. Whitcome was employed at Amgen Inc., a biopharmaceutical company, including service as Director of Strategic Planning. Prior to joining Amgen, he served as Manager of Corporate Development for Medical Products at Bristol-Myers Squibb Company, a pharmaceutical and healthcare products company, and held research and marketing management positions with the Diagnostics Division of Abbott Laboratories, a pharmaceutical and medical products company. Dr. Whitcome holds a Ph.D. in Molecular Biology from the University of California at Los Angeles, an M.B.A. from the Wharton School at the University of Pennsylvania and a B.S. in Physics from Providence College.

Kenneth G. Chahine, Ph.D., was appointed President, Chief Executive Officer and director of Avigen in March 2004. Dr. Chahine joined Avigen in 1998, was appointed Vice President, Business Development in January 1999, and was appointed Chief Operating Officer in July 2002. Prior to joining Avigen, Dr. Chahine worked at the patent law firm of Madson & Metcalf, P.C. in Salt Lake City from 1994 to 1998. Between 1992 and 1993, Dr. Chahine worked as a research scientist at Parke-Davis Pharmaceuticals, a pharmaceutical company, and held another research scientist post at the University of Utah Department of Human Genetics from 1994 through 1996. Dr. Chahine also served as Western Regional News and Legal Correspondent for Nature Biotechnology from 1996 to 2002. Dr. Chahine holds a J.D. from the University of Utah and a Ph.D. in Biochemistry and Molecular Biology from the University of Michigan.

Thomas J. Paulson joined Avigen and was appointed Vice President, Finance, Chief Financial Officer and Secretary of Avigen effective September 20, 1996. Prior to joining Avigen, Mr. Paulson was president of Paulson Associates, a biotechnology consulting firm. From its inception in 1989 until 1994, Mr. Paulson was Chief Financial Officer of Neurogen Corporation, a pharmaceutical company. From 1986 to 1989, he was Director of Finance at CibaCorning Diagnostics, Gilford Systems, a diagnostics instrument company. From 1984 to 1986, Mr. Paulson served as financial director at Quidel Corporation, a biotechnology company. From 1971 to 1984, Mr. Paulson held various financial management positions at Abbott Laboratories, a pharmaceutical and medical products company. Mr. Paulson holds an M.B.A. from the University of Chicago Graduate School of Business and a B.B.A. in Accounting from Loyola University in Chicago.

Glenn Pierce, Ph.D., M.D., joined Avigen and was appointed Vice President, Research and Clinical Development in November 2002. Before joining Avigen, Dr. Pierce was Vice President, Therapeutic Product Development at Selective Genetics, a gene therapy company he helped found in 1998, which focuses on tissue regeneration, from 1998 to November 2002. From 1994 to 1998, he served as Vice President, Preclinical Development at Prizm Pharmaceuticals, a pharmaceutical company. Prior to that, Dr. Pierce held a number of positions at Amgen Inc., a biopharmaceutical company, and was instrumental in the development of Amgen's neurobiology program. Dr. Pierce holds numerous patents in various areas of drug delivery, tissue engineering, medical devices and viral vectors. He has published more than 100 papers in scientific and medical journals in related areas. He has served three terms as the president of the National Hemophilia Foundation (NHF) in 1992, 1993, and in 2002. He initiated the NHF's first gene therapy committee and founded the NHF's annual gene therapy workshop in 1996. He earned both his M.D. and a Ph.D. in Immunology and Experimental Pathology at Case Western Reserve University, prior to doing a residency and fellowship at Washington University in St. Louis.

Dawn McGuire, M.D., has served as our Chief Medical Officer since January 2004. Dr. McGuire has provided leadership in both pharmaceutical and biotechnical corporate settings, most recently as Chief Scientific Officer of Eunoe, Incorporated (previously CSFluids, Inc.), a medical device company. She was President and Chief Executive Officer of CSFluids from 1999 to 2002. From 1999 to 2000, Dr. McGuire also served as Vice President, Medical Affairs Worldwide at Collagen Corporation, a healthcare products company. From 1997 to 1999, Dr. McGuire served as Vice President, Clinical Research and Medical Affairs at Elan Pharmaceuticals and was responsible for, among other programs, the development through FDA submission of ziconotide (Prialt™). Dr. McGuire is a board-certified neurologist and has led clinical development programs in neuropathic pain, Alzheimer's disease, AIDS dementia, Lou Gehrig's disease, Multiple Sclerosis, and stroke. She is the co-author of over 40 scientific articles, book chapters and invited reviews in neurotherapeutics. Since 2000, Dr. McGuire has served as a Scientific Reviewer and Study Section Member of the National Institute of Neurological Disorders and Stroke. Dr. McGuire received her B.A. with high honors from Princeton University, her M.D. from Columbia University College of Physicians and Surgeons, and trained in Neurology at the University of California, San Francisco, followed by an NIH-funded postdoctoral fellowship in clinical trial design and experimental therapeutics.

PART II

Item 5. *Market for Registrants Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities*

Shares of Avigen's common stock commenced trading on the NASDAQ National Market on May 22, 1996, under the symbol "AVGN". As of March 1, 2004, there were approximately 155 holders of record of our common stock.

We have never paid cash dividends and do not anticipate paying cash dividends in the foreseeable future.

The following table sets forth, for fiscal periods indicated, the range of high and low sales prices available for the years ended December 31, 2002 and 2003.

<u>Year ended December 31, 2002</u>	<u>High</u>	<u>Low</u>
Quarter End 3/31/02	\$11.90	\$7.61
Quarter End 6/30/02	\$11.37	\$6.95
Quarter End 9/30/02	\$ 9.54	\$6.45
Quarter End 12/31/02	\$10.33	\$5.22
 <u>Year ended December 31, 2003</u>	 <u>High</u>	 <u>Low</u>
Quarter End 3/31/03	\$ 6.07	\$2.92
Quarter End 6/30/03	\$ 4.70	\$2.75
Quarter End 9/30/03	\$ 5.73	\$3.33
Quarter End 12/31/03	\$ 7.40	\$5.48

During the quarter ended December 31, 2003, we issued a total of 77,858 shares of our common stock upon the exercise of warrants previously sold in private placements. The purchases of these shares were as follows:

<u>Purchaser</u>	<u>Exercise Date</u>	<u>Number of Shares</u>	<u>Exercise Price</u>	<u>Aggregate Purchase Price</u>
Joseph DiBenedetto, Jr.	11/6/03	2,040	\$6.09	\$ 12,424
Allan Fishbein, M.D.	11/26/03	5,211	4.76	24,804
Richard Gaston	12/5/03	5,211	4.76	24,804
Marc & Ingrid Gelman	12/8/03	2,605	4.76	12,400
Union d'etudes et d'investissements	12/8/03	5,120	5.36	27,443
Veron International Ltd	12/9/03	31,270	4.76	148,845
John & Sandra Leland Trust	12/11/03	2,605	4.76	12,400
Virginia Leung	12/11/03	2,605	4.76	12,400
Hofung Holdings Ltd	12/12/03	10,423	4.76	49,613
Nai-Ping Leung	12/12/03	2,605	4.76	12,400
Lewis Pell	12/17/03	8,163	6.09	49,713
		<u>77,858</u>		<u>\$387,226</u>

These shares were issued in reliance on Section 4(2) under the Securities Act, in that they were issued to the original purchasers of the warrants. These purchasers represented, in connection with the original purchase of the warrants, that they were accredited investors as defined in the Regulation D under the Securities Act.

Item 6. Selected Financial Data

The following tables should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of this report and the financial statements and related notes included in Item 8 of this report.

<i>(in thousands, except per share data)</i>	Year Ended December 31,			(1) Six Months Ended December 31,	Fiscal Years Ended June 30,			October 22, 1992 (Inception) to December 31,
	2003	2002	2001	2001	2001	2000	1999	2003
	(unaudited)							
Statement of Operations Data:								
Revenue	\$ 463	\$ 57	\$ 94	\$ 8	\$ 116	\$ 58	\$ 185	\$ 1,250
Expenses:								
Research and development	21,805	24,809	22,333	11,465	17,041	7,953	6,490	108,161
General and administrative	7,399	8,146	7,559	3,957	6,761	4,516	3,445	43,823
In-license fees	—	—	—	—	—	5,034	—	5,034
	<u>29,204</u>	<u>32,955</u>	<u>29,892</u>	<u>15,422</u>	<u>23,802</u>	<u>17,503</u>	<u>9,935</u>	<u>157,018</u>
Loss from operations	(28,741)	(32,898)	(29,798)	(15,414)	(23,686)	(17,445)	(9,750)	(155,768)
Interest expense	(250)	(278)	(347)	(204)	(180)	(129)	(178)	(2,171)
Interest income	3,282	5,569	9,364	4,316	7,907	2,548	326	25,405
Other expense, net	(65)	(132)	(68)	(17)	(55)	(13)	(9)	(122)
Net loss	<u>\$(25,774)</u>	<u>\$(27,739)</u>	<u>\$(20,849)</u>	<u>\$(11,319)</u>	<u>\$(16,014)</u>	<u>\$(15,039)</u>	<u>\$(9,611)</u>	<u>\$(132,656)</u>
Net loss per share	<u>\$ (1.28)</u>	<u>\$ (1.38)</u>	<u>\$ (1.05)</u>	<u>\$ (0.57)</u>	<u>\$ (0.85)</u>	<u>\$ (1.03)</u>	<u>\$ (0.99)</u>	

<i>(in thousands)</i>	December 31,			June 30,		
	2003	2002	2001 (1)	2001	2000	1999
Balance Sheet Data:						
Cash, cash equivalents, available-for-sale securities, and restricted investments	\$ 98,878	\$ 119,224	\$ 148,254	\$ 157,737	\$ 77,953	\$ 14,881
Working capital	86,051	107,398	137,486	151,341	72,732	13,471
Total assets	116,595	140,686	168,409	174,946	85,287	16,183
Long-term obligations	10,592	8,852	8,558	5,391	4,113	265
Deficit accumulated during development stage	(132,656)	(106,882)	(79,143)	(67,823)	(51,810)	(36,771)
Stockholders' equity	103,886	130,057	157,350	167,182	79,013	14,323

(1) We changed our fiscal year end from June 30 to December 31, effective December 31, 2001.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. Avigen's actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause or contribute to such differences include, but are not limited to, those discussed herein and in "Risk Factors" under Item 1.

Overview

We are focused on developing pharmaceutical products that provide improved treatments for serious and chronic hematological and neurological diseases. Since our inception, we have devoted substantially all of our resources to research and development activities, including the development of our proprietary gene delivery platform technology based on adeno-associated virus vectors, known as "AAV vectors", and the development and clinical testing of DNA-based treatments for targeted hematological and neurological diseases. Our research and development activities to date are supported by a broad base of proprietary intellectual property that we have assembled covering methods of transferring genes into cells, high-yield processes to manufacture contaminant-free AAV vectors, specific genes of interest, specific disease indications, and other proprietary technologies and processes. In addition, we have built the manufacturing capacity necessary to produce clinical-grade AAV vectors and our other DNA-based treatments at volumes we believe will support the commercial needs of our current product candidates.

We currently have one development product in phase I clinical trials, Coagulin-B for the treatment of hemophilia B. We have also submitted an IND to the FDA to initiate a phase I dose-escalation clinical trial for a second development product, AV201, for the treatment of Parkinson's disease, and are currently responding to a request for more information from the FDA. The pace of clinical progress for both development products has been impacted by factors that were unpredictable, including a lengthy and complex regulatory review process by the FDA and the timeliness of recruiting and screening volunteers and coordinating the treatment of a sufficient number of qualified patients in our trials. These and other factors will continue to have a significant effect on the timing and financial cost of the development of our products.

We are a development stage company and have primarily supported the financial needs of our research and development activities since our inception through public offerings and private placements of our equity securities and will continue to seek additional future funding through similar financings, when market conditions allow. We have not received any revenue from the sale of our products in development, and we do not anticipate generating revenue from the sale of products in the foreseeable future. We expect our source of revenue, if any, for the next several years to consist of payments under collaborative arrangements with third parties, government grants, and license fees. We have incurred losses since our inception and expect to incur substantial losses over the next several years due to lack of any substantial revenue and the continuation of our ongoing and planned research and development efforts, including preclinical studies and clinical trials. There can be no assurance that we will successfully develop, commercialize, manufacture, or market our product candidates or ever achieve or sustain product revenues for profitability. At December 31, 2003 we had an accumulated deficit of \$132.7 million and cash, cash equivalents, available-for-sale securities, and restricted investments of approximately \$98.9 million. We believe that our capital resources at December 31, 2003 will be adequate to fund our current operating needs over the next three to four years.

In August 2001, we changed our fiscal year end from June 30 to December 31, beginning with the six months ended December 31, 2001.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments related to revenue recognition, valuation of investments in financial instruments, impairment of property and equipment, and research and development expenses. We base our estimates on historical experience and on various other factors that we believe are reasonable under the

circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described under Note 1 in the Notes to our Financial Statements, we believe the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements.

Revenue recognition

We recognize revenue associated with up-front license, technology access and research and development funding payments under collaborative agreements ratably over the relevant periods specified in the agreements, generally the development phase. This development phase can be defined as a specified period of time, however, in certain cases, the collaborative agreement specifies a development phase that culminates with milestone objectives but does not have a fixed date and requires us to estimate the time period over which to recognize this revenue. Our estimated time periods are based on management's estimate of the time required to achieve a particular development milestone considering level of effort and stage of development. If our estimate of the development-phase time period increases, the amount of revenue we recognize related to up-front license and technology access fees for a given period will decrease.

