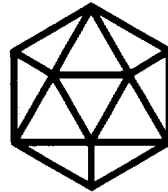


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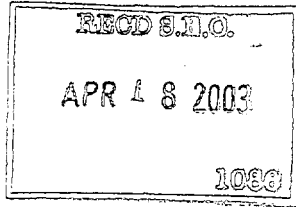


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*John Monahan, Ph.D.
President & Chief Executive Officer*

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

the leader in AAV gene therapy

Gene therapy holds the promise of transforming medicine by introducing genes into a patient's cells that enable the patient's own body to produce the therapeutic protein necessary to treat their condition. This revolutionary approach has the potential to greatly improve the lives of many people suffering from serious diseases. Avigen was founded ten years ago to realize this promise, to build a commercial enterprise based on the many benefits we see in using the adeno-associated virus (AAV) vector as a vehicle for gene delivery.

Today, Avigen is the leader in developing AAV gene therapy for the treatment of serious, chronic diseases. Our initial product candidate, Coagulin-B® for the treatment of hemophilia B, is in a phase I clinical trial at Children's Hospital of Philadelphia and Stanford University Medical Center. We are partnered with Bayer Corporation, a world leader in hemophilia treatment, to support the phase II and III clinical trials of Coagulin-B and to provide sales and distribution upon commercialization. We expect our

second product candidate, for Parkinson's disease, to enter the clinic in the second half of 2003.

Based on many years of ground breaking research, we have built an expansive intellectual property portfolio with 31 issued U.S. patents and 38 pending patent applications. Our patents cover multiple vector formulations, routes of administration and target indications, and scalable, high-yield AAV manufacturing processes, establishing multiple intellectual property barriers to competition.

We have built a state-of-the-art manufacturing facility to stringent Good Manufacturing Practice (GMP) specifications to support our planned clinical trials and the commercial launch of our lead product. At December 31, 2002, Avigen had \$120 million in the bank which we believe is sufficient to support all of our ongoing research and product development activities for the next four to five years.

TO OUR STOCKHOLDERS

Avigen continued to make progress in its clinical trials and preclinical research programs in 2002. We entered 2003 well positioned to advance our clinical trial in hemophilia B and bring our Parkinson's program into the clinic by the second half of the year. Our product development programs are supported by the largest and broadest AAV patent portfolio, industry-leading AAV vector manufacturing capabilities, proprietary gene delivery technology, and top quality teams of Avigen employees.

We met unexpected challenges in 2002 and took strategic steps to resolve them and move forward with renewed focus. We implemented a more clinically oriented strategic plan to take our lead product candidates forward while also reducing expenses so that our financial resources should be sufficient to support our objectives for the next four to five years.

2002 HIGHLIGHTS

Encouraging Clinical Progress: In December, we presented early data from our ongoing Phase I clinical trial of Coagulin-B®, our product for the treatment of hemophilia B, at the American Society of Hematology Annual Meeting. At that time, we had treated six subjects at three increasing dose levels. The first subject treated at the highest dose level achieved circulating levels of Factor IX (FIX) in excess of 10% of normal for approximately four weeks. We believe that levels of 3% to 5% of normal are therapeutic. Beginning in the fifth week, the FIX levels began to decline and the subject experienced a temporary increase in liver enzymes. There were no observable symptoms, and the response resolved without medical intervention.

We are analyzing the relevant data to more fully understand this response and are exploring several alternative clinical strategies. Conducting human clinical trials for gene therapy must be a deliberate and methodical process as we are breaking new ground each step of the way. We believe we can resolve this issue as we move the trial forward and we expect to resume treating subjects by mid-2003.

In recognition of our progress in this trial, our partner for the development and commercialization of Coagulin-B, Bayer Corporation, recently made a \$2.5 million milestone payment to Avigen, underscoring their ongoing support of this program and belief in AAV gene therapy. Both companies are committed to continuing the clinical trial and doing the work necessary to achieve long-term results for patients with hemophilia B.

Our agreement with Bayer is estimated to be worth approximately \$60 million in milestone payments and clinical funding, including their purchase of \$15 million of Avigen stock in February 2001, this current payment, payment of all clinical and manufacturing costs for the planned Phase II/III clinical trials, and future milestones. A key element of the agreement is Avigen's substantial participation in the revenue and profits that will accrue from the eventual sales of Coagulin-B once final regulatory clearance is obtained.

Ongoing Preclinical Developments: Over the last year we also made significant progress in our preclinical studies. We are in the process of completing an expanded non-human primate study to evaluate and optimize our AAV vector construct and delivery mechanism for the treatment of Parkinson's disease. Several primates with severe Parkinson's treated with our vector more than two years ago continue to show sustained gene expression resulting in the virtual elimination of symptoms. We expect the results of these trials to support the filing of an investigational new drug (IND) application for this disease later in 2003.

Also last year, we demonstrated long-term gene expression in a large animal model of hemophilia A. In an ongoing preclinical study, dogs treated with a single injection of AAV vector continue to express stable levels of factor VIII more than two years later. Based on the results of these studies and the future progress of our clinical trial for hemophilia B, we intend to submit an IND to the FDA for our second hemophilia product, Coagulin-A™, in 2004.

Strengthening our Corporate Position: Capitalizing on manufacturing, research and administrative efficiencies, we took several strategic steps to reduce staffing and more tightly focus our organization on our lead product development programs in hemophilia and Parkinson's disease. We expect these steps

to reduce our cash burn rate to less than \$25 million in 2003 and, based on our current expectations, extend the life of our existing financial resources to four or five years.

As part of this effort, we strengthened the clinical development capabilities of our management team. In November, Glenn Pierce, Ph.D., M.D., joined Avigen as Vice President of Research and Clinical Development, bringing extensive research and clinical experience in gene therapy, hemophilia and neurobiology. We also promoted Ken Chahine, Ph.D., J.D., Avigen's Vice President of Business Development and Intellectual Property since 1998, to the new role of Chief Operating Officer, in recognition of his many contributions to Avigen's success and his expanded operating responsibilities.

Building our Intellectual Property Portfolio: Six new patents were issued to Avigen in 2002, bringing our total issued patents, owned, co-owned and licensed, to 31, the largest and broadest AAV-centered patent portfolio in the industry. In addition, we have 38 U.S. patent applications pending, most of which have also been filed internationally. Our patents protect rights to our formulation of specific AAV vectors, our high-yield production methods for contaminant-free AAV vectors, multiple methods of tissue administration, and the use of AAV vectors for the treatment of a number of specific diseases. We believe our significant proprietary position establishes multiple intellectual property barriers to competition.

FINANCIAL RESULTS

Avigen continues to have a very strong balance sheet. At year end, we had approximately \$120 million in cash and securities, which we believe is sufficient to support our planned clinical trials and ongoing research and development programs for the next four to five years. For 2002, we reported a net loss of \$27.7 million, or \$1.38 per share. This compares with a net loss of \$20.8 million, or \$1.05 per share, for the calendar year 2001. This performance was in line with our expectations and reflects increased spending on our research and product development programs and on our clinical trial.

LOOKING AHEAD

Everyone at Avigen is dedicated to developing a viable commercial enterprise using AAV gene therapy to address the unmet medical needs of patients who suffer from serious, chronic disorders that are not effectively treated with conventional approaches. Our goal is to make a real difference in the lives of people in need. We believe the promise of AAV gene therapy to help people with serious chronic diseases is getting closer to reality every day.

We want to thank our shareholders and employees for supporting our efforts over the last year. We look forward to sharing our progress and success with each of you over the coming year.



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



John Monahan, Ph.D.
President and Chief Executive Officer

Cautionary Statement Regarding Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such statements include, but are not limited to, our expectations of or intentions for product development and research, our expectations as to the filing of INDs for the treatment of hemophilia-A and Parkinson's disease, trends in operating or financial performance, the potential efficacy of our AAV vector technology, market growth, competition, our estimates regarding our capital requirements, and our expectations with regard to collaborations and partnerships. 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.

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

NOTICE OF ANNUAL MEETING OF STOCKHOLDERS

TO BE HELD ON MAY 22, 2003

Dear Stockholder:

You are cordially invited to attend the Annual Meeting of Stockholders of AVIGEN, INC., a Delaware corporation. The meeting will be held on Thursday, May 22, 2003 at 10:00 a.m. local time at the offices of Avigen, 1301 Harbor Bay Parkway, Alameda, California 94502, for the following purposes:

- (1) To elect two (2) Class II directors to hold office until the 2006 Annual Meeting of Stockholders.
- (2) To ratify the selection of Ernst & Young LLP as Avigen's independent auditors for its fiscal year ending December 31, 2003.
- (3) To conduct any other business properly brought before the meeting.

The foregoing items of business are more fully described in the Proxy Statement accompanying this Notice.

The record date for the Annual Meeting is April 10, 2003. Only stockholders of record at the close of business on that date may vote at the meeting or any adjournment thereof.

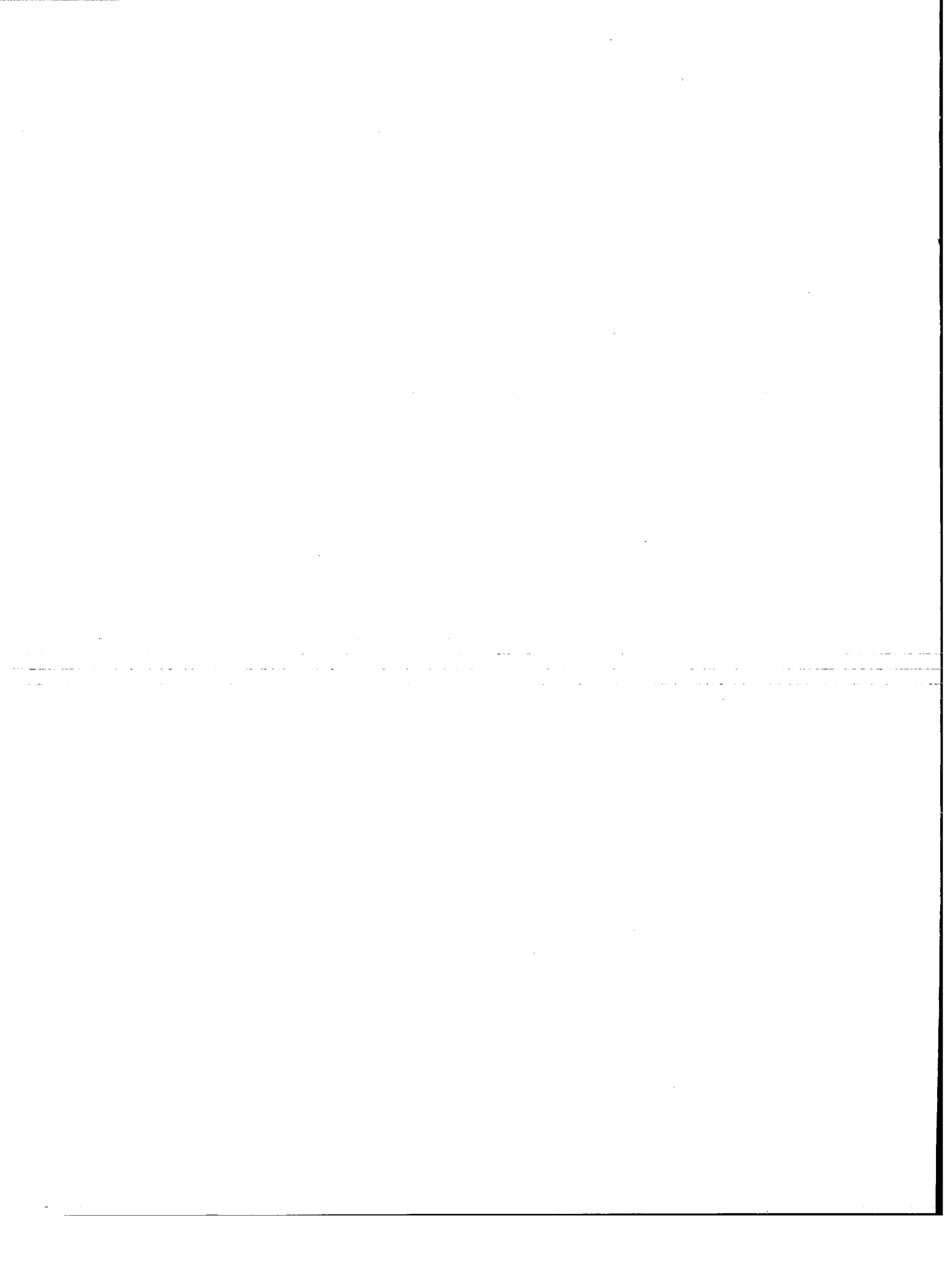
By Order of the Board of Directors



Thomas J. Paulson
Secretary

Alameda, California
April 17, 2003

You are cordially invited to attend the meeting in person. Whether or not you expect to attend the meeting, please complete, date, sign and return the enclosed proxy, or vote over the telephone or the Internet as instructed in these materials, as promptly as possible in order to ensure your representation at the meeting. A return envelope (which is postage prepaid if mailed in the United States) is enclosed for your convenience. Even if you have voted by proxy, you may still vote in person if you attend the meeting. Please note, however, that if your shares are held of record by a broker, bank or other nominee and you wish to vote at the meeting, you must obtain a proxy issued in your name from that record holder.



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

**PROXY STATEMENT
FOR THE 2003 ANNUAL MEETING OF STOCKHOLDERS**

May 22, 2003

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 2003 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 17, 2003 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 10, 2003 will be entitled to vote at the Annual Meeting. On this record date, there were 20,124,765 shares of common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on April 10, 2003 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 10, 2003 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 two matters scheduled for a vote:

- Election of two Class II directors; and
- Ratification of Ernst & Young LLP as Avigen's independent auditors for its fiscal year ending December 31, 2003.

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 21, 2003 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 21, 2003 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 10, 2003.

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" the ratification of Ernst & Young LLP as Avigen's independent auditors for its fiscal year ending December 31, 2003. 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 or her 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 18, 2003, to Avigen's Secretary at 1301 Harbor Bay Parkway, Alameda, California 94502. 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 23, 2004, nor earlier than the close of business on February 22, 2004. 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 the 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. 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.

How many votes are needed to approve each proposal?