We recognize non-refundable product license fees, including fees associated with research license agreements, for which we have no further performance obligations, and no continuing involvement requirements, on the earlier of the dates on when the payments are received or when collection is assured.

Valuation of investments in financial instruments

We carry investments in financial instruments at fair value with unrealized gains and losses included in accumulated other comprehensive income or loss in stockholders' equity. Our investment portfolio does not include equity securities or derivative financial instruments that could subject us to material market risk; however, we do invest in corporate obligations that subject us to varying levels of credit risk. We consider an impairment of a financial instrument to be other-than-temporary if the fair value of the financial instrument has declined below its carrying value for a period in excess of six consecutive months or if the decline is due to a significant adverse event, such that the carrying amount of the investment may not be fully recoverable. We write-down an other-than-temporary decline in fair value of a financial instrument with a charge in net loss. The determination of whether a decline in fair value is other-than-temporary requires significant judgment, and could have a material impact on our balance sheet and results of operations. Our management reviews the securities within our portfolio for other-than-temporary declines in value with our investment advisor on a regular basis. We have not had any write-downs for other-than-temporary declines in the fair value of our financial instruments since our inception. At December 31, 2003, the carrying value of our financial instruments was \$84.6 million in available-for-sale securities and \$11.9 million in restricted investments.

Impairment of property and equipment

We have invested significant amounts on construction for improvements to our research and development facilities, with the largest portion of our spending made to modify manufacturing facilities that are intended to comply with requirements of government mandated manufacturing rules for pharmaceutical production. These assets could be subject to write-down for impairment in the event that our facilities are deemed to fail to comply with these government mandated policies and procedures or if the products for which the manufacturing facilities have been constructed do not receive regulatory approval. These assets could also be subject to write-down to the extent that facilities could be idled due to the adoption of operating efficiencies for an other-than-temporary period, resulting in excess capacity. The determination of whether an impairment in use is other-than-temporary requires significant judgment, and could have a material effect on our balance sheet and our results of operations. We have not had any write-downs for impairments in the fair value of our property and equipment since our inception. At December 31, 2003, the carrying value of our property and equipment was \$15.6 million.

Research and development expenses

Our research and development expenses include salaries and benefits costs, fees for contractors and consultants, fees to collaborators for preclinical research studies, patient treatment costs related to clinical trials and related clinical manufacturing costs, license fees for use of third-party intellectual property rights, and an allocation of

facilities and overhead costs. Research and development expenses consist of costs incurred for drug and product development, manufacturing, clinical activities, discovery research, screening and identification of drug candidates, and preclinical studies. All such costs are charged to research and development expenses as incurred, with the costs of materials and other supplies charged to research and development expense upon receipt.

Clinical development costs are a significant component of research and development expenses. We accrue costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with the clinical trial sites. We determine our estimates through discussion with internal clinical personnel and outside service providers as to the progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor clinical trial activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

Results of Operations

As a result of the change from a June 30 fiscal year to a calendar year effective December 31, 2001, which resulted in a six-month transition period, it is difficult to compare our results of operations, or any of the components of our results of operations, between the full years ended December 31, 2003 and 2002, and the six-month transition period ended December 31, 2001. Therefore, in order to best understand the trends in our results of operations, primarily expenses, over the most recent reporting periods, we have included analyses of variances between the twelve-month periods ended December 31, 2003, 2002, and 2001 using an unaudited twelve-month period ended December 31, 2001.

Revenue

<u>(In thousands, except percentages)</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
Revenue	\$463	\$ 57	\$94
Percentage increase over prior period	712%	(39%)	

In 2003, revenue primarily consisted of the recognition of \$375,000 of deferred revenue from the \$2.5 million payment received from Bayer in March 2003. This payment from Bayer is being recognized ratably over the estimated development period of our hemophilia B product candidate, which was estimated at five years from the date of the payment, resulting in revenue recognition of \$125,000 per quarter beginning with the second quarter of 2003. Research license fees totaled \$79,000, \$38,000, and \$8,000, respectively, in 2003, 2002, and 2001. Research license agreements allow the licensee to make or use products using our patented AAV technologies for research purposes only, and do not allow for the use of our technologies in products for commercial sale. These licenses usually include initiation fees and annual maintenance fees. Royalty revenue totaled \$9,000, \$19,000, and \$500, respectively, in 2003, 2002 and 2001, all of which were attributed to a single royalty license that was entered into in July 2000, which allows for the development, manufacture, use and commercial sale of products using our patented AAV technologies. Revenues in 2001 included grant revenue of \$86,000, consisting of reimbursements under a grant from the National Institutes of Health (NIH), which expired on March 31, 2001. We do not expect to earn significant revenues from, or to be party to, any new NIH grants for the foreseeable future.

In the event that we enter a phase II/III clinical trial with our Coagulin-B product, we expect to earn additional revenues in connection with our collaboration agreement with Bayer, including a milestone payment for initiating a phase II/III clinical trial and reimbursements for the costs of manufacturing AAV vector used in the clinical trials. Under the terms of the agreement, Bayer will also pay for third-party costs of the clinical trials. However, we cannot be certain when or if we will enter a phase II/III clinical trial. We do not expect to earn any other significant revenues for the foreseeable future.

Research and Development Expenses

Our research and development expenses can be divided into two primary functions, costs to support research and preclinical development and costs to support preparation for and implementation of human clinical trials. Research and preclinical development costs include activities associated with general research and exploration,

animal studies, production of vector for use by external collaborators in general research and exploration, and development of processes to translate research achievements into commercial scale capabilities. Clinical development costs include activities associated with preparing for regulatory approvals, maintaining regulated and controlled processes, manufacturing vector for use in human clinical trials, and supporting patient enrollment and patient administration within clinical trials.

During the second-half of 2002, we took strategic steps to focus the work of our research and development organizations on the clinical development of our lead product programs. This included a reduction in staff and the implementation of other operational efficiencies without limiting our production capabilities. Our research and development staff count grew from approximately 80 at the beginning of 2001 to approximately 130 at December 31, 2001, and continued to rise to a peak of approximately 145 in September 2002. The impact of the workforce reduction in October 2002 reduced that staff level to 90 at December 31, 2002. At December 31, 2003, our staff count dedicated to research and development activities totaled 79.

During 2003, our research and preclinical development expenses included activities for our development programs for hemophilia, Parkinson's disease, neuropathic pain, and other neurological targets, and our clinical development expenses included activities to support our development programs for Coagulin-B and AV201. During 2002, our research and preclinical development expenses were focused on our development programs for hemophilia and Parkinson's disease, and other cardiac and neurological targets, and our clinical development expenses were focused on our development programs for Coagulin-B and AV201. During 2001, our research and preclinical development expenses were primarily focused on our development programs for hemophilia and Parkinson's disease, and our clinical development expenses were focused on our development programs for Coagulin-B.

We estimate that the costs associated with these two categories approximate the following (in thousands):

	Year Ended December 31, 2003	Year Ended December 31, 2002	(Unaudited) Twelve Months Ended December 31, 2001
Research and preclinical development	\$13,614	\$14,266	\$12,050
Clinical development	<u>8,191</u>	<u>10,543</u>	<u>10,283</u>
Total research and development expenses	<u>\$21,805</u>	<u>\$24,809</u>	<u>\$22,333</u>

Because a significant percentage of our research and development resources are dedicated to activities that focus on fundamental platform technologies that may be used in many different product applications, including production and administration techniques, the majority of our costs are not directly attributed to individual development programs. Decisions regarding our project management and resource allocation are primarily based on interpretations of scientific data, rather than cost allocations. Our estimates of costs between research and preclinical development and clinical development are primarily based on staffing roles within our research and development departments. As such, costs allocated to specific projects may not necessarily reflect the actual costs of those efforts and, therefore, we do not generally evaluate actual costs-incurred information on a project-by-project basis. In addition, we are unable to estimate the future costs to completion for any specific projects.

Comparison of the Years Ended December 31, 2003 and 2002. The decrease of \$652,000 in our research and preclinical development expenses for 2003, compared to 2002, was primarily due to changes in costs for the following:

- lower materials expenses of \$1.1 million, reflecting the impact of decreased consumption of materials to produce our AAV vectors and support our on-going research which resulted from our lower staff levels in 2003 when compared to the staff level for most of 2002 and the benefits of operating efficiencies we have implemented over the last two years,
- lower personnel-related expenses of \$670,000, primarily reflecting the impact of our lower staff levels in 2003 after the workforce reduction that occurred in October 2002, and
- lower consulting expenses of \$157,000, reflecting decreased involvement by third-party service providers to support our in-house research,

partially offset by:

- higher expenditures for services from third-party collaborators associated with our preclinical animal studies of \$659,000, primarily related to our work with Parkinson's disease,
- higher depreciation expenses of \$253,000, reflecting the full-year impact of newly constructed facilities that were placed in service in the second half of 2002 for general and animal research, and
- higher other facilities-related expenses of \$211,000, related to the rise in costs under the new building lease that went into effect in 2003 and generally higher maintenance costs.

The decrease of \$2.4 million in our clinical development expenses for 2003, compared to 2002, was primarily due to changes in costs for the following:

- lower personnel-related expenses of \$1.3 million, primarily reflecting the impact of our lower staff levels in 2003 after the workforce reduction in October 2002,
- lower materials expenses of \$986,000 reflecting lower levels of material consumed for the production of clinical grade material due to the delayed needs of our Coagulin-B clinical trial, as well as general benefits from manufacturing efficiencies adopted over the last two years for the production of our AAV vectors,
- lower expenditures of \$509,000 to third-party collaborators associated with treating and monitoring subjects in our clinical trial, reflecting the delay in treating Coagulin-B patients in 2003, and
- lower consulting and validation services expenses of \$716,000, primarily in connection with regulatory and quality assurance process improvements and validation of new cGMP facilities that were completed in 2002,

partially offset by,

- higher license origination fees of \$578,000,
- higher depreciation expenses of \$307,000, reflecting the full-year impact of newly constructed facilities that were placed in service in the second half of 2002 for cGMP manufacturing, and
- higher other facilities-related expenses of \$254,000, related to the rise in costs under the new building lease that went into effect in 2003 and generally higher maintenance costs.

Comparison of the Year Ended December 31, 2002 and Unaudited Twelve-Month Period Ended December 31, 2001. The increase of \$2.2 million in our research and preclinical development expenses for 2002, compared to 2001, was primarily due to changes in costs for the following:

- higher expenditures for services from third-party collaborators associated with our preclinical animal studies of \$950,000, primarily related to our work with Parkinson's disease,
- higher personnel-related expenses of \$830,000, reflecting rising staff levels throughout most of 2002, and
- higher depreciation and amortization expenses of \$640,000, reflecting the impact of new facilities placed in service during the year,

partially offset by,

- lower other overall costs of \$200,000.

The increase of \$260,000 in our clinical development expenses for 2002, compared to 2001, was primarily due to changes in costs for the following:

- higher expenditures to third-party collaborators associated with treating and monitoring subjects in our Coagulin-B clinical trial of \$520,000, reflecting the increase in the number of patients treated in 2002 compared to 2001,
- higher depreciation and other facilities-related expenses of \$290,000, due to new facilities placed in service in 2002,
- higher validation services of \$320,000, in connection with the validation of new cGMP facilities that were completed in 2002, and
- higher personnel-related expenses of \$285,000, reflecting rising staff levels throughout most of 2002, partially offset by,
- lower materials expenses of \$490,000, reflecting the benefit of manufacturing efficiencies adopted in 2002 for the production of our AAV vectors,
- lower recruiting and other related costs of \$360,000, and
- lower license milestone payments of \$320,000.

Total research and development expenses in 2003 were lower than management expected due to delays in treating new patients in our Coagulin-B clinical trial. We recognize that regulatory approvals and patient scheduling and coordination will continue to be factors that could cause delays in the progress in our clinical trials; however, we do expect to expand our clinical trial activities in 2004 as we move forward with our hemophilia B clinical trial and, assuming we obtain final regulatory approval of our IND application for AV201 from the FDA, as we begin to enroll patients in a new Parkinson's disease clinical trial. As a result, we expect our total research and development spending to rise in 2004 above our 2003 levels as we conduct our clinical trial activities and to the extent we enhance our manufacturing capabilities and expand our research and development programs for additional hematological and neurological diseases.

General and Administrative Expenses

<u>(In thousands, except percentages)</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
General and administrative expenses	\$7,399	\$8,146	\$7,559
Percentage increase over prior period	(9%)	8%	

The decrease in general and administrative expenses between 2003 and 2002 was primarily related to lower personnel-related costs of approximately \$510,000 reflecting lower staff levels as a result of the October 2002 workforce reduction, lower depreciation and facilities-related expenses related to the reduction in allocation of space for our non-research and development activities of approximately \$440,000, and lower litigation-related legal fees of approximately \$110,000 as a result of the settlement of our lawsuit with RCT. These decreases were partially offset by higher patent-related legal fees of approximately \$200,000 and higher expenses for other professional services and information services of approximately \$160,000.

The increase in general and administrative expenses between 2002 and 2001 was primarily due to approximately \$430,000 in higher personnel-related costs due to the increase in headcount in 2002 prior to our October 2002 staff workforce reduction, \$230,000 in higher legal fees related to the RCT litigation, \$210,000 in higher corporate expenses, including insurance and information services, and \$235,000 in higher depreciation and overhead expenses. These higher costs were partially offset by a \$515,000 decline in other corporate expenses, primarily for professional services, due to the fact that in 2001 we had two audits and prepared and filed two annual reports as a result of the change of our fiscal year end from June 30 to December 31 in that year.