- For the election of directors, the two (2) 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, ratification of Ernst & Young LLP as Avigen's independent auditors for its fiscal year ending December 31, 2003, must receive a "For" vote from the majority of shares present in person or represented by proxy and entitled to vote. Abstentions will be counted toward the tabulation

of votes cast on this proposal and each abstention will have the same effect as an "Against" vote. Broker non-votes are counted towards a quorum, but are not counted for any purpose in determining whether this matter has been approved.

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 20,124,765 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 2003.

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 2003. Each of the nominees for election to this class is currently a director of Avigen who was previously elected by the stockholders. If elected at the Annual Meeting, each of the nominees would serve until the 2006 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until such director's earlier death, resignation or removal.

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 2006 ANNUAL MEETING OF STOCKHOLDERS

Class II Directors

Philip J. Whitcome, Ph.D.

Philip J. Whitcome, Ph.D., 54, 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., 49, 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 DGI BioTechnologies, 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.

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

DIRECTORS CONTINUING IN OFFICE UNTIL THE 2004 ANNUAL MEETING OF STOCKHOLDERS

Class III Directors

John Monahan, Ph.D.

John Monahan, Ph.D., 56, has served as President, Chief Executive Officer and a director of Avigen since its inception in 1992. Prior to joining Avigen, Dr. Monahan was Vice President of Research and Development at Somatix Therapy Corporation, a gene therapy company, from 1989 to 1992, where he was responsible for the initiation and development of all research programs. From 1983 to 1988, he was Director of Molecular and Cell Biology at Berlex Laboratories, a pharmaceutical company. From 1981 to 1983, he was Group Research Chief at Hoffmann-LaRoche, a pharmaceutical company. Dr. Monahan received his Ph.D. in Biochemistry from McMaster University, Hamilton, Canada and his B.S. in Science from University College, Dublin, Ireland.

Daniel Vapnek, Ph.D.

Daniel Vapnek, Ph.D., 64, 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 professorial 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.

DIRECTORS CONTINUING IN OFFICE UNTIL THE 2005 ANNUAL MEETING OF STOCKHOLDERS

Class I Directors

Zola Horovitz, Ph.D.

Zola Horovitz, Ph.D., 68, 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., Diacrin, Inc., Genaera Corporation, Palatin Technologies, Inc., DOV Pharmaceutical 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., 53, 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.

BOARD COMMITTEES AND MEETINGS

During the fiscal year ended December 31, 2002, the Board of Directors held four meetings and acted by unanimous written consent one time. The Board has an Audit Committee and a Compensation Committee.

The Audit Committee meets with Avigen's independent auditors at least annually to review the results of the annual audit and discuss the financial statements, recommends to the Board the independent auditors to be retained, oversees the independence of the independent auditors, evaluates the independent auditors' performance, and receives and considers the independent auditors' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls. The Audit Committee is presently composed of three non-employee directors: Drs. Horovitz, Iwaki and Prendergast. It met eight times during the fiscal year and did not act by unanimous written consent.

The Compensation Committee makes recommendations concerning salaries and incentive compensation, awards stock options to employees and consultants under Avigen's stock option plans and otherwise determines compensation levels and performs such other functions regarding compensation as the Board may delegate. The Compensation Committee is presently composed of three outside directors: Drs. Horovitz, Prendergast and Vapnek. It met one time during the fiscal year and did not act by unanimous written consent.

The Board has no standing Nominating Committee or any committee performing similar functions of such a committee.

During the fiscal year ended December 31, 2002, 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.

REPORT OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS¹

The Audit Committee of the Board of Directors for the fiscal year ended December 31, 2002 consisted of Drs. Horovitz, Iwaki and Prendergast. All members of Avigen's Audit Committee are independent (as independence is defined in Rule 4200(a)(14) of the NASD listing standards). The Audit Committee is governed by a written Audit Committee Charter approved by the Board, 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. 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 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. 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 and 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, 2002.

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, 2002 for filing with the Securities and Exchange Commission. The Audit Committee and the Board of Directors have also recommended, subject to stockholder approval, the selection of Ernst & Young LLP as Avigen's independent auditors for the fiscal year ending December 31, 2003.

AUDIT COMMITTEE

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

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

PROPOSAL 2

RATIFICATION OF SELECTION OF INDEPENDENT AUDITORS

The Audit Committee has selected Ernst & Young LLP as Avigen's independent auditors for the fiscal year ending December 31, 2003 and the Board has further directed that management submit the selection of its 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, will have an opportunity to make a statement if they so desire, and will be available to respond to appropriate questions.

Stockholder ratification of the selection of Ernst & Young LLP as Avigen's independent auditors is not required by Avigen's Bylaws or otherwise. However, the Board 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 their 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 at the Annual Meeting will be required to ratify the selection of Ernst & Young LLP. Abstentions will be counted toward the tabulation of votes cast on this proposal and each abstention will have the same effect as an "Against" vote. Broker non-votes are counted towards a quorum, but are not counted for any purpose in determining whether this proposal has been approved.

Independent Auditor Fee Information

AUDIT FEES. The aggregate fees billed by Ernst & Young LLP for the audit of Avigen's financial statements, review of Avigen's interim financial statements, and services provided in connection with statutory and regulatory filings, were \$116,000 for the year ended December 31, 2002 and \$74,780 for the six-month transition period ended December 31, 2001.

AUDIT-RELATED FEES. During the fiscal year ended December 31, 2002 and during the six-month transition period ended December 31, 2001, no fees were billed by Ernst & Young LLP for employee benefit plan audits, due diligence related to M&A deals, accounting assistance and audits in connection with M&A deals, internal control reviews attest services that are not required by statute or regulation and consultation concerning financial accounting and reporting standards.

TAX FEES. The aggregate fees billed by Ernst & Young LLP in relation to the preparation and review of Avigen's income tax returns and for general tax advice and planning were \$25,750 for the year ended December 31, 2002 and \$21,500 for the six-month transition period ended December 31, 2001.

ALL OTHER FEES. Ernst & Young LLP did not provide any other services to Avigen during fiscal year ended December 31, 2002, nor did it provide any other services to Avigen during the six-month transition period ended December 31, 2001.

The Audit Committee has determined the rendering of all non-audit services by Ernst & Young LLP is compatible with maintaining the auditor's independence.

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

**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, 2003 (except as noted): (i) each director and nominee for director; (ii) each of the executive officers named in the Summary Compensation Table; (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.

<u>Beneficial Owner</u>	<u>Beneficial Ownership (1)</u>	
	<u>Number of Shares</u>	<u>Percent of Total</u>
Directors and Executive Officers		
John Monahan, Ph.D. (2)	477,674	2.34%
Kenneth G. Chahine, Ph.D. (3)	180,936	*
Thomas J. Paulson (4)	235,795	1.16%
Alan McClelland, Ph.D. (5)	179,530	*
Frederick A. Johnson, Ph.D. (6)	74,528	*
Philip J. Whitcome, Ph.D. (7)	654,932	3.15%
Zola Horovitz, Ph.D. (8)	55,965	*
Yuichi Iwaki, M.D., Ph.D. (9)	225,345	1.12%
John K.A. Prendergast, Ph.D. (10)	106,108	*
Daniel Vapnek, Ph.D. (11)	4,950	*
All executive officers and directors as a group (9 persons) (12)	1,956,705	9.06%
5% Stockholders		
Dimensional Fund Advisors Inc. (13)	1,402,815	6.97%
1299 Ocean Avenue, 11 th Floor		
Santa Monica, CA 90401		
Pictet Funds-BIOTECH (14)	1,182,826	5.86%
1, boulevard Royal		
Boîte postale 687		
L-2016 Luxembourg		
Europe		
Adage Capital Partners, L.P. (15)	1,023,876	5.09%
200 Clarendon Street, 52 nd Floor		
Boston, MA 02116		

* 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 20,124,765 shares outstanding on March 15, 2003, 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 257,500 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.
- (3) Includes 173,436 shares issuable upon the exercise of options held by Dr. Chahine that are exercisable within 60 days of the date of this table.

- (4) Includes 212,540 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. McClelland that are exercisable within 60 days of the date of this table. Dr. McClelland served as Vice President, Research and Development since 1998 and resigned from Avigen in February 2003.
- (6) Consists solely of shares issuable upon the exercise of options held by Dr. Johnson that are exercisable within 60 days of the date of this table. Dr. Johnson served as Vice President, Operations since 2000 and resigned from Avigen in February 2003.
- (7) Includes 637,745 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 Whitcome Family Trust. Dr. Whitcome is a trustee of the Whitcome Family Trust and disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (8) 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.
- (9) Includes 36,250 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 148,371 shares of common stock and warrants to purchase 997 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 36,084 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.
- (10) Includes 47,500 shares issuable upon the exercise of options held by Dr. Prendergast that are exercisable within 60 days of the date of this table.
- (11) 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.
- (12) Includes an aggregate of 1,477,967 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. McClelland's and Dr. Johnson's resignations from Avigen in February 2003, such number does not include shares held by either Dr. McClelland or Dr. Johnson, nor does such number include any shares issuable upon the exercise of options held by either Dr. McClelland or Dr. Johnson that are exercisable within 60 days of the date of this table.
- (13) Based upon a Schedule 13G filed with the SEC on February 11, 2003 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, 2002 and, consequently, DFA's beneficial ownership of Avigen's common stock may have changed between December 31, 2002 and March 15, 2003.
- (14) Represents 1,137,290 shares held by Pictet Funds-BIOTECH and 45,536 shares issuable upon exercise of warrants held by Pictet Funds-BIOTECH. Pictet Gestion (Luxembourg) S.A. is the fund manager for Pictet Funds-BIOTECH and, as such, may be deemed to beneficially own the shares held by the fund.
- (15) Represents shares held by Adage Capital Partners, L.P. ("ACP") as of January 31, 2003. Adage Capital Partners GP, L.L.C. ("ACPGP") is a general partner of ACP. Adage Capital Advisors, L.L.C. ("ACA") is a managing member of ACPGP. Phillip Gross and Robert Atchinson are the managing members of ACPGP and ACA, and are general partners of ACP. As such, each of Messrs. Gross and Atchinson, ACA and ACPGP have shared voting and investment power with respect to the shares held by ACP, and may be deemed to beneficially own these shares.

SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Exchange Act requires Avigen's directors and executive officers, and persons who own more than ten percent of a registered class of Avigen'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 Avigen. Officers, directors and greater than ten percent stockholders are required by SEC regulations to furnish Avigen 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, 2002, all Section 16(a) filing requirements applicable to its officers, directors and greater than ten percent beneficial owners were complied with, except as follows:

- Mr. Paulson failed to file one report to include the indirect shareholdings of his spouse. This omission was corrected by the reporting of these shares in his year-end Form 5.
- Dr. Chahine timely filed his year-end Form 5, but inadvertently did not include in that report the total number of his direct shareholdings at December 31, 2002. This omission was corrected by the reporting of these shares on an amended Form 5 for the same period.

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, 2002, the total compensation paid to non-employee directors was \$64,500. 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 Avigen's 1996 Non-Employee Directors' Stock Option Plan (which is referred to as the "Directors' Plan"). Only non-employee directors of Avigen or an affiliate of such directors (as defined in the Internal Revenue Code) are eligible to receive options under the Directors' Plan. Options granted under the Directors' Plan are intended by Avigen not to qualify as incentive stock options under the Internal Revenue Code.

Option grants under the Directors' Plan are non-discretionary. On the date of the Annual Meeting of Stockholders each year, each member of the Board who is not an employee of Avigen and has served as a non-employee director since the previous year's Annual Meeting of Stockholders is automatically granted under the Directors' Plan, without any further action by Avigen, the Board or the stockholders of Avigen, an option to purchase 10,000 shares of common stock of Avigen. If the non-employee director has not served as a director since the previous year's Annual Meeting of Stockholders he or she shall be automatically granted an option to purchase the number of shares of Avigen's common stock (rounded up to the nearest whole share) determined by multiplying 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. Each director who is elected for the first time to be a non-employee director of Avigen is automatically granted under the Directors' Plan, without any further action by Avigen, the Board or the stockholders of Avigen, an option to purchase 15,000 shares 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.

The exercise price of options granted under the Directors' Plan is equal to 100% of the fair market value of the common stock subject to the option on the date of the option grant. Options granted under the Directors' Plan may not be exercised until the date upon which such optionee, or the affiliate of such optionee, as the case may be, has provided one year of continuous service as a non-employee director following the date of grant of such option, whereupon such option shall become exercisable as to 33% of the option shares, 34% of the option shares

shall become exercisable two years after the date of grant, and 33% of the option shares shall become exercisable three years after the date of grant, in accordance with its terms. The term of options granted under the Directors' Plan is ten years. The Directors' Plan will terminate in March 2006, unless earlier terminated by the Board.

In the event of a merger, consolidation, reorganization, dissolution, liquidation, sale of substantially all of the assets of Avigen, or certain other changes in the beneficial ownership of Avigen's securities representing at least 50% change of such ownership, the options outstanding under the Directors' Plan will automatically become fully vested and exercisable, and will terminate if not exercised prior to such event.

During the last fiscal year, Avigen made five 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 and Prendergast received options covering 10,000 shares at an exercise price per share of \$9.43, the fair market value of such common stock on the date of grant. Dr. Vapnek received options covering 15,000 and 2,383 shares at an exercise price per share of \$8.25 and \$9.43, respectively, the fair market value of such common stock on each date of grant. As of March 15, 2003, options to purchase 20,000 shares had been exercised under the Directors' Plan.

During the fiscal year ended December 31, 2002, Avigen paid Dr. Iwaki a total of \$6,000 plus expenses in connection with his representation of Avigen at certain scientific conferences and business meetings.

Compensation of Executive Officers

Summary of Compensation

The following table shows for the calendar years ended December 31, 2000, 2001 and 2002, 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, 2002 (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	Calendar Year	Annual Compensation		Long-Term Compensation	All Other Compensation (\$)(1)
		Salary (\$)	Bonus (\$)	Securities Underlying Options (#)	
John Monahan, Ph.D. President and Chief Executive Officer	2002	344,850	—	50,000	2,175
	2001	315,000	100,000	150,000	2,175
	2000	275,000	175,254	150,000	2,155
Kenneth G. Chahine, Ph.D. Vice President, Business Development, and Chief Operating Officer	2002	241,075	—	37,500	1,911
	2001	197,750	50,000	100,000	1,911
	2000	157,500	87,754	100,000	1,467
Thomas J. Paulson Vice President, Finance, and Chief Financial Officer	2002	234,135	—	37,500	7,005(2)
	2001	217,560	50,000	100,000	7,005(2)
	2000	195,000	87,754	100,000	6,874(2)
Alan McClelland, Ph.D. (3) Vice President, Research and Development	2002	239,367	—	37,500	1,911
	2001	220,080	50,000	100,000	1,911
	2000	200,000	87,754	100,000	1,833
Frederick A. Johnson, Ph.D. (4) Vice President, Operations	2002	206,154	—	15,000	1,911
	2001	175,150	20,000	75,000	1,905
	2000	127,575	30,254	25,000	1,101

- (1) Except as otherwise indicated, represents insurance premiums paid by Avigen with respect to term life insurance for the benefit of the named executive.
- (2) \$5,094 represents insurance premiums paid by Avigen with respect to long term disability insurance for each of the calendar years ended December 31, 2000, 2001 and 2002.
- (3) Dr. McClelland became Vice President, Research and Development in April 1999, and resigned from Avigen in February 2003.
- (4) Dr. Johnson became Vice President, Operations in July 2000, and resigned from Avigen in February 2003.

Stock Option Grants And Exercises

The following tables show for the fiscal year ended December 31, 2002, 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 Avigen's 2000 Equity Incentive Plan.

Option Grants in Last Fiscal Year

Name	Individual Grants		Exercise or Base Price (\$/Sh)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (1)	
	Number of Securities Underlying Options Granted (#) (2)	% of Total Options Granted to Employees in Fiscal year (3)			5% (\$)	10% (\$)
John Monahan, Ph.D.	50,000	5.81%	\$8.525	7/1/12	\$268,066	\$679,333
Kenneth G. Chahine, Ph.D.	37,500	4.36%	\$8.525	7/1/12	\$201,050	\$509,500
Thomas J. Paulson	37,500	4.36%	\$8.525	7/1/12	\$201,050	\$509,500
Alan McClelland, Ph.D. (4)	37,500	4.36%	\$8.525	7/1/12	\$201,050	\$509,500
Frederick A. Johnson, Ph.D. (5)	15,000	1.74%	\$8.525	7/1/12	\$ 80,420	\$203,800

- (1) The potential realizable value is based on the term of the option at the time of grant (10 years). 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.
- (2) 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.
- (3) Based on 860,917 options granted to employees of Avigen during the fiscal year ended December 31, 2002.
- (4) Dr. McClelland resigned from Avigen in February 2003.
- (5) Dr. Johnson resigned from Avigen in February 2003.

Aggregated Option Exercises in Last Fiscal Year ("FY-End") and FY-End Option Values

<u>Name</u>	<u>Shares Acquired on Exercise (#)</u>	<u>Value Realized (\$)</u>	<u>Number of Securities Underlying Unexercised Options at FY-End</u>	<u>Value of Unexercised In-the-Money Options at FY-End (\$)</u>
			<u>Exercisable/ Unexercisable (1)</u>	<u>Exercisable/ Unexercisable (2)</u>
John Monahan, Ph.D.	—	—	207,500/225,000	93,872/3,141
Kenneth G. Chahine, Ph.D.	7,500	59,250	137,810/154,690	4,763/1,099
Thomas J. Paulson	—	—	179,013/153,283	171,800/1,884
Alan McClelland, Ph.D. (3)	—	—	134,842/162,658	—/—
Frederick A. Johnson, Ph.D. (4)	—	—	58,592/78,908	55,502/785

(1) Reflects shares vested and unvested at December 31, 2002.

(2) Fair market value of Avigen's common stock at December 31, 2002 (\$5.71) minus the exercise price of the options.

(3) Dr. McClelland resigned from Avigen in February 2003.

(4) Dr. Johnson resigned from Avigen in February 2003.

Employment, Severance and Change of Control Agreements

In August 1992, Avigen entered into an employment agreement with John Monahan, Avigen's President and Chief Executive Officer. The employment agreement provides for, among other items: (i) a minimum base salary of at least \$150,000 per year and (ii) 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. The employment agreement automatically renews for successive one year periods unless 30 days' prior written notice is provided by either party or unless terminated by either party for just cause.

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.

Avigen entered into severance agreements with Frederick A. Johnson and Alan McClelland in connection with their resignations from Avigen in February 2003. Under the terms of the severance agreements, Drs. Johnson and McClelland each received a one time payment equal to six months of their respective full-time base salaries. In addition, the severance agreements provide that the vesting of stock options held by each of Drs. Johnson and McClelland will continue for six months after their respective resignation dates and the vested portions of such stock options will be exercisable for a period of one year thereafter.

REPORT OF THE COMPENSATION COMMITTEE OF THE BOARD OF DIRECTORS ON EXECUTIVE COMPENSATION¹

Compensation Committee Report

The Compensation Committee of the Board of Directors is currently composed of Drs. Horovitz, Prendergast and Vapnek, none of whom are currently officers or employees of Avigen. 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.

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

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 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, 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 2002 compensation, including whether to grant stock options or pay a bonus to Dr. Monahan, reflects the Compensation Committee's subjective assessment of (1) his performance, (2) his skills in relation to other CEOs in Avigen's industry, (3) the Compensation Committee's confidence in Dr. Monahan's ability to lead Avigen's continued development and (4) the Compensation Committee's assessment of Avigen's performance. Considering these factors, the Compensation Committee set Dr. Monahan's base salary for the twelve-month period ended June 30, 2003 at \$359,700 and granted Dr. Monahan a stock option to purchase 50,000 shares of Avigen's common stock at an exercise price of \$8.525 per share, the fair market value of a share of Avigen's common stock on the date of grant. The Compensation Committee previously set Dr. Monahan's base salary for the twelve-month period ended June 30, 2002 at \$330,000, and, accordingly, Dr. Monahan's base salary for the fiscal year ended December 31, 2002 was \$344,850. The Compensation Committee subjectively concluded that Dr. Monahan had performed well with respect to his individual performance objectives, and was therefore awarded a commensurate base salary increase. However, the Compensation Committee determined not to pay Dr. Monahan a bonus for fiscal 2002 after considering Avigen's overall strategic progress and fiscal challenges.

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.

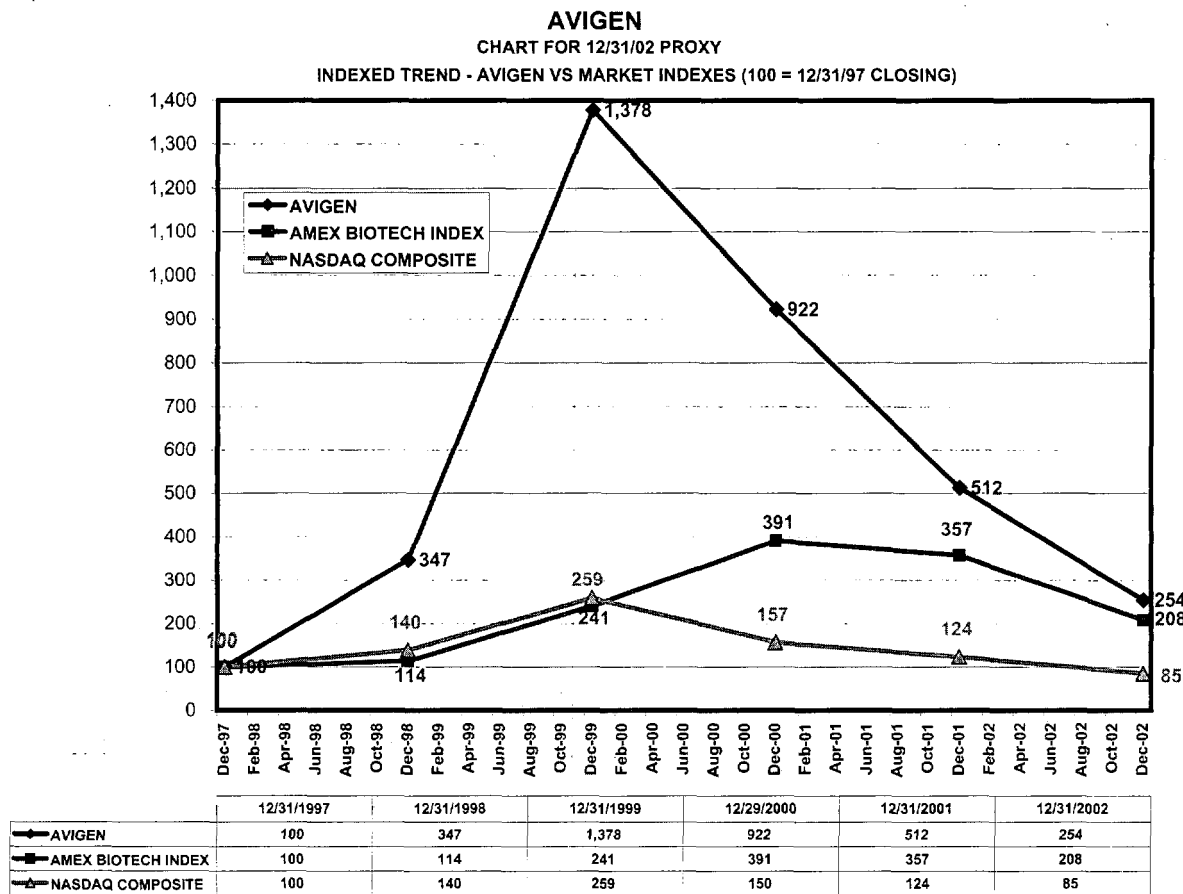
COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Drs. Horovitz, Prendergast and Vapnek served as members of the Compensation Committee during the fiscal year ended December 31, 2002. Drs. Horovitz and Prendergast served as members of the Compensation Committee throughout the last fiscal year and Dr. Vapnek was appointed as a member of the Compensation Committee in May 2002. 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, 1997 for (i) Avigen's common stock, (ii) the Nasdaq Stock Market (U.S.) ("Nasdaq") and (iii) the American Stock Exchange Biotechnology Index ("AMEX Biotech"). All values assume reinvestment of the full amount of all dividends and are calculated as of December 31 of each year:



- (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 Avigen 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.

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.

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 will 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 they will be "householding" communications to your address, "householding" will continue until you are notified otherwise or until you revoke your consent. If, at any time, you no longer wish to participate in "householding" and would prefer to receive a separate proxy statement and annual report, please notify your broker, direct your written request to: Investor Relations, Avigen, Inc., 1301 Harbor Bay Parkway, Alameda, California 94502 or 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.

OTHER MATTERS

The Board 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 black ink that reads "Thomas J. Paulson". The signature is written in a cursive style with a large, sweeping initial 'T'.

Thomas J. Paulson
Secretary

April 17, 2003

A copy of Avigen's Annual Report to the Securities and Exchange Commission on Form 10-K for the fiscal ended December 31, 2002 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 experience 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 POLICY

The Audit Committee shall provide assistance to the Board in fulfilling its responsibility to the stockholders, potential stockholders, and investment community relating to corporate accounting and reporting practices of the Company, 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.

RESPONSIBILITIES

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 non-audit services to be performed by the independent auditors, 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.
- Evaluate on a periodic basis the 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, 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.

- 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 (to the extent not previously approved by the corporation's Board of Directors) 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, 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.

**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, 2002

OR

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

For the transition period from _____ to _____.

Commission File Number: 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 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 voting stock held by non-affiliates of the registrant as of June 28, 2002, was approximately \$151,415,000 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 15, 2003, was 20,124,765 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2003 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 10-13 of this Form 10-K.

(1) Excludes approximately 4,000,000 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 28, 2002. 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, 2002**

TABLE OF CONTENTS

	<u>Page</u>
PART I	
Item 1. Business	2
Item 2. Properties	23
Item 3. Legal Proceedings	23
Item 4. Submission of Matters to a Vote of Security Holders	24
PART II	
Item 5. Market for Registrant's Common Equity and Related Stockholder Matters	25
Item 6. Selected Financial Data	26
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	27
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	36
Item 8. Financial Statements and Supplementary Data	37
Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	61
PART III	
Item 10. Directors and Executive Officers of the Registrant	62
Item 11. Executive Compensation	62
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	62
Item 13. Certain Relationships and Related Transactions	63
Item 14. Controls and Procedures	63
PART IV	
Item 15. Exhibits, Financial Statement Schedules, and Reports on Form 8-K	64
SIGNATURES	68
CERTIFICATIONS	69-70

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 progress of our product development programs, including Coagulin-B;
- our expectations as to when we will file investigational new drug applications for our product candidates for the treatment of hemophilia A and Parkinson's disease, currently in preclinical development;
- our expectations as to when we will resume treating patients in our Coagulin-B clinical trial;
- developments 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;
- developments 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.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "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, Inc. is a Delaware corporation that was incorporated on October 22, 1992. Since 1993, Avigen has focused on the development of adeno-associated-virus-based gene therapy products for the treatment of serious, chronic diseases. We have developed a proprietary gene delivery platform technology based on adeno-associated virus vectors, known as "AAV vectors". We have assembled a broad base of proprietary intellectual property covering methods of transferring genes into cells, high-yield processes to manufacture contaminant-free AAV vectors, specific genes of interest and other proprietary technologies and processes. In addition, we have built the manufacturing capacity necessary to produce clinical-grade AAV vectors for our lead product candidates through commercial launch. We have also established expertise in preclinical research, manufacturing and manufacturing process scale-up, quality control, quality assurance, regulatory affairs and clinical trial design and implementation.

Our proposed gene delivery products are designed for the direct administration of DNA into the cells of patients in order to achieve expression of therapeutic proteins within the body as an alternative to existing pharmaceutical and surgical treatments. Traditional medicine primarily focuses on treating the symptoms of disease. We believe that our gene-based products, by targeting the root cause of the disease at the fundamental cellular level, have the potential to treat a wide variety of diseases and conditions that are not adequately addressed by current medical science.