We expect our general and administrative expenses for 2004 to remain steady or increase slightly from 2003 levels.

Interest Income

<u>(In thousands, except percentages)</u>	<u>2003</u>	<u>2002</u>	<u>2001</u>
Interest income	\$3,282	\$5,569	\$9,364
Percentage increase over prior period	(41%)	(40%)	

Almost all of our interest income is generated from our investments in high-grade marketable securities of government and corporate debt. The declines in interest income between 2003 and 2002 and between 2002 and 2001, were primarily due to the general decline in market interest rates between those periods and the decrease in outstanding interest-bearing cash and securities balances due to resources having been used to fund our on-going operations and finance construction of additional research and development facilities.

Adoption of Recently Issued Accounting Standards

In January 2003, the FASB issued FASB Interpretation No. 46, or FIN 46, "*Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51.*" FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact on our financial position, cash flows or results of operations.

In May 2003, the FASB issued SFAS No. 150, "*Accounting For Certain Financial Instruments with Characteristics of Both Liabilities and Equity,*" which establishes standards for how an issuer of financial instruments classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or in some circumstances, as an asset) if, at inception, the monetary value of the obligation is based solely or predominantly on: (a) a fixed monetary amount known at inception, (b) variations in something other than the fair value of the issuer's equity shares or (c) variations inversely related to changes in the fair value of the issuer's equity shares. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of SFAS No. 150 did not have an impact on our financial statements.

Deferred Income Tax Assets

In accordance with FAS 109, "*Accounting for Income Taxes,*" which is described in the Notes to our Financial Statements, we have calculated a deferred tax asset based on the potential future tax benefit we may be able to realize in future periods as a result of the significant tax losses experienced since our inception. However, the value of such deferred tax asset must be calculated using the tax rates expected to apply to the taxable income in the years in which such income occurs. Since we have no history of earnings, and cannot reliably predict when we might create taxable income, if at all, we have recorded a valuation allowance for the full amount of our calculated deferred tax asset.

Liquidity and Capital Resources

Since our inception in 1992, cash expenditures have significantly exceeded our revenue. We have funded our operations primarily through public offerings and private placements of our equity securities. Subsequent to our initial public offering in May 1996, through December 2000 we raised \$171.0 million from private placements and public offerings of our common stock and warrants to purchase our common stock. Pursuant to our collaboration agreement for Coagulin-B with Bayer Corporation, we received net proceeds of \$15.0 million from the sale of our common stock to Bayer AG in February 2001 and we received \$2.5 million in research support from Bayer Corporation in March 2003. Also, during the three years ended December 31, 2003, we raised an additional \$2.5 million as a result of exercises of previously issued warrants and options to purchase our common stock. The timing of and amounts realized from the exercise of these warrants and options are determined by the decisions of the respective warrant and option holders, and are not controlled by us. Therefore, funds raised from exercises of stock options and warrants in past periods should not be considered an indication of additional funds to be raised in the future periods.

In addition to funding our operations through sales of our common stock, we have attempted to contain costs and reduce cash flow requirements by renting scientific equipment and facilities, contracting with third parties to conduct research and development and using consultants, where appropriate. We expect to incur additional future expenses, resulting in significant additional losses, as we continue to expand our research and development activities and undertake additional preclinical studies and clinical trials of our gene therapy product candidates. We also expect to incur substantial additional expenses relating to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims.

At December 31, 2003, we had cash, cash equivalents, available-for-sale securities, and restricted investments, of approximately \$98.9 million, compared to approximately \$119.2 million at December 31, 2002 and \$148.3 million at December 31, 2001. At December 31, 2003, 2002 and 2001, \$11.9 million, \$11.5 million, and \$10.0 million, respectively, was pledged to secure certain long-term liabilities. At December 31, 2003, these long-term liabilities include \$10.0 million for our line of credit, \$1.5 million for equipment operating leases, and approximately \$428,000 for letters of credit that we entered into in May 2003 which serve as security deposits on our building lease. Our restricted investments are reported as a long-term asset and would not be considered a current source of additional liquidity.

The following are contractual commitments at December 31, 2003 associated with debt obligations, lease obligations, and contractual commitments to fund third-party research (in thousands):

<u>Contractual Commitment</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>After 5 years</u>
Revolving line of credit	\$ 8,000	\$ —	\$ 8,000	\$ —	\$ —
Operating leases	15,045	2,503	5,241	4,550	2,751
Research funding for third-parties	1,089	1,089	—	—	—
Total	<u>\$24,134</u>	<u>\$3,592</u>	<u>\$13,241</u>	<u>\$4,550</u>	<u>\$2,751</u>

In June 2002, we amended the terms of our \$10 million revolving line of credit which had been put in place with Wells Fargo Bank in June 2000 to provide support for construction related activities. Under the terms of the amendment, the expiration date of the borrowing was extended from June 1, 2003 to June 1, 2005, thereby deferring the timetable to repay the principal borrowed for two years. The debt instrument bears interest at a floating rate based on the London Inter-Bank Offered Rate, which is reset in three-month increments after the date of each drawdown, until such expiration. As of December 31, 2003 and 2002, the average annual rate of interest charged on the borrowing was approximately 2.75% and 3.11%, respectively. Also under the terms of this agreement, we pledged a portion of our portfolio of available for sale securities as collateral and have identified the amount of the pledged securities as restricted investments on our balance sheets. The amount of the pledged securities is equal to the amount of utilized borrowing capacity on the line of credit. At December 31, 2003, we had borrowed \$8 million from the line of credit and had reserved the remaining \$2 million in borrowing capacity to secure a letter of credit in connection with the property lease entered into in November 2000. As a result, at December 31, 2003, we have no more borrowing capacity under this facility. As collateral for the revolving line of credit, our restricted investments would not be considered a current source of additional liquidity. The total amount of restricted investments at December 31, 2003, including the portion of our investment portfolio that is pledged as collateral for this line of credit and other securities that have been pledged to secure equipment operating leases and other letters of credit, was \$11.9 million.

Our current office and facility includes approximately 112,500 square feet of space. Of this, approximately 45,000 square feet of space is leased through May 2008 and approximately 67,500 square feet of space is leased through November 2010. Payments scheduled under these lease commitments are included in the table above under operating leases.

We enter into commitments to fund collaborative research and clinical work performed by third parties. While these contracts are cancelable by either party, we expect the research studies and clinical work to be completed as defined in the terms of the agreements, and all amounts paid when due. Payments scheduled to be made under these contracts are included in the table above under research funding for third-parties.

For the years ended December 31, 2003 and 2002, net cash used in operating activities was \$19.3 million and \$24.2 million, respectively. The change in cash used in operating activities between 2003 and 2002 was primarily

due to the reduction in our net loss due to the decrease in research and development costs, as a result of our adoption of operating efficiencies and the impact of our October 2002 workforce reduction discussed above, and the receipt of a \$2.5 million payment from Bayer Corporation in March 2003, which was recorded as deferred revenue.

For the years ended December 31, 2002 and June 30, 2001, net cash used in operating activities was \$24.2 million and \$15.2 million, respectively. The change in cash used in operating activities between these two comparable periods was primarily due to the increase in our net loss as a result of the increase in our research and development costs due to increased staff and expanded product development programs, partially offset by a decrease in accrued interest and an increase in accounts payable and other liabilities.

During the six-month period ended December 31, 2001 and unaudited six-month period ended December 31, 2000, net cash used in operating activities was \$8.3 million and \$7.4 million, respectively. The change in cash used in operating activities between the comparable six-month periods was primarily due to the increase in our net loss as a result of the increase in our research and development costs due to increased staff and expanded product development programs, partially offset by a decrease in accrued interest and an increase in accounts payable and other liabilities.

For the year ended December 31, 2003, net cash provided by investing and financing activities was \$13.1 million and \$718,000, respectively. The cash provided by investing activities consisted of maturities, net of purchases, of available-for-sale securities of \$14.1 million, which we used to fund our operating activities, offset in part by purchases of property and equipment of \$555,000 and increases in restricted investments of \$428,000. The cash provided by financing activities consisted of proceeds from the exercise of stock options and warrants during the year.

For the year ended December 31, 2002, net cash provided by investing and financing activities was \$18.0 million and \$860,000, respectively. The cash provided by investing activities consisted of maturities, net of purchases, of available-for-sale securities of \$24.6 million, which we used to fund our operating activities, offset in part by purchases of property and equipment of \$5.0 million and increases in restricted investments of \$1.5 million. The cash provided by financing activities consisted of proceeds from the exercise of stock options and warrants during the year.

During the six-month transition period ended December 31, 2001, approximately \$12.3 million and \$3.1 million, were provided by investing and financing activities, respectively. The cash provided by investing activities consisted of maturities, net of purchases, of available for sale securities, which we used to fund our operating activities, offset in part by purchases of property and equipment of \$5.5 million and increases in restricted investments of \$3.0 million. The cash provided by financing activities primarily consisted of additional borrowings from our revolving line of credit to provide funding for construction related activities.

For the year ended June 30, 2001, approximately \$103.5 million was provided by financing activities and \$95.6 million was used by investing activities. The cash provided by financing activities, which was used in investing activities and to fund our operating activities, primarily consisted of proceeds from the issuance of common stock during a public offering in November 2000 and in connection to our collaboration agreement with Bayer in March 2001. The cash used by investing activities consisted of purchases, net of maturities, of available for sale securities of \$82.9 million, purchases of property and equipment of \$9.7 million and increases in restricted investments of \$3.0 million.

We believe we will continue to require substantial additional funding in order to complete the research and development activities currently contemplated and to commercialize our proposed products. We believe that our capital resources at December 31, 2003 will be adequate to fund our current operating needs over the next three to four years. However, this forward-looking statement is based upon our current plans and assumptions regarding our future operating and capital requirements, which may change. Our future operating and capital requirements will depend on many factors, including:

- continued scientific progress in research and development programs;
- the scope and results of preclinical studies and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in filing, prosecuting and enforcing patents claims and other intellectual property rights;
- competing technological developments;

- the cost of manufacturing scale-up;
- the costs of commercialization activities; and
- other factors which may not be within our control.

We intend to continue to seek additional funding through public or private equity or debt financing, when market conditions allow, or through additional collaborative arrangements with corporate partners. If we raise additional funds by issuing equity securities, there may be further dilution to existing stockholders. We cannot assure our investors that we will be able to enter into such financing arrangements on acceptable terms or at all. Without such additional funding, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio and our long-term debt. We do not hold derivative financial investments, derivative commodity investments or other financial investments or engage in foreign currency hedging or other transactions that exposes us to other market risks. None of our investments are held for trading purposes. Our investment objectives are focused on preservation of principal and liquidity. By policy, we manage our exposure to market risks by limiting investments to high quality issuers and highly liquid instruments with effective maturities of less than three years, and an average aggregate portfolio duration of approximately one year. Our entire portfolio is classified as available-for-sale and, as of December 31, 2003, consisted of approximately 93% fixed-rate securities and 7% variable-rate securities. This compares to approximately 84% fixed-rate securities and 16% variable-rate securities at December 31, 2002.

We have evaluated the risk associated with our portfolios of investments in marketable securities and have deemed this market risk to be immaterial. If market interest rates were to increase by 100 basis points, or 1%, from their December 31, 2003 levels, we estimate that the fair value of our securities portfolio would decline by approximately \$1.1 million. Our estimated exposure at December 31, 2003 is lower than our estimated \$1.3 million exposure at December 31, 2002 due to the reduction in size of our overall portfolio. The modeling technique used measures duration risk sensitivity to estimate the potential change in fair value arising from an immediate hypothetical shift in market rates and quantifies the ending fair market value including principal and accrued interest.

Our long-term debt includes a \$10.0 million revolving line of credit due June 1, 2005, of which we have drawn down \$8.0 million in cash that will need to be repaid. Interest charged on the borrowing is based on LIBOR and is reset in three-month increments based on the date of each original drawdown. As of December 31, 2003, the average annual rate of interest charged on the borrowing was approximately 2.75%.

Item 8. *Financial Statements and Supplementary Data*

INDEX TO FINANCIAL STATEMENTS

The following financial statements are filed as part of this Report on Form 10-K. Condensed supplementary data for each of the quarters in the years ended December 31, 2003 and 2002 are set forth under Note 12 of our financial statements.

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders of Avigen, Inc.