Solving complex biological responses in the developing field of human genetics makes product development challenging; however, we believe that our AAV vectors have the potential to effectively deliver genes that will promote therapeutic responses in patients suffering from many types of diseases. Our efforts are primarily focused on our two lead product candidates. We are conducting a phase I clinical trial for our first lead product candidate, Coagulin-B®, for the treatment of hemophilia B. We intend to submit an investigational new drug (IND) application with the Food and Drug Administration (FDA) for our second lead product candidate for the treatment of Parkinson's disease later in 2003. Our product candidate for the treatment for hemophilia A, Coagulin-A™, is currently in preclinical development and based on the results of preclinical studies in animals and the results of our clinical trials for hemophilia B, we expect to submit an IND with the FDA for Coagulin-A in 2004. We also have active research programs underway to explore certain potential neurologic, metabolic and cardiac disease targets.

Recent Highlights

On December 9, 2002, we presented data at the annual meeting of the American Society of Hematology which showed that we had achieved therapeutic circulating levels of a protein called factor IX in a subject in our phase I clinical trial for Coagulin-B, our gene transfer product for the treatment of hemophilia B. Hemophilia B is a blood clotting disorder characterized by the reduction or absence of factor IX. We achieved circulating levels of factor IX in excess of 10% of normal in this subject for approximately four weeks after gene transfer. We believe that levels of 3% to 5% of normal can be considered therapeutic. In week four, the subject experienced a temporary elevation in the levels of two liver enzymes, at which point the circulating levels of factor IX began to decline. During this time, all other liver function tests were normal, and the subject remained in excellent health. The temporary elevation in the levels of two liver enzymes was unexpected and had not been predicted by the results of any of our preclinical animal studies. We suspended enrollment of additional subjects in order to gather additional data from the current study participants and to evaluate the cause of this unexpected response, its potential connection to the decline in effectiveness of the Coagulin-B treatment, and any potential health risks to future subjects. We have submitted modifications to the clinical trial protocol to the FDA and we expect to resume treating subjects by the middle of 2003.

On February 5, 2003, we announced a realignment of our management team and the departure of two senior executives, in a strategic move to better focus our organization on bringing our lead product development programs to market. This move followed the announcement on October 22, 2002 that we had reduced our workforce by approximately 28%. This workforce reduction was made possible by advances in our manufacturing processes that achieved significant operating efficiencies without limiting our production capabilities. These cutbacks were

intended to extend the projected life of our existing financial resources and allow us to support our current and planned clinical trials and ongoing research and development programs for approximately four to five years without turning to outside financial resources.

In March 2003, we received a \$2.5 million milestone payment from Bayer Corporation under the terms of our collaboration agreement, in recognition of the clinical progress to date in our Coagulin-B liver trial. This milestone payment is expected to be recorded as revenue in 2003.

Gene Therapy and AAV Gene Delivery

Many serious human diseases are caused by the absence or inappropriate presence of proteins. Genes control the production of these proteins. Traditional medicine focuses on alleviating the symptoms of these conditions rather than focusing on the root cause of diseases. Gene therapy attempts to address the root cause of disease at the fundamental cellular level.

The first biotech products for the treatment of chronic protein deficiencies were manufactured therapeutic proteins produced through genetic engineering and recombinant technology. These manufactured proteins can be administered directly to patients. However, most proteins must be delivered by injection since they are digested when taken orally. 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. There are also a number of diseases and conditions, including Parkinson's disease and congestive heart failure, where beneficial proteins or enzymes have been identified but cannot be delivered to patients through injection.

Gene therapy is intended to give a patient's own cells 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. In addition, by producing steady protein expression, gene therapy, if effective, would minimize the fluctuations in protein levels commonly associated with many disease complications. Researchers are investigating several alternative gene delivery mechanisms for gene therapy, including the use of a variety of viral and non-viral vectors.

All of our products in development are based on our proprietary AAV vector-based gene delivery technology. This technology is designed to take advantage of the natural efficiency with which viruses deliver genes to cells, without the safety concerns that arise from disease-related viruses. AAV is a very simple, small, stable and non-pathogenic virus that has never been associated with any disease. More than 80% of the population has been exposed to AAV at some point. In Avigen's manufacturing process to create an AAV vector for gene delivery, the viral genes are removed from the virus and replaced with the appropriate therapeutic gene.

We believe AAV vectors have many advantages over other types of gene delivery mechanisms, including:

- **Safety** — The AAV virus has never been associated with any human disease. Avigen's proprietary manufacturing process produces AAV vectors free of wild-type or helper virus contaminants.
- **Efficiency** — AAV is very efficient at getting into cells.
- **The 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 can 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, skin, and others.
- **Stability** — AAV vector is stable under a wide range of conditions which should simplify manufacturing, storage and handling of the final product.

Manufacturing large amounts of high quality, contaminant-free AAV vectors is very challenging. We have dedicated significant resources to advancing our production methods and developing effective and scalable techniques that meet these quantity and quality objectives. For example, normally AAV only reproduces in a cell that has been infected with a helper virus. A key difference between our manufacturing technology and that of other companies is that we do not use live helper viruses in the production of AAV vectors. This eliminates the possibility

of helper virus contamination, greatly simplifying purification, and significantly improving yields. We have also developed advanced cell culture and vector purification processes that utilize similar technologies as those employed by biotechnology leaders to commercialize therapeutic recombinant proteins. We believe these processes will support highly scalable levels of production of our AAV vectors. We believe that our success in resolving many production limitations sets us apart from others, and will enable us to manufacture sufficient commercial quantities of our AAV vectors, as well as amounts needed to support our further research efforts to identify additional potential disease targets that might benefit from the advantages of our AAV vector system.

Research and Development Programs

We evaluate possible research and development programs against several criteria that we feel comprise a desirable profile for Avigen’s gene therapy research, including:

- the application should capitalize on the unique capabilities of AAV vectors, including their safety and effectiveness profile and their potential to produce long-term expression of therapeutic levels of the desired protein;
- the role of the therapeutic gene should be well understood;
- it is clear that replacing a missing protein can provide at least partial correction of the disease; and
- relatively small clinical trials can show clear, statistically significant clinical benefits with measurable end points.

We believe a combination of these criteria provides Avigen with the best opportunity for success. Based on these criteria we have identified a number of promising areas and have established several research and development programs. We characterize our programs in one of three stages. Research programs are typically in an early stage of laboratory exploration, potentially involving small animal models, attempting to identify a reliable AAV-based approach for treating a disease or condition. Product development programs can be characterized in one of two stages: the first is preclinical, which involves safety and efficacy studies on large animal models which are designed to provide data that would support the progression into human studies; and the second is clinical, which typically includes multiple phases of human clinical trials designed to evaluate safety first, referred to as “Phase I”, followed by subsequent phases to evaluate therapeutic responsiveness.

Product Development Programs

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

AAV Vector-Based Gene Therapy Product Development Programs

<u>Program</u>	<u>Disease</u>	<u>Protein/Enzyme</u>	<u>Target Cell</u>	<u>Status</u>
Blood Diseases	Hemophilia B	Factor IX	Liver	Phase I
	Hemophilia A	Factor VIII	Liver	Preclinical
Neural Disease	Parkinson’s Disease	Aromatic amino acid decarboxylase	Brain	Preclinical

Hemophilia B

Our most developed product candidate is Coagulin-B for the treatment of hemophilia B. Hemophilia B is a blood clotting disorder characterized by the reduction or absence of a protein called factor IX, and primarily affects males. Due to the lack of sustained levels of factor IX protein, patients with hemophilia B can experience frequent internal bleeding during the course of normal daily activities. Currently, patients with a severe form of the disease inject themselves with factor IX protein several times a week to stop these bleeding episodes. These factor IX protein injections provide temporary relief, but the protein breaks down after a few days and the bleeding often recurs. Since the bleeding typically takes place in the joints and soft tissue, these patients also frequently suffer crippling bone and joint problems. A small percentage of patients can also suffer permanent disability or even die from bleeding into the central nervous system. Furthermore, when blood-derived replacement therapy is used there is a small risk of blood-transmitted viral infection.

Hemophilia B affects approximately one in every 30,000 males, afflicting an estimated 10,000 to 15,000 individuals in developed countries worldwide, with an estimated 40% to 50% of those affected having a severe form of the disease. According to data published by the National Hemophilia Foundation, the average cost of currently available recombinant protein factor IX can exceed \$100,000 per year per patient. In addition, because this protein therapy cannot prevent bone and joint damage, each patient may also require an additional \$100,000 to \$150,000 in other medical treatment costs annually. Based on this information, we believe the current market for providing recombinant protein factor IX to patients with the severe form of the disease exceeds \$400 million per year, and that the aggregate cost of treating hemophilia B patients with replacement protein factor IX and other associated disease treatments exceeds \$650 million per year worldwide.

Extensive experience with factor IX over the last 25 years has established that circulating factor IX protein levels equivalent to only 1% of the normal level found in humans can often reduce the frequency of spontaneous bleeding episodes experienced by patients with a severe form of the disease. Furthermore, factor IX protein levels equivalent to 3% to 5% of the normal level found in humans will significantly reduce the patient's reliance on replacement injections of factor IX protein and greatly improve the patient's condition. To maintain either of these levels using conventional injections of replacement factor IX protein is costly, has associated infection risks and is impractical. Avigen's approach is designed to continuously deliver therapeutic levels of factor IX protein into the blood of treated patients in order to improve the patient's quality of life, and decrease associated complications. We believe Coagulin-B has the potential to substantially reduce the need for daily or weekly injections of factor IX protein and meet this objective.

Clinical Trial – phase I with dose escalations

In December 2002, we presented interim data at the annual meeting of the American Society of Hematology on the first six subjects with severe hemophilia B to be treated in our ongoing Coagulin-B phase I clinical trial targeting liver delivery. We previously reported results from a phase I clinical trial in which we targeted Coagulin-B delivery to skeletal muscle tissue. In that study we showed safety, effective gene transfer, and protein expression. However, protein expression did not reach therapeutic levels. Based on these results, and the stronger efficacy results observed in preclinical animal studies with a small group of dogs, we initiated our second phase I trial targeting liver delivery.

In line with the second phase I clinical trial protocol targeting liver delivery, subjects one through four received relatively low doses of AAV vector. All of these subjects tolerated the procedures well and showed no side effects or vector toxicity. While measurable levels of circulating factor IX were occasionally observed at the limits of detection, none of these subjects exhibited sustained levels above 1.0%.

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 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. During this time, all other liver function tests were normal. The subject reported no other symptoms and continued to feel healthy. Subject six exhibited much lower, but detectable, levels of circulating factor IX for a few weeks. Subject six did not experience an elevation in the levels of his liver enzymes.

The temporary elevation in the levels of liver enzymes was unexpected and had not been predicted by the results of any of our preclinical studies in standard animal models. In all of our animal studies, once a stable expression level was reached, it remained stable for the life of the cell that received the AAV vector. In our preclinical studies for the treatment of hemophilia B, the first dog treated with an AAV vector with the gene for factor IX continues to express therapeutic levels more than four years after treatment. We have suspended enrollment of additional subjects in order to gather additional data from the current study participants and evaluate the cause of the temporary elevation of liver enzymes, its potential connection to the decline in effectiveness of the Coagulin-B treatment, and any potential health risks to future subjects. Relying on four years of safety data, covering 13 human subjects in two phase I clinical trials using our AAV vector gene delivery technology, and given the evidence of effectiveness in humans exhibited by subject five in our current clinical trial, we are committed to enrolling additional subjects and gathering additional human data to solve these complex issues.

We have submitted modifications to our clinical trial protocol to the FDA and expect to resume treating subjects by the middle of 2003.

All progress and results reported in this document or otherwise regarding our Coagulin-B clinical trials prior to the conclusion of those trials are preliminary and should not be considered a guarantee that subsequent subjects in these or other studies will demonstrate the same results or that these treated subjects will exhibit beneficial results over a longer period of time.

Hemophilia A

We are developing a second hemophilia product, Coagulin-A, for the treatment of hemophilia A. Like hemophilia B, hemophilia A is a genetic disorder that almost exclusively affects males and is characterized by a protein deficiency in the blood, causing patients to have a reduced ability to form blood clots. Instead of lacking the protein factor IX, patients with hemophilia A lack the protein factor VIII.

Hemophilia A affects approximately one in every 10,000 males, afflicting approximately 40,000 to 50,000 individuals in developed countries worldwide. The National Hemophilia Foundation has also published data suggesting that the average cost of currently available replacement protein factor VIII can exceed \$100,000 per year per patient. Because protein therapy has not proven completely effective at preventing bone and joint damage that is common among hemophilia A patients, each patient may also require an additional \$100,000 to \$150,000 in other medical treatment costs annually. Based on this information, we believe the current worldwide market for providing protein factor VIII to patients with hemophilia A exceeds \$2 billion per year, and that the aggregate cost of treating hemophilia A patients with replacement protein factor VIII and other related disease treatments is over \$3 billion per year worldwide.

Preclinical Studies

In April 2002, we presented data from hemophilic mice and dog studies at the National Hemophilia Foundation's Fifth Annual Workshop on Gene Therapies for Hemophilia. These data showed that both species could achieve long-term expression of the clotting factor VIII with a single injection of our AAV vector containing the gene for factor VIII. In a study with hemophilia A dogs, considered the best large animal models for the condition, treated dogs demonstrated a decrease in whole blood clotting time from approximately 15.5 minutes to approximately 5.0 minutes. Whole blood clotting time in normal dogs is approximately 3 to 4 minutes. This improvement in the hemophilia A dogs reflects an increase in their circulating levels of factor VIII to between 1.5% and 2.5% of normal levels. All dogs treated continue to express stable levels of circulating factor VIII, including the first dog treated more than two years ago.

Assuming these studies, when complete, produce favorable results, we believe that the data from these studies will support the feasibility of using AAV vectors containing the factor VIII gene to treat human subjects.

Parkinson's Disease

Parkinson's disease is a neurological disorder that affects an estimated 1.5 million people in the United States and Europe. Characterized by an increase in spontaneous movements, gait difficulty, postural instability, rigidity and tremor, Parkinson's disease results from a decrease in the levels of dopamine, a neurotransmitter essential to the control of movement in the brain. Dopamine is produced in a region of the brain called the substantia nigra by the interaction of tyrosine and aromatic amino acid decarboxylase, or AADC. In patients who suffer from Parkinson's disease, cells in this area of the brain degenerate over time for unknown reasons, which reduces the patient's ability to produce dopamine.

Currently, the primary treatment for Parkinson's disease is oral administration of L-dopa, a dopamine precursor, which can be converted to dopamine inside the brain by AADC. Dopamine itself cannot be administered directly as it cannot pass through the blood/brain barrier. While this approach can help relieve symptoms for several years, it becomes progressively less effective as the level of AADC produced by the substantia nigra continues to decline as those cells continue to die. To compensate for this decline in effectiveness, dosage levels of L-dopa must be increased, which can result in serious side effects. 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.

Our strategy for treating Parkinson's disease is to use an AAV vector to deliver the gene for AADC directly to the striatum, the part of the brain that needs dopamine to control movement, bypassing the degenerating substantia nigra. Then, when the patient takes L-dopa, it is converted to dopamine only in the region of the brain where it is needed. This "pro-drug" approach enables the patient and physician to control the level of dopamine in the brain by regulating how much L-dopa is taken. We believe this approach has the potential to offer significant advantages to patients by prolonging the effectiveness of L-dopa.

Initial research studies on both rodent and primate model systems have been promising and suggest that our AAV gene therapy for Parkinson's disease may be effective in supplementing existing therapies. Primates with induced Parkinson's disease respond like humans to the administration of L-dopa. As the number of functioning cells in the substantia nigra declines, the effectiveness of taking L-dopa also declines. Primates with severe Parkinson's symptoms that no longer respond to L-dopa, when treated with our AAV-AADC, have shown significant clinical improvement. This improvement is shown to correlate with measured increases in dopamine activity in the brains of these animals. Several primates treated more than two years ago continue to show gene expression and a decrease in Parkinson's symptoms when treated with L-dopa.

We have been working closely with an independent collaborator on these studies over the past few years and in June 2001, our collaborator presented data at the American Society for Gene Therapy meeting in Seattle that demonstrated improved preliminary results in animals. Based on the results of these earlier studies, in October 2001 we announced our intent to use our AAV technology and manufacturing expertise in connection with expanded preclinical studies in order to assess the safety and efficacy of this approach prior to seeking to initiate human clinical studies. We expect to file an IND application for our Parkinson's product later in 2003.

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.

Programs in this early research stage are commonly characterized by activities related to designing, constructing and testing vectors in specific target cell types, sometimes in small animal models, in order to evaluate gene expression and other effects on disease models. Programs in this early research stage may never progress to more advanced levels of development, and may be discontinued or suspended at any time. For example, we have previously conducted research studies to explore potential new disease targets including Gaucher's disease, anemia, and thalassemia. These studies advanced our understanding of AAV vectors and produced intellectual property that has supported research in other areas and may support future research for these and related indications. However, at this time we have chosen to focus our current attention and resources on other projects that we feel may have greater near-term potential.

Current examples of internal and collaborative research programs to explore promising new disease targets include other chronic neurological disorders, heart disease, and metabolic disorders.

Research and Development Expenses

We incurred approximately \$24.8 million in 2002, \$11.5 million for the six months ended December 31, 2001, and \$17.0 million and \$8.0 million for the fiscal years ended June 30, 2001 and 2000, respectively, in research and development expense. Of these amounts, we received \$86,000 and \$58,000, respectively, for the fiscal years ended June 30, 2001 and 2000 in reimbursements from a research grant, and reported such receipts as grant and other revenues on our statements of operations. No reimbursements by third parties were received for the year ended December 31, 2002 or the six months ended December 31, 2001.

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 the treatment of 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 the planned Phase II/III clinical trials for Coagulin-B and Bayer will receive exclusive worldwide marketing and distribution rights to the product. We will file for regulatory approvals and will be the holder of regulatory licenses worldwide, including the United States, the European Union, Canada, and Japan. We will manufacture the product and will receive a substantial share of the gross revenues from 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, 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 deal was announced. The sale of the common stock to Bayer was completed in February 2001. In March 2003, we received a commitment from Bayer to make a \$2.5 million milestone payment under this agreement in recognition of clinical progress in the liver trial.

Patents and Intellectual Property

Patents and other proprietary rights are important to our business. An important aspect of 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 February 28, 2003, we owned, co-owned, or held licenses to 31 issued U.S. patents and 38 pending U.S. patent applications, most of which have also been filed internationally. The patents we own or hold as licensee protect rights 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 2019.

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 the genes for enzymes associated with lysosomal storage diseases;
- high-yield methods of producing AAV vectors free from contamination from wild-type AAV or helper viruses, and large-scale manufacturing and purification processes;
- most 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
- the use of AAV vectors for treating certain diseases such as hemophilia A, hemophilia B, Parkinson's disease, cancer, anemia, and lysosomal storage.

When we identify previously patented technologies which 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 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 a 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.

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. The methods covered by this license include skeletal, smooth, and cardiac muscle, as well as delivery to the bloodstream, including intravenous and intra-arterial injection. This license excludes use of 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 five 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 license to BTG International, we also issued a warrant to purchase shares of our common stock at a strike price equal to the fair market value of our common stock on the effective date of the license agreement.

We currently investigate and use certain gene sequences or proteins encoded by those sequences, including certain forms of the factor VIII gene, and manufacturing processes that may be or could 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.

Vector Production and Manufacturing

AAV vectors have many advantages over other types of gene therapy vector systems. However, developing methods of producing large amounts of high quality, contaminant-free AAV vectors has been very challenging. Avigen scientists have spent years developing effective and scaleable production techniques to meet stringent quality and quantity objectives. We believe our success in resolving many production limitations sets us apart from others. 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 nature, in order to reproduce, AAV must borrow certain genes from “helper” viruses, typically adenovirus or herpes virus. In the laboratory, most researchers producing AAV vectors for gene therapy use one of these viruses in their process. While there has never been evidence to show that AAV causes any human disease, adenovirus, herpes virus, and other helper viruses are pathogenic and do cause disease in humans. The presence of pathogenic helper viruses in the production process, either alive or inactive, can compromise the safety of those AAV vectors. In order to minimize the risk of illness to the patient, AAV vectors produced using helper viruses must be purified to remove the pathogenic virus and residual viral toxins. Purification is therefore a critical step in producing safe AAV vectors, especially when performed on a large scale.

Transfection is the controlled transfer of DNA containing genes that have been isolated from a virus, into target production cells, which then produce new viruses, or in our case vectors. Scientists at Avigen have developed a production process for making AAV vectors without the use of helper viruses by means of a proprietary, patented transfection process. Instead we use only a select handful of helper-virus genes to cause reproduction of our AAV vectors in the cells. Thus, our production cells are never mixed with live viruses and consequently do not produce excess unwanted viral toxins.

Eliminating helper viruses from our process is not only critical to increasing the safety of our products, but also makes purification significantly easier. Furthermore, we can operate our transfection process in a modular fashion. Using standard molecular biology techniques, we can independently introduce all the instructions necessary for producer cells to make specific AAV vectors. As a result, we can use one standard cell line to produce every form of AAV vector needed for our research and clinical studies. With this modular method, we can modify the various forms of AAV vectors we make through the simple substitution of one of three added genetic components. In this way, we can control the identity of the therapeutic gene, DNA control sequences for expressing the gene, and the type of vector coat-protein desired.

Modular transfection also allows us to develop new vectors quickly and easily. Our proprietary process differs from other approaches which may imbed the instructions for producing vector in the producer cell line or by adding helper viruses to the producer cell. It takes much longer to change the genetic makeup of a producer cell line or a helper virus. We estimate that a typical development program must produce and test an average of 10 different constructions of a vector, e.g., different animal versions of the target gene, the human version of the gene, and modifications to optimize the efficiency of the vector in various tissues. In contrast to other production methods, our transfection process allows us to make rapid changes to our vectors, reducing transition between stages of development from months to days.

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 based on using roller bottles to produce AAV vectors in large quantities. 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 also use chromatographic purification techniques to increase the final yield and scale of our process for separating AAV from other cellular material.

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 remainder of the current fiscal year or for the following 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.

Competition

The field of gene therapy drug development is new and rapidly evolving, and it 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.

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, and Wyeth. We are also aware of other companies actively engaged in gene therapy product development programs, including Applied Genetic Technologies Corporation, Cell Genesys, Inc., Ceregene, Inc., Corautus Genetics, Inc., GenVec, Inc., Oxford BioMedica plc, Targeted Genetics Corporation, and Transkaryotic Therapies, 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 Food and Drug Administration ("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 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 or any foreign country. 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, or IND, 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, or BLA, for a biological product;
- successful inspection of manufacturing facilities by the FDA as part of the BLA approval process; and
- FDA approval of the BLA 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. Since 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. As products approach licensure, additional long-term nonclinical safety studies are generally required by the FDA. 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 indicates that the product is safe and effective, a BLA 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.

Once a BLA 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. The FDA may 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 of 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, 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.

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 15, 2003, Avigen had 102 full-time employees, 28 of whom have Ph.D. or M.D. degrees. Approximately 83 employees are involved in our research and development activities, including manufacturing, quality assurance and quality control, regulatory affairs and clinical affairs, 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. 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.

In October 2002, we implemented a workforce reduction of approximately 28% of our employees at that time, or 42 positions, primarily in operations and administration roles. All employees impacted by the workforce reduction were offered severance, company-sponsored COBRA health insurance coverage through December 2002, and varying levels of outplacement support. All impacted employees completed a separation agreement and general release of claims form and there are no current pending or threatened claims with regard to this reduction. All costs associated with the transaction were fully paid and reported in our results of operations for the year ended December 31, 2002.

Scientific Advisory Board

We have established a Scientific Advisory Board, consisting of experts in the field of medicine, genetics and molecular biology, which reviews and evaluates our research programs and advises us with respect to technical matters in fields in which we are involved. The members of the Scientific Advisory Board are prominent scholars in their field and, as a result, may serve as consultants to a wide variety of companies. Our Scientific Advisory Board currently consists of the following individuals:

Jef D. Boeke, Ph.D., D.Sc., is Professor of Molecular Biology & Genetics and Professor of Oncology at The Johns Hopkins University School of Medicine. Dr. Boeke studies the mechanism of insertion of mobile elements into DNA and other forms of DNA arrangements. His laboratory is also developing methods for high-throughput functional genomics. He has authored more than 150 publications.

Mark A. Israel, M.D., is Professor of Pediatrics and Genetics at Dartmouth Medical School. He is the Director of the Norris Cotton Cancer Center of Dartmouth-Hitchcock Medical Center. Dr. Israel's research has focused on the molecular and cellular biology of tumors of the nervous system. He has authored more than 200 publications.

Y.W. Kan, M.D., D.Sc., is the Louis K. Diamond Professor of Hematology at the University of California at San Francisco. He also is an Investigator of the Howard Hughes Medical Institute. Dr. Kan was the 1991 recipient of the Albert Lasker Clinical Medical Research Award and is noted as a leader in the fields of sickle cell anemia and thalassemia.

Dr. Randal J. Kaufman, Ph.D., is a Professor of Biological Chemistry and Investigator of the Howard Hughes Medical Institute at the University of Michigan Medical School. Dr. Kaufman and scientists at Genetics Institute were the first to isolate the factor VIII gene and develop recombinant factor VIII for the treatment of hemophilia A. Dr. Kaufman is an expert on the molecular biology of factor VIII and the treatment of hemophilia A. A major part of his present research is aimed at elucidating fundamental mechanisms that regulate protein folding and cellular responses to unfolded protein within the secretory pathway. He has authored over 200 publications.

Mark Kay, M.D., Ph.D., is the Director of the Program in Human Gene Therapy, and Professor in the Department of Pediatrics and Genetics at Stanford University School of Medicine. Dr. Kay is one of the founders of the American Society of Gene Therapy. Dr. Kay received the E. Mead Johnson Award for Research in Pediatrics in 2000 and was elected to the American Society for Clinical Investigation in 1997. He is respected worldwide for his work in gene therapy for hemophilia. He is also an Associate Editor of *Human Gene Therapy* and a member of the editorial boards of *Gene Therapy* and *Molecular Therapy*.

Haig H. Kazazian, Jr., M.D., is the Seymour Gray Professor and Chairman in the Department of Genetics at the University of Pennsylvania School of Medicine. He is the immediate past president of the American Board of Medical Genetics and a member of the Institute of Medicine. Dr. Kazazian is best known for his research which was instrumental to the molecular characterization of beta-thalassemia. He also was first to discover active "jumping genes" in human beings and has elucidated a number of mechanisms by which these mobile elements have a major impact on the evolution of our genome. In addition, Dr. Kazazian's laboratory has characterized the molecular defects in hemophilia A and developed a mouse model of the disease. He has also authored more than 300 publications.

Keiya Ozawa, M.D., Ph.D., is a professor and chairman of the Division of Hematology, Department of Medicine, Division of Cell Transplantation and Transfusion, and Division of Genetic Therapeutics, Center for Molecular Medicine, at Jichi Medical School in Japan, where he has established research and preclinical programs in gene therapy. Dr. Ozawa is regarded as one of the leading authorities on gene therapy in Japan and is responsible for drafting the Japanese government's gene therapy guidelines. He has authored more than 250 publications regarding hematology, virology and gene therapy.

Jeffrey M. Rosen, Ph.D., is the C.C. Bell Professor of Molecular and Cellular Biology and Medicine and Distinguished Service Professor at Baylor College of Medicine. Dr. Rosen is an internationally recognized expert in the field of gene expression. His research focuses primarily on the mechanisms by which hormones and growth factors regulate gene expression and development in the mammary gland and how these mechanisms have been altered in breast cancer. Dr. Rosen has served on the editorial boards of the *Journal of Biological Chemistry*, *Molecular and Cellular Endocrinology*, and Executive Editor of *Nucleic Acids Research* and he is currently an Associate Editor of *Molecular Endocrinology*. He is the recipient of the Endocrine Society Edwin B. Astwood Lecture Award.

David W. Russell, M.D., Ph.D., is an Associate Professor in the Department of Medicine at the University of Washington in Seattle. He is an expert on the development of viral vectors for gene therapy, especially on the transduction mechanisms of AAV vectors. Dr. Russell's research interests focus on stem cells and the manipulation of mammalian chromosomes.