We have audited the accompanying balance sheets of Avigen, Inc. (a development stage company) as of December 31, 2003 and 2002, and the related statements of operations, stockholders' equity and cash flows for the years ended December 31, 2003 and 2002, the six months ended December 31, 2001, the fiscal year ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Avigen, Inc. at December 31, 2003 and 2002, and the results of its operations and its cash flows for the years ended December 31, 2003 and 2002, the six months ended December 31, 2001, the fiscal year ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 30, 2004

AVIGEN, INC.
(a development stage company)

BALANCE SHEETS
(in thousands, except share and per share information)

	December 31,	
	2003	2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,384	\$ 7,879
Available-for-sale securities	84,566	99,845
Accrued interest	774	993
Prepaid expenses and other current assets	444	458
Total current assets	88,168	109,175
Restricted investments	11,928	11,500
Property and equipment, net	15,641	18,726
Deposits and other assets	858	1,285
Total assets	\$ 116,595	\$ 140,686
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 1,140	\$ 1,156
Accrued compensation and related expenses	477	621
Deferred revenue—current	500	—
Total current liabilities	2,117	1,777
Long-term loan payable	8,000	8,000
Deferred rent	967	852
Deferred revenue	1,625	—
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding, in 2003 and 2002	—	—
Common stock, \$0.001 par value, 50,000,000 shares authorized at December 31, 2003 and 2002, and 20,276,394 and 20,100,546 shares issued and outstanding at December 31, 2003 and 2002, respectively ..	20	20
Additional paid-in capital	236,120	235,337
Accumulated other comprehensive income	402	1,582
Deficit accumulated during development stage	(132,656)	(106,882)
Total stockholders' equity	103,886	130,057
Total liabilities and stockholders' equity	\$ 116,595	\$ 140,686

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF OPERATIONS
(in thousands, except for share and per share information)

	Year Ended		Six Months Ended		Year Ended	Period from
	December 31,		December 31,		June 30,	October 22,
	2003	2002	2001	2000	2001	1992 (inception) Through December 31, 2003
				(unaudited)		
Revenue	\$ 463	\$ 57	\$ 8	\$ 30	\$ 116	\$ 1,250
Operating expenses:						
Research and development	21,805	24,809	11,465	6,173	17,041	108,161
General and administrative	7,399	8,146	3,957	3,159	6,761	43,823
In-license fees	—	—	—	—	—	5,034
Total operating expenses	<u>29,204</u>	<u>32,955</u>	<u>15,422</u>	<u>9,332</u>	<u>23,802</u>	<u>157,018</u>
Loss from operations	(28,741)	(32,898)	(15,414)	(9,302)	(23,686)	(155,768)
Interest expense	(250)	(278)	(204)	(38)	(180)	(2,171)
Interest income	3,282	5,569	4,316	2,860	7,907	25,405
Other expense, net	(65)	(132)	(17)	(4)	(55)	(122)
Net loss	<u>\$ (25,774)</u>	<u>\$ (27,739)</u>	<u>\$ (11,319)</u>	<u>\$ (6,484)</u>	<u>\$ (16,014)</u>	<u>\$ (132,656)</u>
Basic and diluted net loss per common share	<u>\$ (1.28)</u>	<u>\$ (1.38)</u>	<u>\$ (0.57)</u>	<u>\$ (0.37)</u>	<u>\$ (0.85)</u>	
Shares used in basic and diluted net loss per common share calculation	<u>20,149,214</u>	<u>20,080,998</u>	<u>19,959,941</u>	<u>17,745,484</u>	<u>18,730,437</u>	

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at October 22, 1992 (inception)	—	\$—	—	\$—	—	\$—	\$ —	\$—	\$ —	\$ —
Issuance of common stock at \$.004 per share in November and December 1992	—	—	896,062	1	—	—	4	—	—	5
Issuance of common stock at \$.554 per share from January to June 1993 for services rendered	—	—	20,316	—	—	—	11	—	—	11
Issuance of common stock at \$.004 to \$.222 per share from November 1992 to March 1993 for cash	—	—	1,003,406	1	—	—	54	—	—	55
Issuance of Class B common stock at \$.004 per share in December 1992 for cash	—	—	—	—	90,293	—	1	—	—	1
Issuance of Series A preferred stock at \$4.43 per share from March to June 1993 for cash (net of issuance costs of \$410,900)	678,865	1	—	—	—	—	2,595	—	—	2,596
Issuance of Series A preferred stock at \$3.85 per share in March 1993 for cancellation of note payable and accrued interest	68,991	—	—	—	—	—	266	—	—	266
Issuance of common stock at \$.004 per share in November 1993 pursuant to antidilution rights	—	—	22,869	—	—	—	1	—	—	1
Issuance of Series A preferred stock at \$4.43 per share from July to November 1993 for cash and receivable (net of issuance costs of \$187,205) ...	418,284	—	—	—	—	—	1,665	—	—	1,665
Issuance of Series B preferred stock at \$5.54 per share in March 1994 for cash (net of issuance costs of \$34,968)	128,031	—	—	—	—	—	674	—	—	674
Issuance of Series C preferred stock at \$4.87 per share from July 1994 to June 1995 for cash and receivables (net of issuance costs of \$259,620) ...	739,655	1	—	—	—	—	3,344	—	—	3,345
Issuance of Series C preferred stock at \$4.87 per share in June 1995 for cancellation of notes payable	35,500	—	—	—	—	—	173	—	—	173
Net loss and comprehensive loss from inception to June 30, 1995	—	—	—	—	—	—	—	—	(8,608)	(8,608)
Balance at June 30, 1995	2,069,326	2	1,942,653	2	90,293	—	8,788	—	(8,608)	184

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Class B Convertible Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Gain (Loss)</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Issuance of Series C preferred stock at \$4.87 per share in July 1995 for cash (net of issuance costs of \$26,000)	41,042	\$—	—	\$—	—	\$—	\$ 174	\$—	\$ —	\$ 174
Issuance of Series D preferred stock at \$7.09 per share from October 1995 to February 1996 for cash (net of issuance costs of \$25,279)	205,351	—	—	—	—	—	1,430	—	—	1,430
Issuance of Series D preferred stock at \$7.09 per share in March 1996 in settlement of accounts payable	22,574	—	—	—	—	—	160	—	—	160
Issuance of common stock at \$.004 per share in March 1996 pursuant to antidilution rights ..	—	—	17,630	—	—	—	1	—	—	1
Issuance of stock options in February 1996 in settlement of certain accrued liabilities	—	—	—	—	—	—	137	—	—	137
Conversion of Class B common stock to common stock	—	—	231,304	1	(90,293)	—	(1)	—	—	—
Issuance of warrants to purchase common stock in connection with 1996 bridge financing in March 1996	—	—	—	—	—	—	300	—	—	300
Conversion of preferred stock to common stock in May 1996 ..	(2,338,293)	(2)	2,355,753	2	—	—	(1)	—	—	(1)
Issuance of common stock at \$8.00 per share in connection with the May 1996 initial public offering (net of issuance costs of \$798,414 and underwriting discount of \$1,500,000)	—	—	2,500,000	2	—	—	17,699	—	—	17,701
Proceeds from exercise of options at \$0.44 per share in June 1996 ..	—	—	6,178	—	—	—	3	—	—	3
Repurchase of common stock ..	—	—	(18,325)	—	—	—	(1)	—	—	(1)
Deferred compensation	—	—	—	—	—	—	164	—	—	164
Amortization of deferred compensation	—	—	—	—	—	—	(128)	—	—	(128)
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(4,097)	(4,097)
Balance at June 30, 1996	—	—	7,035,193	7	—	—	28,725	—	(12,705)	16,027

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Issuance of common stock at \$8.00 per share in July 1996 in connection with the exercise of underwriters' over-allotment option (net of underwriting discount of \$150,000)	—	\$—	250,000	\$—	—	\$—	\$ 1,850	\$—	\$ —	\$ 1,850
Proceeds from exercise of options at \$0.44 to \$0.71 per share ...	—	—	3,387	—	—	—	1	—	—	1
Amortization of deferred compensation	—	—	—	—	—	—	41	—	—	41
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(5,578)	(5,578)
Balance at June 30, 1997	—	—	7,288,580	7	—	—	30,617	—	(18,283)	12,341
Proceeds from exercise of options at \$0.44 to \$0.71 per share ...	—	—	17,278	—	—	—	10	—	—	10
Amortization of deferred compensation	—	—	—	—	—	—	41	—	—	41
Compensation expense related to options granted for services ...	—	—	—	—	—	—	68	—	—	68
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(8,877)	(8,877)
Balance at June 30, 1998	—	—	7,305,858	7	—	—	30,736	—	(27,160)	3,583
Proceeds from exercise of options at \$0.44 to \$4.31 per share ...	—	—	181,045	—	—	—	222	—	—	222
Amortization of deferred compensation	—	—	—	—	—	—	41	—	—	41
Issuance of common stock at \$2.25-\$2.94 per share and warrants in August to September 1998 in connection with a Private Placement (net of issuance cost of \$233,584)	—	—	1,306,505	1	—	—	2,734	—	—	2,735
Issuance of common stock at \$3.81-\$4.88 per share and warrants in December 1998 in connection with a Private Placement (net of issuance cost of \$438,183)	—	—	1,367,280	2	—	—	5,195	—	—	5,197
Issuance of common stock at \$5.50-\$6.00 per share and warrants in February to April 1999 in connection with a Private Placement (net of issuance cost of \$1,033,225) ..	—	—	2,198,210	2	—	—	12,154	—	—	12,156
Net loss and comprehensive loss ..	—	—	—	—	—	—	—	—	(9,611)	(9,611)
Balance at June 30, 1999	—	—	12,358,898	12	—	—	51,082	—	(36,771)	14,323

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Class B Convertible Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Gain (Loss)</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Proceeds from exercise of options at \$0.44 to \$15.50	—	\$—	440,259	\$ 1	—	\$—	\$ 1,533	\$ —	\$ —	\$ 1,534
Proceeds from exercise of warrants at \$2.81 to \$31.95 ...	—	—	1,017,215	1	—	—	8,427	—	—	8,428
Amortization of deferred compensation	—	—	—	—	—	—	5	—	—	5
Compensation expense related to options granted for services ...	—	—	—	—	—	—	89	—	—	89
Warrants granted for patent licenses	—	—	—	—	—	—	3,182	—	—	3,182
Warrants granted for building lease	—	—	—	—	—	—	1,738	—	—	1,738
Issuance of common stock at \$16.19 to \$25.56 per share and warrants in October and November 1999 in connection with a Private Placement (net of issuance cost of \$2,804,255)	—	—	2,033,895	2	—	—	37,220	—	—	37,222
Issuance of common stock at \$26 per share in April and May 2000 in connection with a Public Offering (net of issuance cost of \$2,288,966) ...	—	—	1,150,000	1	—	—	27,610	—	—	27,611
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(15,039)	(15,039)
Net unrealized loss on available-for-sale securities	—	—	—	—	—	—	—	(80)	—	(80)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(15,119)
Balance at June 30, 2000	—	—	17,000,267	17	—	—	130,886	(80)	(51,810)	79,013

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Proceeds from exercise of options at \$0.44 to \$34.00 per share . .	—	\$—	165,700	\$—	—	\$—	\$ 869	\$ —	\$ —	\$ 869
Proceeds from exercise of warrants at \$2.18 to \$23.43 . . .	—	—	174,255	1	—	—	771	—	—	772
Compensation expense related to options granted for services . . .	—	—	—	—	—	—	336	—	—	336
Issuance of common stock at \$37.50 to \$45.06 per share in November 2000 Public Offering (net of issuance cost of \$4,622,188)	—	—	2,291,239	2	—	—	86,084	—	—	86,086
Issuance of common stock at \$47.82 per share in February 2001 pursuant to a collaboration agreement	—	—	313,636	—	—	—	15,000	—	—	15,000
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(16,014)	(16,014)
Net unrealized gain on available-for-sale securities . .	—	—	—	—	—	—	—	1,120	—	1,120
Comprehensive loss	—	—	—	—	—	—	—	—	—	(14,894)
Balance at June 30, 2001	—	—	19,945,097	20	—	—	233,946	1,040	(67,824)	167,182
Proceeds from exercise of options at \$2.13 to \$6.75 per share . . .	—	—	11,282	—	—	—	60	—	—	60
Proceeds from exercise of warrants \$7.50 per share	—	—	9,955	—	—	—	75	—	—	75
Compensation expense related to options granted for services . . .	—	—	—	—	—	—	179	—	—	179
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(11,319)	(11,319)
Net unrealized gain on available-for-sale securities . .	—	—	—	—	—	—	—	1,173	—	1,173
Comprehensive loss	—	—	—	—	—	—	—	—	—	(10,146)
Balance at December 31, 2001	—	—	19,966,334	20	—	—	234,260	2,213	(79,143)	157,350
Proceeds from exercise of options at \$1.875 to \$8.525 per share . .	—	—	34,627	—	—	—	113	—	—	113
Proceeds from exercise of warrants at \$7.50 per share . . .	—	—	99,585	—	—	—	747	—	—	747
Compensation expense related to options granted for services . . .	—	—	—	—	—	—	217	—	—	217
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(27,739)	(27,739)
Net unrealized loss on available- for-sale securities	—	—	—	—	—	—	—	(631)	—	(631)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(28,370)
Balance at December 31, 2002	—	—	20,100,546	20	—	—	235,337	1,582	(106,882)	130,057

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

Period from October 22, 1992 (inception) through December 31, 2003
(in thousands, except for share information)

	Preferred Stock		Common Stock		Class B Convertible Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Deficit Accumulated During the Development Stage	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				
Proceeds from exercise of options at \$2.12 to \$6.50 per share	—	—	63,746	—	—	—	242	—	—	242
Proceeds from exercise of warrants at \$2.47 to \$6.09 per share	—	—	112,102	—	—	—	476	—	—	476
Compensation expense related to options granted for services	—	—	—	—	—	—	65	—	—	65
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(25,774)	(25,774)
Net unrealized loss on available- for-sale securities	—	—	—	—	—	—	—	(1,180)	—	(1,180)
Comprehensive loss	—	—	—	—	—	—	—	—	—	(26,954)
Balance at December 31, 2003	—	\$—	<u>20,276,394</u>	<u>\$20</u>	—	—	<u>\$236,120</u>	<u>\$ 402</u>	<u>\$(132,656)</u>	<u>\$103,886</u>