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, 2002, we had an accumulated deficit of \$106.9 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 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. 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 would 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 and dog 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. 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, the recent report of serious adverse events in a retroviral trial for infants with severe combined immune deficiency (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 with SCIDS 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 the AAV vector or the expressed protein, it remains to be seen whether our product candidates cause 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 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 only one product candidate, Coagulin-B for the treatment of hemophilia B, in clinical trials, and this product candidate is only in phase I of the clinical trial process. We are not aware of any other gene therapy products of other companies that have received regulatory approval for commercial sale, and do not expect any of our prospective products, including Coagulin-B, to be commercially available for at least several years. As results of future stages of 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. At times, we have experienced delays in enrolling patients in our clinical trials for treatment at sub-therapeutic dose levels. 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 recent reported development of the 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 gene therapy 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 and will not become profitable.

Failure to comply with applicable FDA or other regulatory requirements may result in criminal prosecution, civil penalties and other actions that would seriously impair our ability to conduct our business. Even if regulatory approval is granted for a product, this approval will be limited to those disease states and conditions for which the product is proven to be useful, as demonstrated through clinical trials.

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 be assured 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 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-invented 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-inventor 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 gene, 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 gene therapy 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 Research Corporation Technologies is able to enforce patent protection for an invention relating to certain formulation technologies, the rights to which were previously licensed to us, the commercializing of our Coagulin-B product may be prevented or delayed

In May 1992, we entered into a license agreement with Research Corporation Technologies, Inc. (RCT) for rights to an invention related to a cell-specific promotor in AAV vectors. The invention was the subject of a pending U.S. patent application at the time the license agreement was entered into. Two U.S. patents relating to the invention subsequently issued: U.S. Patent Nos. 5,252,479 and 6,261,834. In February 2002, we filed a complaint against RCT for breach of contract in connection with the license agreement and exercised our right to terminate the license agreement. In our complaint, we sought financial damages and a determination by the court that RCT's actions rendered U.S. Patent No. 6,261,834 unenforceable and that this was a breach of the terms of the license agreement. RCT then filed a counter-claim alleging our failure to pay royalties under the license agreement and seeking \$100,000 in damages. We have since entered into an agreement with RCT resulting in the dismissal of both our complaint and RCT's counterclaim; however, this agreement and dismissal do not affect our rights to assert

unenforceability and/or invalidity of any of RCT's patents in any future proceedings or suit. If RCT is successful in enforcing these patent rights against us in the future, we may be forced to develop alternative technologies to replace the functions of the technologies covered by the RCT patents. Any requirements to modify the formulation of our Coagulin-B product from what is being tested in clinical trials could cause substantial delays in our current and future clinical trials, which would delay our ability to market our Coagulin-B product. In addition, if we are unable to develop alternative technologies to replace the functions of the technologies covered by the RCT patents, we may be forced to seek a new license from RCT to market our Coagulin-B product, which we may not be able to do, or may only be able to do on unfavorable terms.

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 AAV gene therapy 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 Coagulin-B. However, if Bayer Corporation does not perform under this agreement, we would need to 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 gene therapy 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 of 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, 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 vector needed to support our clinical trials or future commercialization

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 could use their materials in the manufacture of our clinical vector 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, 2002, will be adequate to fund our needs for at least the next four to five 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 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, 2001 to March 15, 2003, our stock price has fluctuated between a range of \$22.50 and \$2.90 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 biotech 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.

Available Information and Website Address

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 pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. We make available on our website at <http://www.avigen.com>, free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing the information 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.

Code of Ethics

In 2003, we intend to adopt a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We intend to post the text of our code of ethics on our website at <http://www.avigen.com> in connection with "Investor Information" materials. In addition, we intend to promptly disclose (1) the nature of any amendment to our code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 2. *Properties*

We lease approximately 90,500 square feet and sublease approximately 22,000 square feet in two adjacent buildings, for a total of 112,500 square feet of manufacturing, research laboratory and office space in an established commercial neighborhood in Alameda, California. One lease and the sublease account for approximately 45,000 square feet, and expire in May 2003; however, we have an extension for the combined space that runs for an additional five years and expires in 2008. Also, in December 2000, we entered into an additional 10-year lease for 67,500 square feet in a second building adjacent to the original facility. 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*

On February 12, 2003, we settled a lawsuit that we had initiated on February 21, 2002 in the United States District Court for the Northern District of California alleging that Research Corporation Technologies, Inc. (RCT) engaged in a breach of contract as a result of RCT's failure to disclose material information to the Patent and Trademark Office in connection with the prosecution of U.S. Patent Application No. 07/789,917 relating to a cell-specific promoter in AAV vectors which issued as U.S. Patent No. 6,261,834 on July 17, 2001. In May 1992, we entered into a license agreement with RCT for rights to the invention that was covered by the claims of U.S. Patent

No. 6,261,834. The license was exclusive and worldwide and included two issued U.S. patents as well as foreign counterparts. In consideration for the license, we paid an initial license fee and issued 247,949 shares of our common stock to RCT. On June 20, 2002, RCT filed an answer to the complaint and a counterclaim alleging our failure to pay royalties under the license agreement and seeking \$100,000 in damages. The parties agreed to the dismissal of both our complaint and RCT's counterclaim with prejudice except that the parties' agreement and the dismissal does not affect our rights to assert unenforceability and/or invalidity of any of RCT's patents, including U.S. Patent No. 6,261,834 (and any co-pending applications, continuations, continuations in part, reexaminations, reissues, and divisionals thereof, and any foreign counterparts thereof, if applicable) in any future proceeding or suit. On February 21, 2003, the United States District Court for the Northern District of California, having learned of the parties' agreement to dismiss our complaint and RCT's counterclaim, dismissed the lawsuit without prejudice.

As of March 15, 2003, we were not involved in any legal proceedings.

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

None.

Executive Officers of the Company

Our executive officers and their respective ages and positions as of March 15, 2003, are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Philip J. Whitcome, Ph.D.	54	Chairman of the Board
John Monahan, Ph.D.	56	President, Chief Executive Officer and Director
Kenneth G. Chahine, Ph.D.	38	Chief Operating Officer
Thomas J. Paulson	56	Vice President, Finance, Chief Financial Officer and Secretary
Glenn Pierce, Ph.D., M.D.	47	Vice President, Research and Clinical Development

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.

John Monahan, Ph.D., has served as President, Chief Executive Officer and a director of Avigen since its inception in 1992. Prior to joining Avigen, Dr. Monahan was Vice President of Research and Development at Somatix Therapy Corporation, a gene therapy company, from 1989 to 1992, where he was responsible for the initiation and development of all research programs. From 1983 to 1988, he was Director of Molecular and Cell Biology at Berlex Laboratories, a pharmaceutical company. From 1981 to 1983, he was Group Research Chief at Hoffmann-LaRoche, a pharmaceutical company. Dr. Monahan received his Ph.D. in Biochemistry from McMaster University, Hamilton, Canada and his B.S. in Science from University College, Dublin, Ireland.

Kenneth G. Chahine, Ph.D., joined Avigen in 1998 and 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 in November 2002 and serves as Vice President, Research and Clinical Development. 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 1994 to 1998, he served as Vice President, Preclinical Development at Prizm Pharmaceuticals, a biopharmaceutical 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.

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

Shares of Avigen's common stock commenced trading on the Nasdaq National Market on May 22, 1996, under the symbol "AVGN". As of March 15, 2003, there were approximately 163 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 fiscal year ended June 30, 2001, the six-month transition period ended December 31, 2001, and the fiscal year ended December 31, 2002.

<u>Fiscal year ended June 30, 2001</u>	<u>High</u>	<u>Low</u>
Quarter End 9/30/00	\$47.88	\$29.63
Quarter End 12/31/00	\$49.75	\$19.75
Quarter End 3/31/01	\$21.50	\$ 9.75
Quarter End 6/30/01	\$22.50	\$ 9.81
 <u>Transition Period ended December 31, 2001</u>	 <u>High</u>	 <u>Low</u>
Quarter End 9/30/01	\$20.13	\$ 9.10
Quarter End 12/31/01	\$14.88	\$ 8.90
 <u>Fiscal 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

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.

(in thousands, except per share data)	Year Ended December 31,		(1) Six Months Ended December 31,		Fiscal Years Ended June 30,				October 22, 1992 (Inception) to December 31,
	2002	2001	2001	2000	2001	2000	1999	1998	2002
	(unaudited)		(unaudited)						
Statement of Operations Data:									
Grant and other revenue	\$ 57	\$ 94	\$ 8	\$ 30	\$ 116	\$ 58	\$ 185	\$ -0-	\$ 787
Expenses:									
Research and development	24,809	22,333	11,465	6,173	17,041	7,953	6,490	6,235	86,356
General and administrative	8,146	7,559	3,957	3,159	6,761	4,516	3,445	2,990	36,424
In-license fees	-0-	-0-	-0-	-0-	-0-	5,034	-0-	-0-	5,034
	<u>32,955</u>	<u>29,892</u>	<u>15,422</u>	<u>9,332</u>	<u>23,802</u>	<u>17,503</u>	<u>9,935</u>	<u>9,225</u>	<u>127,814</u>
Loss from operations	(32,898)	(29,798)	(15,414)	(9,302)	(23,686)	(17,445)	(9,750)	(9,225)	(127,027)
Interest expense	(278)	(347)	(204)	(38)	(180)	(129)	(178)	(222)	(1,921)
Interest income	5,569	9,364	4,316	2,860	7,907	2,548	326	587	22,123
Other income, net	(132)	(68)	(17)	(4)	(55)	(13)	(9)	(17)	(57)
Net loss	<u>\$(27,739)</u>	<u>\$(20,849)</u>	<u>\$(11,319)</u>	<u>\$(6,484)</u>	<u>\$(16,014)</u>	<u>\$(15,039)</u>	<u>\$(9,611)</u>	<u>\$(8,877)</u>	<u>\$(106,882)</u>
Net loss per share	<u>\$ (1.38)</u>	<u>\$ (1.05)</u>	<u>\$ (0.57)</u>	<u>\$ (0.37)</u>	<u>\$ (0.85)</u>	<u>\$ (1.03)</u>	<u>\$ (0.99)</u>	<u>\$ (1.22)</u>	

(in thousands)	December 31,		June 30,			
	2002	2001	2001	2000	1999	1998
Balance Sheet Data:						
Cash, cash equivalents and available for sale						
securities, including restricted investments	\$ 119,224	\$ 148,254	\$ 157,737	\$ 77,953	\$ 14,881	\$ 4,477
Working capital	118,898	147,486	158,341	76,732	13,471	4,635
Total assets	140,686	168,409	174,946	85,287	16,183	5,997
Long-term obligations	8,852	8,558	5,391	4,113	265	1,052
Deficit accumulated during development stage	(106,882)	(79,143)	(67,823)	(51,810)	(36,771)	(27,160)
Stockholders' equity	130,057	157,350	167,182	79,013	14,323	3,583

(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 a differences include, but are not limited to, those discussed herein and in "Risk Factors" under Item 1.

Overview

Since our inception, we have devoted substantially all of our resources to research and development activities. We are a development stage company and have not received any revenue from the sale of products, 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 government grants and payments under collaborative arrangements. We have incurred losses since our inception and expect to incur substantial losses over the next several years due to 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 products or ever achieve or sustain product revenues for profitability. At December 31, 2002 we had an accumulated deficit of \$106.9 million.

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

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make judgments, assumptions and estimates that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ materially from those estimates. We consider the following to be critical accounting policies important to our financial condition and results of operations that require management to make judgments, assumptions and estimates that are inherently uncertain.

Valuation of investments in financial instruments

Investments in financial instruments are carried 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. If the fair value of a 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 these investments may not be fully recoverable, the impairment is considered other than temporary. An other than temporary decline in fair value of a financial instrument would be subject to write-down with a charge included 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. In 2002, we did not write down the value of any of our financial instruments because we did not determine that any of the declines in fair value of our financial instruments were other than temporary.

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. 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. In 2002, we did not write down the value of any of our property and equipment for impairments in fair value.

Valuation Allowance for net deferred tax assets

To date we have incurred significant tax losses that have resulted in deferred tax assets. Due to our history of losses and the uncertainty of generating taxable profits in the future, management has determined that a valuation allowance should be provided against the full amount of the net deferred tax assets. If the uncertainty regarding our ability to generate taxable income in the future changes, a reduction in the level of the valuation allowance may be required.

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. The progress and timing of activities associated with our research and development efforts in the future may cause variability in the future level of our research and development spending.

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, 2002 and June 30, 2001 to the six-month transition period ended December 31, 2001. 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 fiscal year ended December 31, 2002 and the unaudited twelve-month period ended December 31, 2001;
- the fiscal year ended December 31, 2002 and the fiscal year ended June 30, 2001; and
- the fiscal year ended June 30, 2001 and the fiscal year ended June 30, 2000.

Comparison of the fiscal year ended December 31, 2002 and the unaudited twelve-month period ended December 31, 2001

Revenue

Total revenue for the fiscal year ended December 31, 2002 was \$57,000, consisting of \$19,000 in royalties and \$38,000 in new research license agreement fees. Total revenue for the twelve-month period ended December 31, 2001 was \$94,000, consisting of \$86,000 of grant revenue and \$8,000 in new research license agreement fees. 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 is from a single royalty license, which allows for the development, manufacture, use and sale of products using our patented AAV technologies. We entered into this license agreement in July 2000. We did not receive any grant revenue during 2002. Grant revenue consists 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 either new or existing research license agreements or royalty licenses, or to be party to any new NIH grants, for the foreseeable future.

Operating expenses

Our research and development expenses totaled \$24.8 million for the fiscal year ended December 31, 2002 and \$22.3 million for the twelve-month period ended December 31, 2001. The increase of \$2.5 million was primarily due to the rising costs associated with the growth in staff and research programs. 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 before the impact of a workforce reduction in the fourth quarter of that year. At December 31, 2002, we had reduced our research and development staff level to approximately 95. Rising personnel costs account for approximately \$1.1 million of the total increase in research and development expenses, while expanded preclinical activities with third-party collaborators in 2002 added approximately \$950,000, and an increase in the number of patients treated in our Coagulin-B clinical trial in 2002 added approximately \$520,000 to the total increase. Depreciation expense in 2002 was approximately \$970,000 higher for assets associated with research and development activities, primarily due to the impact of newly constructed facilities that were placed in service during the year for general and animal research, and validation services related to our pilot plant were \$320,000 higher. Offsetting the impact of these rising costs between the two periods was a reduction in recruiting expenses of approximately \$500,000 and a reduction in license fees paid of approximately \$320,000, as well as broad-based reduction in costs of approximately \$530,000 associated with the use of materials to produce our AAV vector as we began to benefit from recent advances in our facilities and processes that achieved significant operating efficiencies.