See accompanying notes

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		Six Months Ended December 31,		Year Ended June 30,	Period from October 22, 1992 (inception) Through December 31, 2003
	2003	2002	2001	2000 (unaudited)	2001	2003
Operating activities						
Net loss	\$(25,774)	\$(27,739)	\$(11,319)	\$ (6,484)	\$ (16,014)	\$(132,656)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization	3,640	3,136	1,167	309	1,203	12,367
Amortization of deferred compensation	—	—	—	—	—	164
Non-cash rent expense for warrants issued in connection with the extension of the building lease	217	217	109	124	217	832
Amortization of deferred rent	115	294	167	—	278	854
Non-cash compensation expense for common stock, warrants, and stock options issued for services	65	217	179	209	336	1,475
Warrants issued for patent license	—	—	—	—	—	3,182
Changes in operating assets and liabilities:						
Accrued interest	219	342	1,066	(1,104)	(1,462)	(590)
Prepaid expenses and other current assets	14	(60)	178	—	(575)	(628)
Deposits and other assets	210	107	26	60	408	(26)
Accounts payable, other accrued liabilities and accrued compensation and related expenses	(160)	(724)	128	(468)	449	2,029
Deferred revenue	2,125	—	—	—	—	2,125
Net cash used in operating activities	(19,329)	(24,210)	(8,299)	(7,354)	(15,160)	(110,872)
Investing activities						
Purchases of property and equipment	(555)	(5,049)	(5,492)	(4,540)	(9,666)	(27,711)
Increase in restricted investments	(428)	(1,500)	(3,000)	(3,000)	(3,000)	(11,928)
Purchases of available-for-sale securities	(84,834)	(82,242)	(60,817)	(64,704)	(177,757)	(625,415)
Maturities of available-for-sale securities	98,933	106,809	81,592	37,051	94,825	541,253
Net cash provided by (used in) investing activities	13,116	18,018	12,283	(35,193)	(95,598)	(123,801)
Financing activities						
Proceeds from long-term obligations	—	—	3,000	1,000	1,000	10,133
Repayment of long-term obligations	—	—	—	—	—	(1,710)
Proceeds from bridge financing	—	—	—	—	—	1,937
Repayment of bridge financing	—	—	—	—	—	(2,131)
Payments on capital lease obligations	—	—	—	(193)	(237)	(2,154)
Proceeds from sale-leaseback of equipment	—	—	—	—	—	1,927
Proceeds from issuance of preferred stock, net of issuance costs	—	—	—	—	—	9,885
Proceeds from warrants and options exercised	718	860	135	859	1,640	13,551
Proceeds from issuance of common stock, net of issuance costs and repurchases	—	—	—	86,099	101,086	205,619
Net cash provided by financing activities	718	860	3,135	87,765	103,489	237,057

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS (Continued)
(in thousands)

	Year Ended December 31,		Six Months Ended December 31,		Year Ended June 30, 2001	Period from October 22, 1992 (inception) Through December 31, 2003
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2000</u>		
				(unaudited)		
Net (decrease) increase in cash and cash equivalents	\$(5,495)	\$(5,332)	\$ 7,119	\$45,218	\$(7,269)	\$2,384
Cash and cash equivalents, beginning of period	<u>7,879</u>	<u>13,211</u>	<u>6,092</u>	<u>13,361</u>	<u>13,361</u>	<u>—</u>
Cash and cash equivalents, end of period	<u>\$ 2,384</u>	<u>\$ 7,879</u>	<u>\$13,211</u>	<u>\$58,579</u>	<u>\$ 6,092</u>	<u>\$2,384</u>
Supplemental disclosure						
Issuance of preferred stock for cancellation of accounts payable, notes payable and accrued interest	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 499
Issuance of stock options for repayment of certain accrued liabilities	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 137
Issuance of warrants in connection with bridge financing	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 300
Issuance of warrants in connection with the extension of the building lease	\$ —	\$ —	\$ —	\$ —	\$ —	\$1,738
Deferred compensation related to stock option Grants	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 164
Purchase of property and equipment under capital lease financing	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 226
Cash paid for interest	\$ 250	\$ 278	\$ 204	\$ 38	\$ 180	\$1,678

See accompanying notes.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Avigen, Inc. was incorporated on October 22, 1992 in Delaware and is focused on the development of pharmaceutical products for serious and chronic hematological and neurological diseases. We have developed gene delivery technologies that are designed to generate the expression of therapeutic proteins within the body when administered to patients. We are currently enrolling subjects in a phase I clinical trial for Coagulin-B, our gene therapy product candidate for the treatment of hemophilia B, and have filed an IND application with the FDA for approval to initiate a clinical trial for AV201, our gene therapy product candidate for Parkinson's disease. Since our inception, our activities have consisted principally of acquiring product rights, raising capital, establishing facilities and performing research and development. Accordingly, we are considered to be in the development stage. We operate in a single segment.

At December 31, 2003, we had an accumulated deficit of \$132.7 million and expect to continue to incur substantial losses over the next several years while we continue in this development stage. We plan to meet our capital requirements primarily through issuances of equity securities, research and development contract revenue, collaborative agreement revenue, and in the longer term, revenue from approved product sales. We intend to seek additional funding through public or private equity or debt financing, when market conditions allow. There can be no assurance that we will be able to enter into financing arrangements on acceptable terms in the future, if at all.

In August 2001, we changed our fiscal year end from June 30 to December 31, effective December 31, 2001.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires our management to make judgments, assumptions and estimates that affect the amounts reported in the financial statements and the accompanying notes. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. These amounts are recorded at cost, which approximates fair market value.

Available-for-Sale Securities

We invest our excess cash balances in marketable securities, primarily corporate debt securities, federal agency obligations, asset-backed securities, and municipal bonds, with the primary investment objectives of preservation of principal, a high degree of liquidity, and maximum total return. In accordance with statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," we have classified our investments in marketable securities as available-for-sale. Available-for-sale securities are reported at market value and unrealized holding gains and losses, net of the related tax effect, if any, are excluded from earnings and are reported in other comprehensive income and as a separate component of stockholders' equity until realized. A decline in the market value of a security below its cost that is deemed to be other than temporary is charged to earnings, and would result in the establishment of a new cost basis for the security.

Our available-for-sale securities consist principally of obligations with a minimum short-term rating of A1/P1 and a minimum long-term rating of A- and with effective maturities of less than three years. The cost of securities sold is based on the specific identification method. Interest on securities classified as available for sale is included in interest income.

Restricted Investments

In June 2000, we initially entered into a financing arrangement to support construction related activities. Under this arrangement, we have pledged \$10.0 million of our portfolio of available-for-sale securities to secure this long-term obligation.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

In January 2002, we also entered into equipment operating leases for certain research and development equipment. Under the terms of these leases, we have pledged \$1.5 million of our portfolio of available-for-sale securities to secure these equipment operating leases.

In May 2003, we secured two letters of credit to serve as security deposits in connection with a building lease that became effective July 1, 2003. This building lease was executed in February 2000 and replaced our previous building lease and sublease on the same premises that expired June 30, 2003 under the original terms of the agreements. Under the terms of these letters of credit, we have pledged \$428,000 of our portfolio of available-for-sale securities to secure these letters of credit.

At December 31, 2003 and 2002, \$11.9 million and \$11.5 million, respectively, were classified as restricted investments in long term assets, representing the combined aggregate portion of our portfolio of available-for-sale securities that were pledged in connection with these long-term liabilities.

Concentration of Credit Risk

Cash, cash equivalents, available-for-sale securities and restricted investments consist of financial instruments that potentially subject us to concentrations of credit risk to the extent of the value of the assets recorded on the balance sheet. We believe that we have established guidelines for investment of our excess cash that maintain safety and liquidity through our policies on diversification among asset classes and issuers, as well as across investment maturities.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the respective assets, of in the case of leasehold improvements, over the lesser of the estimated useful lives or the remaining lease terms. The estimated useful lives of our property and equipment range from three to seven years. No impairments of property and equipment were required to be recognized during the years ended December 31, 2003 and 2002, the six months ended December 31, 2001, and the fiscal year ended June 30, 2001.

Expenses for repairs and maintenance are charged to operations as incurred. Upon retirement, disposition, or sale, the cost of the property and equipment disposed of and the related accumulated depreciation are deducted from the accounts, and any resulting gain or loss is credited or charged to operations.

Revenue Recognition

We record revenue associated with up-front license, technology access, and research and development funding payments under collaboration agreements for the development of our product candidates ratably over the relevant periods specified in the agreements, generally the development phase. The development phase can be defined as a specified period of time, however, in certain cases, the collaborative agreement specifies a development phase that culminates with milestone objectives but does not have a fixed date, which requires us to estimate the development period of those product candidates. The estimate of the development period may be revised as additional information is received or actual results differ from expectations. In March 2003, we received a \$2.5 million payment from Bayer Corporation under the terms of our collaboration agreement for the development of Coagulin-B, our product candidate for the treatment of hemophilia B. This amount was recorded as deferred revenue and is being recognized ratably over the estimated development period of five years for this product, or approximately \$125,000 per quarter. In 2003, we recognized \$375,000 as revenue in our statements of operations.

We record grant revenue in the period in which the revenue is earned as defined by the grant agreement. Since our inception, we have recognized approximately \$690,000 of grant revenue, which includes amounts earned pursuant to reimbursements under government grants, of which all have come from the National Institutes of Health.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

We record royalty revenue from license agreements as earned in accordance with the contract terms when third-party results can be reliably determined and collectibility is reasonably assured. We have recorded approximately \$29,000 in royalty revenue in connection with sales from a third party of products that utilize our AAV technologies over the last three years. These products are sold for research purposes only and were primarily sold within the U.S.

Non-refundable product license fees, including fees associated with research license agreements, for which we have no further performance obligations, and no continuing involvement requirements, are recognized on the earlier of when the payments are received or when collection is assured. We have recorded approximately \$155,000 in research license fees since our inception.

Comprehensive Loss

Components of other comprehensive income, including unrealized gains and losses on available-for-sale investments, were included as part of total comprehensive income. For all periods presented, we have disclosed comprehensive income in the statement of stockholders' equity.

Research and Development Expenses

Research and development costs are charged to expense in the period incurred and include related salaries and benefits, laboratory materials, clinical trial and related clinical-trial-manufacturing costs, contract and outside service fees, and facilities and overhead costs. Research and development expenses consist of costs incurred for our independent, as well as our collaborative, research and development activities.

Clinical development costs are a significant component of research and development expenses. We accrue costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with the clinical trial sites. We determine our estimates through discussion with internal clinical personnel and outside service providers as to the progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. These estimates may or may not match the actual services performed by the organizations as determined by patient enrollment levels and related activities. We monitor clinical trial activities to the extent possible; however, if we underestimated activity levels associated with various studies at a given point in time, we could record significant research and development expenses in future periods.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of existing assets and liabilities using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period of enactment. To date, we have no history of earnings. Therefore, our net deferred tax asset has been fully offset by a valuation allowance.

Basic and Diluted Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. The computation of basic net loss per share for all periods presented is derived from the information on the face of the statement of operations, and there are no reconciling items in either the numerator or denominator.

Diluted net loss per common share is computed as though all potential common shares that are dilutive were outstanding during the period using the treasury stock method, for the purposes of calculating the weighted-average number of dilutive common shares outstanding during the year. Potential dilutive common shares consist of stock options and warrants. Securities that could have potentially diluted basic earnings per common share, but were

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NOTES TO FINANCIAL STATEMENTS — (Continued)

excluded from the diluted net loss per common share computation because their inclusion would have been anti-dilutive, were as follows:

	<u>Year Ended</u> <u>December 31,</u>		<u>Six Months Ended</u> <u>December 31, 2001</u>	<u>Year Ended</u> <u>June 30, 2001</u>
	<u>2003</u>	<u>2002</u>		
Potential dilutive stock options outstanding	554,852	796,010	949,077	1,351,018
Potential dilutive warrants to purchase common stock outstanding	—	<u>242,086</u>	<u>456,599</u>	<u>772,866</u>
Potential dilutive common shares	<u>554,852</u>	<u>1,038,096</u>	<u>1,405,676</u>	<u>2,123,884</u>
Outstanding securities excluded from the potential dilutive common shares calculation (1)	4,512,838	3,477,720	3,259,131	1,449,496

- (1) For purposes of computing the potential dilutive common shares, we have excluded outstanding stock options and warrants to purchase common stock whose exercise prices exceed the average of the closing sale prices of our common stock as reported on the NASDAQ National Market for the period.

Impairment of Long-Lived Assets

We regularly evaluate our long-lived assets for indicators of possible impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. To date, we have not experienced any such losses.

Reclassifications

We have reclassified certain prior year amounts to conform to our current year's presentation of restricted investments as a long-term asset and the classification of auction-rate securities as available-for-sale securities instead of cash equivalents. These reclassifications had no impact on our results of operations.

Recently Issued Accounting Standards

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. In December 2003, the FASB issued FIN 46R, a revision to FIN 46. FIN 46R provides a broad deferral of the latest date by which all public entities must apply FIN 46 to certain variable interest entities to the first reporting period ending after March 15, 2004. We do not expect the adoption of FIN 46 to have a material impact on our financial position, cash flows or results of operations.

In May 2003, the FASB issued Statement No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." FAS 150 changes the accounting for certain financial instruments that, under previous guidance, issuers could account for as equity and requires that those instruments be classified as liabilities (or assets in certain circumstances) in statements of financial position. For public companies, FAS 150 became effective at the beginning of the first interim period beginning after June 15, 2003. The adoption of FAS 150 did not have a material impact on our financial position, cash flows, or results of operations.