As a result of the strategic steps we took over the last six months to focus the work of our research and development organizations on our lead product development programs, and our expectations for further efficiencies in our vector production processes, we expect total research and development spending to decline as much as \$2.0 million in 2003 from the 2002 level without adversely affecting the progress of those product development programs. We also expect that total research and development spending in subsequent years will resume an increasing trend from this lower baseline as we continue to conduct our clinical trials, enhance our manufacturing capabilities, and expand our research programs for additional gene therapy applications.

Our general and administrative expenses totaled \$8.1 million for the fiscal year ended December 31, 2002 and \$7.6 million for the twelve-month period ended December 31, 2001, resulting in an increase of approximately \$500,000. The increase between the two periods is primarily due to approximately \$430,000 in higher personnel-related costs, \$230,000 in higher legal fees related to litigation, \$210,000 in higher corporate expenses, including insurance and information services, and \$205,000 in higher depreciation and facilities-related expenses. These higher costs were partially offset by a \$575,000 decline in other expenses, primarily for professional services, due to the fact that in the twelve-month period ended December 31, 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 will decline slightly in 2003 as a result of the reduction of our workforce in October 2002 and to remain steady or return to an increasing trend over subsequent years.

Interest Income

Interest income totaled \$5.6 million for the year ended December 31, 2002 compared to \$9.4 million for the twelve-month period ended December 31, 2001. Since almost all of our interest income comes from our investments in high-grade marketable securities of government and corporate debt with an average maturity of approximately one year, the fluctuations in our interest income between periods is influenced to a large extent by the average size of our portfolio of interest earning cash and investments outstanding during those periods and changes in the short-term interest rate environment.

The \$3.8 million decrease in interest income for the year ended December 31, 2002 versus the twelve-month period ended December 31, 2001 was primarily due to the decline in market interest rates between the two periods, as well as the decrease in outstanding cash and securities balances since resources have been used to fund our ongoing operations and finance construction for additional research and development facilities.

Comparison of the fiscal years ended December 31, 2002 and June 30, 2001

Revenue

Total revenue for the fiscal year ended December 31, 2002 was \$57,000, consisting of \$19,000 in royalties and \$38,000 in new research license agreement fees. Total revenue for the fiscal year ended June 30, 2001 was \$116,000, which consisted of \$86,000 in grant revenue and \$30,000 in connection with the royalty license agreement entered into in July 2000. Revenue decreased by \$59,000, primarily due to the lack of grant revenue

related to an NIH grant that expired on March 31, 2001. This reduction was partially offset by the increase in royalty and new research agreement fee revenue earned in 2002.

Operating expenses

Our research and development expenses totaled \$24.8 million for the fiscal year ended December 31, 2002 compared to \$17.0 million for the fiscal year ended June 30, 2001. The increase of \$7.8 million reflects the expansion of our research and development activities, including increased staff, additional facilities, and expanded activities with third-party collaborators in preclinical studies and clinical trials. Personnel costs rose \$2.7 million between the two periods as our staff count attributable to research and development activities rose from 64 at the beginning of the June 30, 2001 fiscal year to 122 at the end of that period, and continued to rise to a peak of approximately 145 in September 2002 before the impact of a workforce reduction in the fourth quarter of that year. Also contributing to the rise in total research and development expenses between these periods were \$870,000 in higher costs associated with the increased facilities-related costs and validation services associated with the expansion of our research and pilot plant manufacturing facilities, \$1.8 million in additional depreciation and amortization of the same facilities, \$1.1 million in higher costs for materials consumed to meet the rising demand for production of research and clinical grade quantities of our AAV vectors, and \$1.7 million in higher payments to third parties for expansion of our collaborative preclinical studies, primarily with respect to Parkinson's disease, and costs associated with the treatment of increased numbers of patients in our clinical trial for Coagulin-B. These increases were partially offset by a reduction in recruiting expenses, license fees paid, and other support costs of approximately \$450,000.

Our general and administrative expenses were \$8.1 million for the year ended December 31, 2002 compared to \$6.8 million for the fiscal year ended June 30, 2001. The \$1.3 million increase was due to \$520,000 in higher personnel-related costs, \$230,000 in higher legal fees related to litigation, \$250,000 in higher corporate expenses, including insurance and information services, and \$780,000 in higher depreciation and facilities-related expenses associated with our increased office space. These increases were partially offset by a decrease of approximately \$390,000 in professional services.

Interest Income

Interest income totaled \$5.6 million for the fiscal year ended December 31, 2002 compared to \$7.9 million for the fiscal year ended June 30, 2001. The \$2.3 million decrease in interest income was primarily due to the decline in market interest rates between the two periods, as well as the decrease in outstanding cash and securities balances since resources have been used to fund our on-going operations and finance construction for additional research and development facilities.

Comparison of the fiscal years ended June 30, 2001 and 2000

Revenue

Total revenue for the fiscal years ended June 30, 2001 and 2000 was \$116,000 and \$58,000, respectively. All revenue for the 2000 fiscal year was grant revenue. The increase in total revenue between the two fiscal years was due to the \$28,000 increase in grant revenue received, caused by the irregular timing of milestones in connection with the grant, and the receipt of \$30,000 in connection with the royalty license agreement entered into during the fiscal year ended June 30, 2001.

Operating expenses

Our research and development expenses for the fiscal years ended June 30, 2001 and 2000 were \$17.0 million and \$8.0 million, respectively. The increase of \$9.0 million in total research and development expenses was primarily related to a significant increase in personnel and new research and production facilities placed in operation, as well as higher consumption of materials used to support the progress of our initial clinical trial for Coagulin-B and develop scalable manufacturing processes to meet the capacity of our pilot plant. Our staff almost doubled between June 2000 and June 2001 and we significantly increased our premises under lease. We entered into a sublease for approximately 22,000 additional square feet in March 2000, when we began construction of our pilot

plant and other research facilities, and added additional space to support our research and development activities when we entered into a lease of a second building adjacent to our original facility in December 2000.

Our general and administrative expenses were \$6.8 million and \$4.5 million, respectively, for the fiscal years ended June 30, 2001 and 2000, an increase of \$2.3 million. This increase was primarily due to the impact of higher personnel and recruitment costs, higher legal costs associated with intellectual property activities, and increases in other corporate expenses such as insurances and property taxes.

In the fiscal year ended June 30, 2000, we incurred in-license fees of \$5.0 million in connection with new agreements to in-license certain patents that we use in our research and development efforts. The expense included cash payments to licensors of approximately \$1.8 million and a non-cash charge for a warrant issued to a licensor that was valued at approximately \$3.2 million. These expenses were primarily initiation fees, and are not predictive of initial in-license fees to be incurred in future periods. No such in-license fees have been incurred since.

Interest Income

Interest income totaled \$7.9 million and \$2.5 million for the fiscal years ended June 30, 2001 and 2000, respectively. Between November 2000 and June 2001, we raised approximately \$102.7 million through equity transactions, which included sales of stock pursuant to a public offering in November 2000 and a collaborative agreement with Bayer Corporation in February 2001, and on-going exercises of previously issued warrants and options. These funds were included in our investment portfolio and were the dominant reason for the \$5.4 million in higher interest income.

Research and development expenses

Our research and development expenses can be divided into two primary functions, representing costs to support research and preclinical development and costs to support clinical development for 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. During the years ended December 31, 2002 and 2001, our programs in the research and preclinical phase were directed primarily at potential treatments of hemophilia, Parkinson's disease and congestive heart failure. Clinical development costs include activities associates with maintaining regulated and controlled processes, manufacturing vector for use in human clinical trials, and supporting patient accrual and patient administration within clinical trials. During the years ended December 31, 2002 and 2001, our programs in the clinical development phase were directed at the potential treatment of hemophilia B and preparing for filing an IND for a potential treatment for Parkinson's disease.

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

	Year Ended December 31, 2002	(Unaudited) Twelve Months Ended December 31, 2001	Six Months Ended December 31, 2001	Fiscal Year Ended June 30, 2001	Fiscal Year Ended June 30, 2000
Research and preclinical development	\$14,266	\$12,050	\$ 6,024	\$10,010	\$6,112
Clinical development	<u>10,543</u>	<u>10,283</u>	<u>5,441</u>	<u>7,031</u>	<u>1,841</u>
Total research and development expenses	<u>\$24,809</u>	<u>\$22,333</u>	<u>\$11,465</u>	<u>\$17,041</u>	<u>\$7,953</u>

Because a significant percentage of our research and development resources are dedicated to activities that focus on fundamental AAV vector characteristics and production and administration techniques, which are considered platform technologies that may be used in many different product applications, the majority of our costs are not directly attributed to individual projects. 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.

The \$2.2 million increase in research and preclinical development expenses for the year ended December 31, 2002 over the unaudited twelve-month period ended December 31, 2001 was due to increases in personnel costs of \$830,000, depreciation and amortization for new facilities placed in service during the year of \$640,000, and payments to third-party collaborators of \$950,000, primarily to support the progress in our preclinical animal studies for the treatment of Parkinson's disease partially offset by a reduction of \$200,000 in other costs. The \$4.2 million increase in research and preclinical development expenses between the year ended December 31, 2002 and the fiscal year ended June 30, 2001 reflected the same progress and expansion of our programs that occurred in 2002 as compared to the earlier period. This increase included \$1.5 million in higher personnel costs due to higher staff levels, \$980,000 in higher depreciation for new facilities placed in service in 2002, \$1.3 million in higher payments to outside collaborators, primarily in connection with the expansion of our Parkinson's disease program, and \$400,000 for increased consumption of materials in the course of our work. The \$3.9 million increase between the fiscal years ended June 30, 2001 and 2000, primarily reflect the early stages of the diversification of our research programs and efforts to enhance our production techniques which led to the significant increase in staff levels, facilities used, and outside collaborations described previously.

Clinical development expenses increased \$260,000 for the year ended December 31, 2002 over the unaudited twelve-month period ended December 31, 2001, and included approximately \$285,000 in higher personnel costs, \$520,000 in higher clinical payments associated with treating a larger number of patients in 2002, \$290,000 in higher depreciation for new facilities, and \$320,000 in higher validation services related to our pilot plant. These increases were partially offset by a decrease of \$490,000 for materials used to make our AAV vector due to the adoption of improvements that made our production processes more efficient, \$320,000 in lower license milestone payments, and \$360,000 for recruiting and other costs. Because our clinical development programs expanded significantly during 2001, the total expenses for the year ended December 31, 2002, which included a full twelve months of mature operations, were \$3.5 million higher than the total expenses for the fiscal year ended June 30, 2001, while much of the growth was still in progress. The higher costs in 2002 include \$1.1 million in higher personnel expenses, \$400,000 in higher clinical payments, \$450,000 in higher validation services costs, \$730,000 in higher depreciation costs and \$750,000 in higher materials costs. In the same manner, the \$5.2 million increase in costs for the fiscal year ended June 30, 2001 over the fiscal year ended June 30, 2000 reflected the rise in costs during the very early stages of our first Coagulin-B clinical trial as we began to add staff and facilities to establish greater manufacturing capacity.

Adoption of Recently Issued Accounting Standards

In November 2002, the FASB issued FASB Interpretation No. 45, "*Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*," and interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34. FIN 45 clarifies the requirements of FAS 5, "*Accounting for Contingencies*," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 are effective for financial statements of periods that end after December 15, 2002. However, the provision for the initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002. This interpretation does not currently have any impact on our financial position, results of operations or disclosure.

In December 2002, the FASB issued Statement No. 148, "*Accounting for Stock-Based Compensation — Transition and Disclosure*." FAS 148 amends FAS 123 "*Accounting for Stock-Based Compensation*" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based

employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB 25 to account for employee and director stock options. The impact of FAS 148 will be limited to the interim reporting of the effects on net income and net loss per share if we accounted for stock-based compensation under FAS 123.

In January 2003, the FASB issued FASB Interpretation No. 46, "*Consolidation of Variable Interest Entities.*" FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "*Consolidated Financial Statements,*" to certain entities in which equity investors 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. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applied in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. We do not believe there will be a material effect upon our financial condition or results of operations from the adoption of FIN 46.

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. Since our initial public offering in May 1996, we have completed private placements of our common stock and warrants to purchase our common stock, raising net proceeds of approximately \$57.6 million, and two public offerings raising net proceeds of approximately \$113.7 million. In addition, we also completed a sale of common stock to Bayer AG in February 2001 pursuant to a collaboration agreement that raised net proceeds of \$15.0 million. Also, during the period since May 1996, as a result of exercises of warrants and options to purchase our common stock, we raised an additional \$12.9 million. 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, 2002, we had cash, cash equivalents, available for sale securities, and restricted investments, including accrued interest, of approximately \$120.2 million, compared to \$149.6 million at December 31, 2001. Of the amount at December 31, 2002, \$11.5 million was pledged to secure our line of credit and equipment operating leases.

In October 2002, we announced the implementation of a revised strategic plan to reduce our projected cash burn rate and extend the anticipated life of our existing financial resources. As a result, we reduced our workforce

by approximately 28%, or 42 positions, primarily in operations and administration. The total costs of implementing the staff reduction was approximately \$500,000 in compensation, extended health benefits and outplacement training. All of these costs were incurred prior to December 31, 2002, and will not impact future periods.

The following are contractual commitments at December 31, 2002 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>2-3 years</u>	<u>4-5 years</u>	<u>After 5 years</u>
Revolving line of credit	\$ 8,000	\$ —	\$ 8,000	\$ —	\$ —
Operating leases	17,892	2,343	5,089	5,198	5,262
Research funding for third-parties	876	876	—	—	—
Total Contractual Commitments	<u>\$26,768</u>	<u>\$3,219</u>	<u>\$13,089</u>	<u>\$5,198</u>	<u>\$5,262</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, 2002, the average annual rate of interest charged on the borrowing was approximately 3.11%. 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, 2002, 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, 2002, 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, 2002, 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, was \$11.5 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, 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 fiscal year ended December 31, 2002, net cash used in operating activities was \$24.2 million compared to \$16.1 million for the comparable twelve-month period ended December 31, 2001. This change in cash used in operating activities between the two periods included approximately \$4.3 million in higher cash expenditures in the 2002 period, primarily due to increased staff costs and payments to third-party collaborators to support preclinical and clinical activities as discussed above, and approximately \$3.8 million in lower interest income in the 2002 period to offset operating expenses.