Stock-Based Compensation

We have elected to continue to follow Accounting Principles Board Opinion No. 25 (or APB 25), "Accounting for Stock Issued to Employees," and related interpretations, to account for stock options granted to our employees

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NOTES TO FINANCIAL STATEMENTS — (Continued)

and directors. Under APB 25, using the prescribed intrinsic value method of accounting, no compensation expense is recognized because the exercise price of the stock options equals the market price of the underlying stock on the date of the option grant.

The information regarding net loss and loss per common share as required by FAS 123 has been determined as if we had accounted for our employee stock options under the fair value method prescribed by FAS 123. The resulting effect on net loss and loss per common share pursuant to FAS 123 is not likely to be representative of the effects on net loss and loss per common share pursuant to FAS 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

The following table illustrates the effect on our net loss and loss per common share if we had applied the fair value recognition provisions of FAS 123 to our stock-based employee compensation:

	<u>Year Ended</u> <u>December 31,</u>		<u>Six Months</u> <u>Ended</u> <u>December 31,</u>	<u>Year Ended</u> <u>June 30,</u>
	<u>2003</u>	<u>2002</u>	<u>2001</u>	<u>2001</u>
Net loss—as reported	\$(25,774)	\$(27,739)	\$(11,319)	\$(16,014)
Add: Stock-based employee compensation included in reported net loss	28	—	—	—
Less: Total stock-based employee compensation expense determined under the fair-value-based method for all awards	<u>(9,941)</u>	<u>(12,202)</u>	<u>(7,282)</u>	<u>(10,134)</u>
Net loss—pro forma	<u>\$(35,687)</u>	<u>\$(49,941)</u>	<u>\$(18,601)</u>	<u>\$(26,148)</u>
Net loss per common share basic and diluted—as reported	<u>\$ (1.28)</u>	<u>\$ (1.38)</u>	<u>\$ (0.57)</u>	<u>\$ (0.85)</u>
Net loss per common share basic and diluted—pro forma ...	<u>\$ (1.77)</u>	<u>\$ (1.99)</u>	<u>\$ (0.93)</u>	<u>\$ (1.40)</u>

During the preparation of our Notes to the Financial Statements for the year ended December 31, 2003, we determined that the calculation of total stock-based employee compensation expense determined under the fair-value-based method for the year ended December 31, 2002, the six months ended December 31, 2001 and the fiscal year ended June 30, 2001, as reported in those respective years, inadvertently included data that overstated the expected volatility used in those calculations. Accordingly, the amounts of the total stock-based employee compensation expense determined under the fair-value-based method reported under FAS 123 for the year ended December 31, 2002, the six months ended December 31, 2001 and the year ended June 30, 2001 presented in the table above, and the respective volatilities for those periods presented in the table below, have been revised, resulting in decreases in the previously reported amounts of \$2.8 million, \$1.6 million, and \$2.2 million, respectively. This revision had no effect on our previously reported results of operations or financial condition.

For purposes of disclosure pursuant to FAS 123, as amended by FAS 148, the estimated fair value of our employee stock options is amortized to expense on a straight-line basis over the vesting period of the options. We use the Black-Scholes option valuation model to estimate the fair value of our options on the date of grant. Options that were granted during the years ended December 31, 2003 and 2002, the transition period ended December 31, 2001, and the fiscal year ended June 30, 2001 were valued with the following weighted average assumptions:

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NOTES TO FINANCIAL STATEMENTS — (Continued)

	Year Ended December 31,		Six Months Ended December 31,	Year Ended June 30,
	2003	2002	2001	2001
Expected volatility	0.8343	1.0459	1.0616	1.0944
Risk free interest rate	2.97%	4.00%	4.50%	5.50%
Expected life of options in years	5	5	5	5
Expected dividend yield	—	—	—	—

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options and warrants that have no vesting restrictions and are fully transferable. In addition, option valuation models, including Black-Scholes, require the input of highly subjective assumptions, including the expected stock price volatility. Because our stock options and warrants are not traded, they have characteristics significantly different from those of traded options and warrants, and because changes in the subjective input assumptions can materially affect the fair value estimate, in our opinion, the existing option valuation models, including Black-Scholes, do not necessarily provide a reliable single measure of the fair value of our stock options and warrants.

For equity awards to non-employees, including lenders, lessors, and consultants, we also apply the Black-Scholes method to determine the fair value of such investments in accordance with FAS 123 and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring or in Conjunction with Selling, Goods, or Services." The options and warrants granted to non-employees are re-measured as they vest and the resulting value is recognized as an expense against our net loss over the period during which the services are received or the term of the related financing.

2. Available-for-Sale Securities

The following is a summary of cash, restricted investments, and available-for-sale securities as of December 31, 2003 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	\$ 2,384	\$ —	\$ —	\$ 2,384
Corporate debt securities	45,474	232	(25)	45,681
Federal agency obligations	24,813	81	(21)	24,873
Asset-backed and other securities	17,048	134	(3)	17,179
Short-term municipals	2,000	—	—	2,000
Treasury obligations	<u>6,757</u>	<u>9</u>	<u>(5)</u>	<u>6,761</u>
Total	98,476	456	(54)	98,878
Amounts reported as:				
Cash and cash equivalents	2,384	—	—	2,384
Restricted investments	<u>11,928</u>	<u>—</u>	<u>—</u>	<u>11,928</u>
Available-for-sale securities	<u>\$84,164</u>	<u>\$456</u>	<u>\$(54)</u>	<u>\$84,566</u>

The weighted average maturity of our investment portfolio at December 31, 2003 was 405 days, with \$46.3 million carrying an effective maturity of less than twelve months, and \$52.5 million carrying an effective maturity between one and three years.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

The following is a summary of cash, restricted investments, and available-for-sale securities as of December 31, 2002 (in thousands):

	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash	\$ 3,578	\$ —	\$ —	\$ 3,578
Corporate debt securities	47,780	437	(11)	48,206
Federal agency obligations	42,977	855	—	43,832
Asset-backed and other securities	23,307	301	—	23,608
Short-term municipals	—	—	—	—
Treasury obligations	—	—	—	—
Total	<u>117,642</u>	<u>1,593</u>	<u>(11)</u>	<u>119,224</u>
Amounts reported as:				
Cash and cash equivalents	7,879	—	—	7,879
Restricted investments	<u>11,500</u>	<u>—</u>	<u>—</u>	<u>11,500</u>
Available-for-sale securities	<u>\$ 98,263</u>	<u>\$ 1,593</u>	<u>\$ (11)</u>	<u>\$ 99,845</u>

The weighted average maturity of our investment portfolio at December 31, 2002 was 421 days, with \$56.3 million carrying an effective maturity of less than twelve months, and \$62.9 million carrying an effective maturity between one and three years.

Net realized gains were approximately \$444,000 and \$822,000 for the years ended December 31, 2003 and 2002, respectively, and \$650,000 for the six-month transition period ended December 31, 2001. Net realized gains were not material for the year ended June 30, 2001.

3. Property and Equipment

Property and equipment consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Leasehold improvements	\$ 18,429	\$ 18,450
Laboratory equipment	6,789	6,406
Office furniture and equipment	<u>2,140</u>	<u>2,011</u>
	27,358	26,867
Less accumulated depreciation and amortization	<u>(11,717)</u>	<u>(8,141)</u>
Property and equipment, net	<u>\$ 15,641</u>	<u>\$ 18,726</u>

Total depreciation and amortization expense for the years ended December 31, 2003 and 2002, the six-month transition period ended December 31, 2001, and the year ended June 30, 2001, was \$3.6 million, \$3.1 million, \$1.2 million, and \$1.2 million, respectively.

4. Deferred Revenue

In March 2003, we received a \$2.5 million payment from Bayer Corporation under the terms of our collaboration agreement for the development of Coagulin-B, our product candidate for the treatment of hemophilia B. This amount was recorded as deferred revenue and is being recognized as revenue in our statements of operations ratably over the estimated development period for this product, which was determined to be five years, or approximately \$125,000 per quarter.

5. Loan Payable

In June 2000, we entered into a financing arrangement for construction related activities. Under this arrangement, we had the right to borrow up to \$10.0 million through June 1, 2003. This revolving line of credit

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NOTES TO FINANCIAL STATEMENTS — (Continued)

was amended in June 2002 to extend the expiration date to June 1, 2005, thereby deferring the timetable to repay the principal borrowed for two additional years. Amounts borrowed under this arrangement bear interest at the London Inter-Bank Offered Rate plus 1.5% on the date of each drawdown and this interest rate is subsequently reset every three months. The weighted average interest rate for all outstanding drawdowns on this long-term obligation was 2.75% at December 31, 2003 and 3.11% at December 31, 2002. We have pledged a portion of our portfolio of available-for-sale securities equal to the amount of outstanding borrowings to secure this long-term obligation, and have identified these pledged assets as restricted investments on our balance sheets. As of both December 31, 2003 and 2002, we had borrowed \$8 million from the line of credit. Payments of interest only are due monthly through June 1, 2005, at which time a balloon payment of outstanding principal is due. In November 2000, we reserved \$2 million in borrowing capacity from the line of credit to secure a letter of credit. The letter of credit was established pursuant to the terms required under a ten-year property lease entered into in November 2000, and was issued in favor of the property owner. As a result of the cash borrowings and the establishment of the letter of credit, we did not have any remaining borrowing capacity under the line of credit at December 31, 2003.

6. Stockholders' Equity

Common Stock

In August and September 1998, we issued an aggregate of 1,306,505 shares of our common stock at \$2.25 to \$2.94 per share to selected institutional investors. The offering was completed through a private placement. As part of the transaction, we issued warrants to purchase 261,301 shares of our common stock with an exercise price of \$2.18 to \$3.67 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$2,969,000, net proceeds from this transaction approximated \$2,735,000.

In December 1998, we issued 1,367,280 shares of our common stock at \$3.81 to \$4.88 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 273,456 shares of our common stock with an exercise price ranging from \$4.76 to \$6.09 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$5,635,000, net proceeds from this transaction approximated \$5,197,000.

In February and April 1999, we issued an aggregate of 2,198,210 shares of our common stock at \$5.50 to \$6.00 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 439,642 shares of our common stock with an exercise price of \$6.87 to \$7.50 per share. The exercise price was 125% of the fair market value per share of the underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$13,189,000, net proceeds from this transaction approximated \$12,156,000.

In October and November 1999, we issued an aggregate of 2,033,895 shares of our common stock at \$16.19 to \$25.56 per share to selected institutional investors. The offering was completed through a private placement. As part of this transaction, we issued warrants to purchase 406,779 shares of our common stock with an exercise price of \$20.25 to \$31.95 per share. The exercise price was 125% of the fair market value per share of our underlying stock on the corresponding closing day and the warrants carry a five-year term. After deducting commissions and fees from the gross proceeds of \$40,028,000, net proceeds from this transaction approximated \$37,222,000.

In March 2000, we issued a warrant to purchase 40,000 shares of our common stock as partial consideration for the extension of our building lease. The fair value of this warrant at the date of issuance was approximately \$1,738,000. This fair value is being amortized over the life of the lease extension. This warrant was issued with an exercise price equal to the fair market value per share of our underlying stock at the time of issuance, \$56.00, and carries a five-year term.

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Also, in March 2000, we issued a warrant to purchase 50,000 shares of our common stock as partial consideration for the acquisition of certain patent licenses used in our research and development activities. The fair value of this warrant was approximately \$3,182,000 and was fully expensed in the year ended June 30, 2000. This warrant was issued with an exercise price equal to the fair market value per share of our underlying stock at the time of issuance, \$82.00, and carries a five-year term.

In April and May 2000, we issued an aggregate of 1,150,000 shares of our common stock at \$26.00 per share through a public offering. After deducting commissions and fees from the gross proceeds of \$29,900,000, net proceeds from this transaction totaled \$27,611,000.

In November 2000, we issued an aggregate of 2,291,239 shares of our common stock between \$37.50 and \$45.06 per share through a public offering. After deducting combined commissions and fees from the gross proceeds of \$90,706,000, net proceeds from this transaction totaled \$86,086,000.

In February 2001, we issued 313,636 shares of common stock at \$47.82 per share to Bayer AG, in connection with a collaboration agreement entered into with Bayer Corporation dated November 17, 2000. Net proceeds from this transaction totaled \$15,000,000.

At December 31, 2003, we had outstanding warrants to purchase shares of common stock as follows:

<u>Number Of Shares</u>	<u>Exercise Price</u>	<u>Issue Date</u>	<u>Expiration Date</u>
13,324	\$ 5.36	1995	2005
4,514	\$ 7.09	1995	2005
483,794	\$ 6.05 – \$ 7.50	1999	2004
244,932	\$17.81 – \$20.63	1999	2004
157,540	\$23.43 – \$27.96	1999	2004
18,561	\$28.12 – \$31.95	1999	2004
40,000	\$56.00	2000	2005
<u>50,000</u>	\$82.00	2000	2005
<u>1,012,665</u>	\$ 5.36 – \$82.00		2004 – 2005

Shares Reserved for Future Issuance

We have reserved shares of our common stock for future issuance as follows:

	<u>December 31, 2003</u>
Stock options outstanding	4,362,442
Stock options available for grant	4,289,623
Warrants to purchase common stock	1,012,665
Shares available for Employee Stock Purchase Plan	<u>360,000</u>
	<u>10,024,730</u>

7. Stock Options and Stock Purchase Plan

Employee Stock Option Plans

Under the 1993 Stock Option Plan (the "1993 Plan"), prior to March 1996, incentive and nonqualified stock options could be granted to our key employees, directors and consultants to purchase up to 1,500,000 shares of common stock. Under the 1993 Plan, options could be granted at a price per share not less than the fair market value at the date of grant. In March 1996, the Board determined to grant no further options under the 1993 Plan

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and adopted the 1996 Equity Incentive Plan. At December 31, 2003, there were options to purchase approximately 36,000 shares outstanding under the 1993 Plan, with no further shares available for grant.

The 1996 Equity Incentive Plan ("1996 Plan") provides for grants of incentive and nonqualified stock options, restricted stock purchase awards, stock bonuses and stock appreciation rights to our employees, directors and consultants. The Plan originally authorized the grant of options to purchase up to 600,000 shares of common stock. As a result of a series of amendments which were approved by stockholders, prior to December 31, 2003, there were 3,500,000 shares authorized for grant under the 1996 Plan. Under the 1996 Plan, incentive stock options may be granted at a price per share not less than the fair market value at the date of grant, and nonqualified stock options may be granted at a price per share not less than 85% of the fair market value at the date of grant. Options granted generally have a maximum term of 10 years from the grant date and become exercisable over four years. At December 31, 2003, there were options to purchase approximately 1,491,000 shares outstanding under the 1996 Plan and approximately 1,331,000 shares available for grant.

In June 2000, the Board of Directors adopted the 2000 Equity Incentive Plan ("2000 Plan") which provides for grants of nonqualified stock options, restricted stock purchase awards, and stock bonuses to our employees, directors and consultants to purchase up to 5,000,000 shares of common stock; provided, however, that generally only up to 40% of the shares subject to grants under the 2000 Plan may be made to our directors and officers. Under the 2000 Plan, options may be granted at a price per share not less than 85% of the fair market value at the date of grant. Options granted generally have a maximum term of 10 years from the grant date and become exercisable over four years. At December 31, 2003, there were options to purchase approximately 2,093,000 shares outstanding under the 2000 Plan and approximately 2,906,000 shares available for grant.

Employee Stock Purchase Plan

In September 1997, we adopted the 1997 Employee Stock Purchase Plan ("Purchase Plan"). A total of 360,000 shares of our common stock have been reserved for issuance under the Purchase Plan. As of December 31, 2003, there have been no employee contributions to the Purchase Plan.

Non-employee Stock Options

In July 1995, we granted the Chairman of our Board of Directors an option to purchase 515,248 shares of our common stock at \$0.49 per share, exercisable for 10 years from the date of grant. At December 31, 2003, the option was fully vested; however, no part of this option had been exercised. Such grant was made outside of any of our stock option plans.

The 1996 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") provides for automatic grants of options to purchase shares of our common stock to our non-employee directors. The Plan originally authorized the grant of options to purchase up to 200,000 shares of common stock. The Directors' Plan was later amended and approved by stockholders to increase the number of shares available for grant to 300,000 at December 31, 2003. As of December 31, 2003, nonqualified options to purchase approximately 247,000 shares of common stock between \$2.00 and \$40.75 per share, exercisable for 10 years from the date of grant, have been granted under the Directors' Plan, of which options to purchase 227,000 shares remained outstanding. At December 31, 2003, there were approximately 53,000 shares available for grant under the Directors' Plan.

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NOTES TO FINANCIAL STATEMENTS — (Continued)

The following table summarizes option activity with regard to all stock options:

	<u>Outstanding Options</u>	
	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price per Share</u>
Outstanding at July 1, 2000	2,355,313	\$15.05
Granted	1,774,076	20.27
Canceled	(58,130)	23.54
Exercised	<u>(165,700)</u>	5.25
Outstanding at June 30, 2001	3,905,559	17.71
Granted	175,950	12.00
Canceled	(60,410)	16.71
Exercised	<u>(11,282)</u>	5.32
Outstanding at December 31, 2001	4,009,817	17.51
Granted	946,300	8.33
Canceled	(777,002)	24.01
Exercised	<u>(34,627)</u>	3.28
Outstanding at December 31, 2002	4,144,488	14.31
Granted	685,800	3.73
Canceled	(404,100)	16.21
Exercised	<u>(63,746)</u>	3.81
Outstanding at December 31, 2003	<u>4,362,442</u>	12.62

The following table summarizes information with regard to total stock options outstanding under all stock option plans at December 31, 2003:

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number of Shares</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted-Average Exercise Price</u>	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>
\$ 0.44 – \$.49	525,406	1.56	\$ 0.49	525,406	\$ 0.49
0.71 – 3.53	736,115	8.21	3.35	200,250	2.87
3.63 – 6.30	581,966	6.47	5.40	394,341	5.32
6.31 – 8.53	550,931	8.23	8.15	228,853	7.93
8.62 – 13.02	188,840	7.93	10.24	99,478	10.41
13.65 – 14.63	844,937	7.20	14.60	541,820	14.60
14.95 – 19.31	99,731	6.74	17.67	77,002	17.60
21.47 – 28.00	92,500	6.47	25.61	80,250	25.53
29.00 – 29.00	219,766	6.38	29.00	188,513	29.00
31.00 – 38.19	466,250	6.45	37.43	398,434	37.39
38.88 – 56.00	<u>56,000</u>	6.47	44.33	<u>53,343</u>	44.29
	<u>4,362,442</u>	6.60	\$12.62	<u>2,787,690</u>	\$14.28

The numbers of options exercisable at December 31, 2002, December 31, 2001, and June 30, 2001 were 2,192,689, 1,569,789, and 1,217,656, respectively, with a weighted average exercise price of \$13.33, \$12.13, and \$9.25, respectively.

In February 2003, in connection with the resignation of two executives, we modified the vesting and expiration terms, but did not extend the maximum contractual term, of certain stock options. These modifications resulted in the recognition of \$28,000 in non-cash compensation expense during 2003.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

8. Employee Profit Sharing/401(k) Plan

In January 1996, we adopted a Tax Deferred Savings Plan under Section 401(k) of the Internal Revenue Code (the "Plan") for all full-time employees. Under the Plan, our eligible employees can contribute amounts to the Plan via payroll withholding, subject to certain limitations. Our matching contributions to the Plan are discretionary and can only be made in cash. Effective July 1, 2001, we began matching 25% of an employee's contributions up to \$2,500 per Plan year. These matching contributions vest ratably over a five-year period based on the employee's initial hire date. Our matching contributions for all employees for the years ended December 31, 2003 and 2002 and the six-month transition period ended December 31, 2001 were approximately \$112,000, \$134,000, and \$65,000, respectively.

9. Collaboration Agreement

In November 2000, we entered into a collaboration agreement with Bayer Corporation (Bayer). Under the terms of the agreement, Bayer, in collaboration with us, will conduct Phase II/III clinical trials for our product, Coagulin-B, and receive exclusive worldwide marketing and distribution rights to the product. We will file and bear the cost of regulatory approvals and will be the holder of regulatory licenses worldwide. We will manufacture the product and will receive a share of the gross revenues from future Coagulin-B sales, as well as a royalty on net sales of the product for our intellectual property. Bayer will also make milestone payments, pay for third-party costs of the clinical trials, and reimburse us costs of manufacturing AAV vector used in the clinical trials.

In connection with this collaboration agreement, in February 2001, we issued to Bayer AG, an affiliate of Bayer, 313,636 shares of common stock at \$47.82 per share, resulting in proceeds of \$15 million.

In March 2003, under the terms of the collaboration agreement, we received a \$2.5 million payment from Bayer in connection with the ongoing development of Coagulin-B, which is discussed further in Note 1.

10. Commitments

We lease our laboratory, manufacturing, and office facilities and certain equipment under multiple non-cancelable operating lease agreements, which expire at various times through November 2010. Under our two facilities operating leases, we have pledged \$2.4 million of our available-for-sale securities to secure letters of credit that serve as deposits that are required under the terms of the leases. Under multiple equipment operating leases, we have pledged \$1.5 million of our available-for-sale securities as collateral for the leases. These amounts are included in restricted investments on the balance sheet at December 31, 2003 and December 31, 2002. We have the option to purchase the equipment under these operating leases at the greater of their fair value at the end of the lease or 20% of the original cost.

Future minimum lease payments under non-cancelable operating leases are as follows (in thousands):

	<u>Operating Lease</u>
Year ending December 31:	
2004.....	\$ 2,503
2005.....	2,586
2006.....	2,654
2007.....	2,544
2008.....	2,007
Thereafter	2,751
Total non-cancelable lease payments.....	<u>\$15,045</u>

Rent expense for the years ended December 31, 2003 and 2002, the six-month period ended December 31, 2001, and the fiscal year ended June 30, 2001 was \$2,441,000, \$2,309,000, \$1,147,000, and \$1,923,000, respectively.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

We also enter into commitments to fund collaborative research and clinical work performed by third parties. While these contracts are cancelable, we expect the research studies and clinical work to be completed as defined in the terms of the agreements, and all amounts paid when due. At December 31, 2003 the estimated costs related to these commitments totaled \$1,089,000, all of which is expected to be paid within the next twelve to twenty-four months.

11. Income Taxes

Significant components of our deferred tax assets are as follows (in thousands):

	December 31, 2003	December 31, 2002
Net operating loss carryforward	\$ 44,000	\$ 36,700
Research and development credit carryforwards	6,900	5,300
Capitalized research and development	6,300	5,200
Capitalized patents	1,000	1,300
Other	1,400	600
Gross deferred tax assets	59,600	49,100
Unrealized gain on investment	(100)	(600)
Valuation allowance	(59,500)	(48,500)
Net deferred tax assets	\$ —	\$ —

Deferred income taxes reflect the net tax effects of temporary differences between the carrying value of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Due to our history of losses, a valuation allowance has been provided against the full amount of deferred tax assets due to the uncertainty of realizing any benefits from these assets. The valuation allowance increased by \$11,000,000, \$12,200,000, \$4,620,000, and \$8,860,000 for the years ended December 31, 2003 and 2002, the six-month transition period ended December 31, 2001, and the fiscal year ended June 30, 2001, respectively.

Deferred tax assets related to carryforwards at December 31, 2003 include approximately \$1,340,000 associated with stock option activity for which any subsequently recognized benefits will be credited directly to stockholder's equity.

At December 31, 2003, we had net operating loss carryforwards for federal and state income tax purposes of approximately \$126,000,000 and \$18,600,000, respectively, which expire in 2005 through 2023. At December 31, 2003, we had research and development credit carryforwards for federal and state income tax purposes of approximately \$4,700,000 and \$2,200,000, respectively, which expire in 2009 through 2023.

Because of the "change in ownership" provisions of the Internal Revenue Code of 1986, utilization of our tax net operating loss carryforwards and tax credit carryforwards may be subject to an annual limitation in future periods. As a result of the annual limitation, a portion of these carryforwards may expire before ultimately becoming available to reduce future income tax liabilities.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

12. Condensed Quarterly Financial Information (Unaudited)

	<u>Year ended December 31, 2003</u>			
<u>(amounts in thousands except per share data)</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Total revenue	\$ 30	\$ 128	\$ 140	\$ 165
Net loss	(5,977)	(6,058)	(6,909)	(6,830)
Net loss per share, basic and diluted	(0.30)	(0.30)	(0.34)	(0.34)
	<u>Year ended December 31, 2002</u>			
<u>(amounts in thousands except per share data)</u>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
Total revenue	\$ —	\$ 16	\$ 13	\$ 28
Net loss.....	(6,947)	(7,164)	(7,110)	(6,518)
Net loss per share, basic and diluted.....	(0.35)	(0.36)	(0.35)	(0.32)

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of disclosure controls and procedures. Our management, with the participation of our chief executive officer and chief financial officer, has evaluated our disclosure controls and procedures (as defined in Securities Exchange Act Rules 13a-15(e) and 15d-15(e)) as of December 31, 2003 and concluded that they were effective to provide a reasonable assurance that the information required to be disclosed by us in this Annual Report on Form 10-K was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and Form 10-K.

Changes in internal controls. There were no changes in our internal controls over financial reporting during the quarter and year ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART III

Item 10. *Directors and Executive Officers of the Registrant*

The information required by this Item with respect to Executive Officers may be found under the caption, "Executive Officers of the Registrant" at the end of Part I of this Annual Report on Form 10-K. The information required by this Item with respect to Directors, including information with respect to audit committee financial experts, is incorporated herein by reference from the information under the caption, "Proposal 1—Election of Directors" appearing in the definitive Proxy Statement to be delivered to Avigen's stockholders in connection with the solicitation of proxies for Avigen's 2004 Annual Meeting of Stockholders to be held on May 26, 2004 (the "Proxy Statement").

Section 16(a) Beneficial Ownership Reporting Compliance

The information required by this Item with respect to compliance with Section 16(a) of the Exchange Act is incorporated herein by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

Code of Business Conduct and Ethics

The information required by this Item with respect to our code of ethics is incorporated herein by reference from the section captioned "Proposal 1—Election of Directors—Code of Business Conduct and Ethics" contained in the Proxy Statement.

Item 11. *Executive Compensation*

The information required by this Item is set forth in the Proxy Statement under the captions, "Executive Compensation" and "Compensation Committee Interlocks and Insider Participation." Such information is incorporated herein by reference.

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

The information required by this Item with respect to security ownership of certain beneficial owners and management is set forth in the Proxy Statement under the caption, "Security Ownership of Certain Beneficial Owners and Management." Such information is incorporated herein by reference.

The information required by this Item with respect to securities authorized for issuance under our equity compensation plans is set forth in the Proxy Statement under the caption "Proposal 2 — Approval of Avigen's 1996 Non-Employee Directors' Stock Option Plan, as amended—Equity Compensation Plan Information." Such information is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions*

The information required by this Item is set forth in the Proxy Statement under the heading "Executive Compensation—Certain Relationships and Related Transactions." Such information is incorporated herein by reference.

Item 14. *Principal Accountant Fees and Services*

The information required by this Item is set forth in the Proxy Statement under the heading "Proposal 3—Ratification of Selection of Independent Auditors." Such information is incorporated herein by reference.

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for listing the non-audit services approved by our Audit Committee to be performed by Ernst & Young LLP, our external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. The Audit Committee has approved our recurring engagements of Ernst & Young LLP for the following non-audit services: (1) preparation of tax returns, and tax advice in preparing for and in connection with such filings; (2) tax advice in preparing for and in connection with the filing of sales and use tax returns; (3) all work required to be performed by Ernst &

Young LLP in connection with preparing and giving consents required to be given in connection with our filings with the Securities and Exchange Commission; and (4) advice in preparing for the internal control documentation requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

PART IV

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

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) *Financial Statements:*

Report of Ernst & Young LLP, Independent Auditors
Balance Sheets
Statements of Operations
Statements of Stockholders' Equity
Statements of Cash Flows
Notes to Financial Statements

(2) *Financial Statement Schedules*

Financial statement schedules have been omitted from this Annual Report on Form 10-K because they are either not applicable or the required information is provided in the financial statements or the notes thereto.

(3) *Exhibits*

<u>Exhibit Number</u>	<u>Exhibits</u>
3.1(1)	Amended and Restated Certificate of Incorporation
3.1.1(13)	Certificate of Amendment to Certificate of Incorporation
3.2 (1)	Restated Bylaws of the Registrant
4.1(1)	Specimen Common Stock Certificate
10.1(2, 7)	Nonstatutory Stock Option Outside of Plans to Philip J. Whitcome.
10.2(1, 2)	1993 Stock Option Plan
10.3 (2, 17)	1996 Equity Incentive Plan, as amended
10.4(1, 2)	Form of Incentive Stock Option Grant for 1996 Equity Incentive Plan
10.5(1, 2)	Form of Nonstatutory Stock Option Grant for 1996 Equity Incentive Plan
10.6(2, 14)	1996 Non-Employee Directors' Stock Option Plan, as amended
10.7(2, 4)	1997 Employee Stock Purchase Plan
10.8(1, 2)	Form of Indemnification Agreement between Avigen and its directors and executive officers.
10.9(1)	Form of Common Stock Warrant
10.10(2, 5)	2000 Equity Incentive Plan
10.11(2, 12)	Form of Nonstatutory Stock Option Grant for 2000 Equity Incentive Plan
10.12(1)	Form of Series C Preferred Stock Warrant
10.13(3)	Form of Common Stock and Warrant Purchase Agreement, dated October 29, 1999
10.14(2, 15)	Form of Incentive Stock Option Grant for 1993 Stock Option Plan
10.15(2, 15)	Form of Nonstatutory Stock Option Grant for 1993 Stock Option Plan
10.27(1, 2)	Employment Agreement dated August 10, 1992, between Avigen and John Monahan.
10.29(2, 6)	Employment Agreement dated August 14, 1996, between Avigen and Thomas J. Paulson.
10.32(15)	Revolving line of credit note signed November 2, 2000 with Wells Fargo Bank.
10.33(15)	Letter Agreement to the revolving line of credit note signed November 2, 2000 with Wells Fargo Bank.
10.36(2, 8)	Management Transition Plan
10.37(15)	Form of Common Stock Warrant Issued in February 1999 Private Placement.
10.38(4, 11)	Factor IX patent and know-how exclusive license agreement between The Children's Hospital of Philadelphia and Avigen, dated May 20, 1999.
10.39(9, 11)	License Agreement between Avigen and the University of Florida Research Foundation, Inc., dated November 13, 1992, and its First Amendment, dated March 25, 1996.
10.40(10, 11)	License Agreement, dated March 3, 2000, by and between BTG International Ltd., a British corporation and Avigen
10.41(10)	Property Lease Agreement between ARE-1201 Harbor Bay, LLC and Avigen, dated February 29, 2000
10.43(11, 13)	Agreement between Bayer Corporation and Avigen, dated November 17, 2000

<u>Exhibit Number</u>	<u>Exhibits</u>
10.44(13)	Subscription and Registration Rights Agreement by and between Bayer AG and Avigen, Inc., dated November 17, 2000.
10.45(13)	Office Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated November 2, 2000.
10.46(13)	First Amendment to Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated December 1, 2000.
10.47(13)	Second Amendment to Lease Agreement between Lincoln-RECP Empire OPCO, LLC and Avigen, Inc., dated February 12, 2001.
10.48(15)	Amendment to Agreement between Bayer Corporation and Avigen, dated June 30, 2001.
10.49(16)	Revolving line of credit note with Wells Fargo Bank, dated June 1, 2002.
10.50(16)	Letter of Agreement to the revolving line of credit note signed June 1, 2002 with Wells Fargo Bank.
10.51(18)	License Agreement, dated November 21, 2003, by and between University of Colorado and Avigen
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney (included on the signature pages hereto)
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
31.2	Certification required by Rule 13a-14(a) or Rule 15d-14(a)
32.1(19)	Certification required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350)

Keys to Exhibits:

- (1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 (No. 333-03220) and incorporated herein by reference.
- (2) Management Contract or Compensation Plan.
- (3) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended December 31, 1999, as filed with the SEC.
- (4) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 1999, as filed with the SEC.
- (5) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-42210) filed with the SEC on July 25, 2000.
- (6) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 1997, as filed with the SEC.
- (7) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-12087) filed with the SEC on September 16, 1996.
- (8) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998, as filed with the SEC.
- (9) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K/A for the year ended June 30, 1999, as filed with the SEC.
- (10) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000, as filed with the SEC.
- (11) Portions of this exhibit have been omitted pursuant to a grant of confidential treatment.

- (12) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 2000, as filed with the SEC on September 27, 2000.
- (13) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended December 31, 2000, as filed with the SEC.
- (14) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-56274) filed with the SEC on February 27, 2001.
- (15) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Annual Report on Form 10-K for the year ended June 30, 2001, as filed with the SEC on September 27, 2001.
- (16) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Quarterly Report on Form 10-Q for the quarter ended June 30, 2002, as filed with the SEC.
- (17) Incorporated by reference from such document filed with the SEC as an exhibit to Avigen's Registration Statement on Form S-8 (Registration No. 333-90504) filed with the SEC on June 14, 2002.
- (18) Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
- (19) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Avigen under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

(b) ***Reports on Form 8-K***

On October 29, 2003, we filed a current report on Form 8-K to furnish under Item 12 the announcement of our financial results for the third quarter of fiscal year 2003, which announcement included our consolidated statements of operations and consolidated balance sheets for the period.

(c) ***Exhibits***

See Item 15(a)(3) above.

(d) ***Financial Statement Schedules***

See Item 15(a)(1) above.

SIGNATURES

Pursuant to the requirements of Section 13 of 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.

AVIGEN, INC.

By: /s/ KENNETH G. CHAHINE

Kenneth G. Chahine, Ph.D.

President and Chief Executive Officer

Dated: March 9, 2003

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kenneth G. Chahine and Philip J. Whitcome, and each or any one of them, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Kenneth G. Chahine</u> Kenneth G. Chahine, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 9, 2004
<u>/s/ Thomas J. Paulson</u> Thomas J. Paulson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 9, 2004
<u>/s/ Philip J. Whitcome</u> Philip J. Whitcome, Ph.D.	Chairman of the Board	March 9, 2004
<u>/s/ Zola Horovitz</u> Zola Horovitz, Ph.D.	Director	March 9, 2004
<u>/s/ Yuichi Iwaki</u> Yuichi Iwaki, M.D., Ph.D.	Director	March 9, 2004
<u>/s/ John K.A. Prendergast</u> John K.A. Prendergast, Ph.D.	Director	March 9, 2004
<u>/s/ Daniel Vapnek</u> Daniel Vapnek, Ph.D.	Director	March 9, 2004

EXHIBIT INDEX

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- (19) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Avigen under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

CONSENT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

We consent to the incorporation by reference in the Registration Statements on Form S-8 (Reg. Nos. 333-12087, 333-68637, 333-94111, 333-42210, 333,56274, and 333-90504) pertaining to the 1993 Stock Option Plan, the Non-Statutory Stock Option, the 1996 Equity Incentive Plan, the 1996 Non-Employee Directors' Stock Option Plan, the 1997 Employee Stock Purchase Plan, and the 2000 Equity Incentive Plan, and Registration Statements on Form S-3 (Reg. Nos. 333-68117, 333-72225, 333-79925, 333-92355, and 333-47680) and in the related Prospectuses of Avigen, Inc. of our report dated January 30, 2004, with respect to the financial statements of Avigen, Inc. included in its Annual Report on Form 10-K for the year ended December 31, 2003.

/s/ ERNST & YOUNG LLP

Palo Alto, California
March 11, 2004

CERTIFICATION

I, Kenneth G. Chahine, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avigen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2003

/s/ KENNETH G. CHAHINE

Kenneth G. Chahine
Chief Executive Officer and President
(Principal Executive Officer)

CERTIFICATION

I, Thomas J. Paulson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avigen, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2003

/s/ THOMAS J. PAULSON

Thomas J. Paulson
*Vice President, Finance,
Chief Financial and Accounting Officer, and
Secretary*
(Principal Financial Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Kenneth G. Chahine, Chief Executive Officer of Avigen, Inc. (the "Company"), and Thomas J. Paulson, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2003, and to which this Certification is attached as Exhibit 32.1 (the "Periodic Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 8th day of March, 2004.

/s/ KENNETH G. CHAHINE

Kenneth G. Chahine
Chief Executive Officer

/s/ THOMAS J. PAULSON

Thomas J. Paulson
Chief Financial Officer

BOARD OF DIRECTORS

Philip J. Whitcome, Ph.D.
Chairman of the Board

Kenneth G. Chahine, Ph.D., J.D.
President, Chief Executive Officer

Zola Horovitz, Ph.D.
Pharmaceutical Consultant,
Former Vice President,
Business Development & Planning,
Bristol-Myers Squibb Co.

Yuichi Iwaki, M.D., Ph.D.
Professor of Urology,
Pathology and Surgery,
Director of Transplantation
Immunology,
University of Southern California
School of Medicine

John K. A. Prendergast, Ph.D.
President, SummerCloud Bay, Inc.

Daniel Vapnek, Ph.D.
Adjunct Professor,
University of California,
Santa Barbara
Former Senior Vice President of
Research, Amgen, Inc.

OFFICERS

Philip J. Whitcome, Ph.D.
Chairman of the Board

Kenneth G. Chahine, Ph.D., J.D.
President, Chief Executive Officer

Thomas J. Paulson
Chief Financial Officer & Secretary

Glenn Pierce, M.D., Ph.D.
Vice President, Research and
Clinical Development

Dawn McGuire, M.D.
Chief Medical Officer

Kirk Johnson, Ph.D.
Associate Vice President,
Preclinical Development

CORPORATE HEADQUARTERS

1301 Harbor Bay Parkway
Alameda, California 94502
510-748-7150 Telephone
510-748-7155 Facsimile
www.avigen.com

LEGAL COUNSEL

Cooley Godward LLP
Palo Alto, California

INDEPENDENT AUDITORS

Ernst & Young LLP
Palo Alto, California

TRANSFER AGENT & REGISTRAR

Stockholders with questions
regarding stock transfer
requirements, lost certificates,
and changes of address should
contact our Transfer Agent:

American Stock
Transfer & Trust Co.
59 Maiden Lane
New York, New York 10038
1-800-937-5449

COMMON STOCK INFORMATION

Avigen's common stock is traded
on the Nasdaq National Market
under the symbol AVGN. As of
March 1, 2004 there were
approximately 155 stockholders of
record of Avigen's common stock
and 20,353,387 shares of common
stock outstanding.

Avigen has not paid dividends on
its common stock since its inception,
and does not anticipate paying any
dividends in the foreseeable future.

INVESTOR RELATIONS

For additional information about
Avigen, please see our web page at
www.avigen.com. Investor inquiries
and requests for additional copies of
this report, free of charge, should be
directed to Investor Relations at
510-748-7150 or via e-mail at
ir@avigen.com.

ANNUAL MEETING

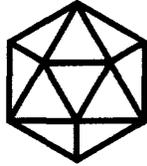
The annual meeting of
stockholders will be held on
Wednesday, May 26, 2004,
at 10:00 a.m. PDT, at Avigen's
corporate headquarters,
1301 Harbor Bay Parkway
Alameda, California 94502.

TRADEMARKS

Coagulin-B is a registered
trademark of Avigen, Inc.



Left to right:
Dawn McGuire, M.D.
Kirk Johnson, Ph.D.
Kenneth G. Chahine, Ph.D., J.D.
Thomas J. Paulson
Glenn Pierce, M.D., Ph.D.



AVIGEN

1301 Harbor Bay Parkway
Alameda, CA 94502
510-748-7150 phone
510-748-7155 fax
www.avigen.com