During the six-month transition period ended December 31, 2001, net cash of approximately \$8.3 million was used in operating activities versus \$7.4 million for the unaudited comparable six-month period ended December 31, 2000. The increase of \$900,000 reflected \$2.2 million in higher expenses related to higher staff levels, additional facilities under lease, and an increase in general consumption of materials for the production of greater quantities of our AAV vectors to support our research and clinical activities. This increase in expenses was partially offset by an increase of \$1.4 million in interest income in the 2001 period that reduced the net cash used by operating activities.

Net cash used in operating activities during the fiscal year ended June 30, 2001 was \$15.2 million, approximately \$9.0 million less than the fiscal year ended December 31, 2002. This difference was primarily due

to higher expenses in the 2002 period related to the growth in our staff and facilities, increased consumption of materials to meet the growing demand for production of our AAV vectors, and higher payments to third party collaborators for preclinical research studies and clinical activities, as discussed above. This difference also reflects approximately \$2.3 million in lower interest income in the 2002 period to offset operating expenses.

Net cash used in operating activities was \$11.7 million for the year ended June 30, 2000, approximately \$3.5 million less than the fiscal year ended June 30, 2001. This difference included \$8.8 million in higher expenses related to growth in personnel, facilities and operating activities, partially offset by an increase of \$5.3 million in interest income in the 2001 fiscal year.

During the fiscal year ended December 31, 2002, approximately \$18.0 million and \$860,000, respectively, were provided by investing and financing activities, primarily to fund ongoing operations. The cash provided by investing activities consisted of maturities, net of purchases, of available for sale securities, offset in part by purchases of property, equipment and construction in progress 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 options and warrants during the year.

During the six-month transition period ended December 31, 2001, approximately \$12.3 million and \$3.1 million, respectively, were provided by investing and financing activities, primarily to fund ongoing operations. The cash provided by investing activities consisted of maturities, net of purchases, of available for sale securities, offset in part by purchases of property, equipment and construction in progress 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.

During the fiscal year ended June 30, 2001, approximately \$95.6 million was used in investing activities and consisted mostly of purchases, net of maturities, of available for sale securities, as well as purchases of property, equipment and construction in progress of \$9.7 million and increases in restricted investments of \$3.0 million. These investing activities were primarily funded by the approximately \$103.5 million that was provided by financing activities that were not immediately used to fund ongoing operations. The cash provided by financing activities primarily consisted of proceeds from the issuance of \$86.1 million of our common stock, net of issuance costs, in connection with a public offering in November 2000 and proceeds from the sale of \$15.0 million of our common stock to Bayer AG under the terms of our collaboration agreement in February 2001.

During the fiscal year ended June 30, 2000, approximately \$56.1 million was used in investing activities and consisted mostly of purchases, net of maturities, of available for sale securities, as well as purchases of property, equipment and construction in progress of \$3.4 million and increases in restricted investments of \$4.0 million. These investing activities were primarily funded by the approximately \$78.2 million that was provided by financing activities that were not immediately used to fund ongoing operations. The cash provided by financing activities primarily consisted of proceeds from the issuance of \$64.8 million of our common stock and warrants to purchase our common stock, net of issuance costs, in connection with a private placement in October and November 1999 and a public offering in April 2000. The remaining cash provided by financing activities consisted of \$10.0 million from the exercise of options and warrants during the year and \$4.0 million in additional borrowings from our revolving line of credit.

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 with the implementation of our revised strategic plan, our cash burn rate will be approximately \$25 million in 2003, and we anticipate that our capital resources at December 31, 2002 will be adequate to fund our future needs over the next four to five years. However, this forward-looking statement is based upon our current plans and assumptions, 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. 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, 2002, consisted of approximately 84% fixed-rate securities and 16% variable-rate securities.

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, 2002 levels, we estimate that the fair value of our securities portfolio would decline by approximately \$1.3 million. Our estimated exposure at December 31, 2002 is lower than our estimated \$1.8 million exposure at December 31, 2001 due to the reduction in size of the overall portfolios and the reduction in average aggregate duration of the instruments. 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. 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, 2002, the average annual rate of interest charged on the borrowing was approximately 3.11%.

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 year ended December 31, 2002, the transition period ended December 31, 2001, and the fiscal year ended June 30, 2001 are set forth under Note 11 of our financial statements.

	<u>Page</u>
Report of Ernst & Young LLP, Independent Auditors	38
Balance Sheets	39
Statements of Operations	40
Statements of Stockholders' Equity	41
Statements of Cash Flows	46
Notes to Financial Statements	48

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, 2002 and 2001, and the related statements of operations, stockholders' equity and cash flows for the year ended December 31, 2002, for the six months ended December 31, 2001, for each of the two fiscal years in the period ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2002. 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, 2002 and 2001, and the results of its operations and its cash flows for the year ended December 31, 2002, for the six months ended December 31, 2001, for each of the two fiscal years in the period ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

Palo Alto, California
January 31, 2003

AVIGEN, INC.
(a development stage company)

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

	December 31,	
	2002	2001
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,879	\$ 13,211
Available for sale securities	99,845	125,043
Restricted investments	11,500	10,000
Accrued interest	993	1,335
Prepaid expenses and other current assets	458	398
Total current assets	120,675	149,987
Property and equipment, net	18,726	16,813
Deposits and other assets	1,285	1,609
Total assets	\$ 140,686	\$168,409
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and other accrued liabilities	\$ 1,156	\$ 1,643
Accrued compensation and related expenses	621	858
Total current liabilities	1,777	2,501
Long-term loan payable	8,000	8,000
Deferred rent	852	558
Commitments		
Stockholders' equity		
Preferred stock, \$0.001 par value, 5,000,000 shares authorized, none issued and outstanding, in 2002 and 2001	—	—
Common stock, \$0.001 par value, 50,000,000 shares authorized at December 31, 2002 and 2001, and 20,100,546 and 19,966,334 shares issued and outstanding at December 31, 2002 and 2001, respectively .	20	20
Additional paid-in capital	235,337	234,260
Accumulated other comprehensive income	1,582	2,213
Deficit accumulated during development stage	(106,882)	(79,143)
Total stockholders' equity	130,057	157,350
Total liabilities and stockholders' equity	\$ 140,686	\$168,409

See accompanying notes.

AVIGEN, INC.
(a development stage company)

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

	Year Ended December 31, 2002	Six Months Ended December 31, 2001 2000		Year Ended June 30, 2001 2000		October 22, 1992 (inception) Through December 31, 2002
		(unaudited)				
Grant and other revenue	\$ 57	\$ 8	\$ 30	\$ 116	\$ 58	\$ 787
Operating expenses:						
Research and development	24,809	11,465	6,173	17,041	7,953	86,356
General and administrative	8,146	3,957	3,159	6,761	4,516	36,424
In-license fees	—	—	—	5,034	5,034	
	<u>32,955</u>	<u>15,422</u>	<u>9,332</u>	<u>23,802</u>	<u>17,503</u>	<u>127,814</u>
Loss from operations	(32,898)	(15,414)	(9,302)	(23,686)	(17,445)	(127,027)
Interest expense	(278)	(204)	(38)	(180)	(129)	(1,921)
Interest income	5,569	4,316	2,860	7,907	2,548	22,123
Other (expense) income, net	(132)	(17)	(4)	(55)	(13)	(57)
Net loss	<u>\$ (27,739)</u>	<u>\$ (11,319)</u>	<u>\$ (6,484)</u>	<u>\$ (16,014)</u>	<u>\$ (15,039)</u>	<u>\$ (106,882)</u>
Basic and diluted net loss per share	<u>\$ (1.38)</u>	<u>\$ (0.57)</u>	<u>\$ (0.37)</u>	<u>\$ (0.85)</u>	<u>\$ (1.03)</u>	
Shares used in basic and diluted net loss per share calculation	<u>20,080,998</u>	<u>19,959,941</u>	<u>17,745,484</u>	<u>18,730,437</u>	<u>14,557,999</u>	

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY

Period from October 22, 1992 (inception) through December 31, 2002
(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, 2002
(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 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, 2002
(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, 2002
(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 \$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, 2002
(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	—	<u>1,120</u>
Comprehensive loss	—	—	—	—	—	—	—	—	—	<u>(14,894)</u>
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	—	<u>1,173</u>
Comprehensive loss	—	—	—	—	—	—	—	—	—	<u>(10,146)</u>
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 gain on available-for-sale securities ..	—	—	—	—	—	—	—	(631)	—	<u>(631)</u>
Comprehensive loss	—	—	—	—	—	—	—	—	—	<u>(28,370)</u>
Balance at December 31, 2002	<u>—</u>	<u>\$—</u>	<u>20,100,546</u>	<u>\$20</u>	<u>—</u>	<u>\$—</u>	<u>\$235,337</u>	<u>\$1,582</u>	<u>\$(106,882)</u>	<u>\$130,057</u>

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31, 2002	Six Months Ended December 31,		Year Ended June 30,		Period from October 22, 1992 (inception) through December 31, 2002
	2001	2000	2001	2000		
(unaudited)						
Operating activities						
Net loss	\$ (27,739)	\$(11,319)	\$ (6,484)	\$ (16,014)	\$ (15,039)	\$(106,882)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization of fixed assets	3,136	1,167	309	1,203	394	8,727
Amortization of deferred compensation	—	—	—	—	5	164
Amortization of warrants issued in connection with the extension of the building lease	217	109	124	217	72	615
Amortization of deferred rent expense	294	167	—	278	—	739
Common stock, warrants, and stock options issued for services	217	179	209	336	89	1,410
Warrants issued for patent license	—	—	—	—	3,182	3,182
Changes in operating assets and liabilities:						
Accrued interest	342	1,066	(1,104)	(1,462)	(755)	(809)
Prepaid expenses and other current assets	(60)	178	—	(575)	—	(642)
Deposits and other assets	107	26	60	408	(636)	(236)
Accounts payable, other accrued liabilities and accrued compensation and related expenses	(724)	128	(468)	449	988	2,189
Net cash used in operating activities	(24,210)	(8,299)	(7,354)	(15,160)	(11,700)	(91,543)
Investing activities						
Purchases of property and equipment and construction in progress	(5,049)	(5,492)	(4,540)	(9,666)	(3,369)	(27,156)
Increase in restricted investments	(1,500)	(3,000)	(3,000)	(3,000)	(4,000)	(11,500)
Purchases of available for sale securities	(82,242)	(60,817)	(64,704)	(177,757)	(146,233)	(540,581)
Maturities available for sale securities	106,809	81,592	37,051	94,825	97,497	442,320
Net cash provided by (used in) investing activities	18,018	12,283	(35,193)	(95,598)	(56,105)	(136,917)
Financing activities						
Proceeds from long-term obligations	—	3,000	1,000	1,000	4,000	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)	(572)	(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	860	135	859	1,640	9,962	12,833
Proceeds from issuance of common stock, net of issuance costs and repurchases	—	—	86,099	101,086	64,831	205,619
Net cash provided by financing activities	860	3,135	87,765	103,489	78,221	236,339

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS (Continued)
(in thousands)

	Year Ended December 31, 2002	Six Months Ended December 31,		Year Ended June 30,		Period from October 22, 1992 (inception) through December 31, 2002
		2001	2000	2001	2000	
				(unaudited)		
Net (decrease) increase in cash and cash equivalents	\$ (5,332)	\$ 7,119	\$45,218	\$ (7,269)	\$10,416	\$7,879
Cash and cash equivalents, beginning of period .	<u>13,211</u>	<u>6,092</u>	<u>13,361</u>	<u>13,361</u>	<u>2,945</u>	<u>—</u>
Cash and cash equivalents, end of period	<u>\$ 7,879</u>	<u>\$13,211</u>	<u>\$58,579</u>	<u>\$ 6,092</u>	<u>\$13,361</u>	<u>\$7,879</u>
Supplemental disclosures						
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 Building lease	\$ —	\$ —	\$ —	\$ —	\$ 1,738	\$1,738
Deferred compensation related to stock option grants	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 164
Purchase of property and equipment under capital lease financing	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 226
Cash paid for interest	\$ 278	\$ 204	\$ 38	\$ 180	\$ 129	\$1,428

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 for the purpose of development and commercialization of gene-based therapeutic products. Our activities since inception 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. In accordance with statement of Financial Accounting Standards (FAS) No. 131, we have determined that we operate in a single segment.

We 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 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, government agencies, 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 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.

At December 31, 2002 and 2001, \$11.5 million and \$10.0 million, respectively, were classified as restricted investments, representing the combined aggregate portion of our portfolio for available for sale securities that were pledged in connection with our financing arrangement and equipment operating leases.

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 is provided over the estimated useful lives of the respective assets, which range from three to seven years, using the straight-line method.

Leasehold improvements are amortized over the remaining life of the lease or their estimated useful lives, whichever is shorter, using the straight-line method.

Revenue Recognition

Grant revenue is recorded in the period in which the revenue is earned as defined by the grant agreement. Since our inception, our revenue has consisted primarily of grant revenue, which includes amounts earned pursuant to reimbursements under government grants. Between inception and December 31, 2002, all reimbursements under government grants have come from the National Institutes of Health.

Royalty revenue from license agreements is recorded as earned in accordance with the contract terms when third-party results can be reliably determined and collectibility is reasonably assured. During 2002, we recorded \$19,000 in royalty revenue in connection with sales from a third party of products that utilize our AAV technologies. 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.

Comprehensive Loss

Comprehensive loss is comprised of net loss and unrealized holding gains and losses on available-for-sale securities, in accordance with Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income." Comprehensive loss is shown in the statement of stockholders' equity.

Research and Development Expenses

Research and development expenses 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 independent, as well as collaborative, research and development. These costs are charged to expense as incurred.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

Income Taxes

Income taxes are accounted for in accordance with Statement of Financial Accounting Standards No. 109 "Accounting for Income Taxes" ("FAS 109"). Under the asset and liability method of FAS 109, 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. As such, we cannot anticipate taxable income as outlined in FAS 109. Therefore, the deferred tax asset has been fully offset by a valuation allowance.

Basic and Diluted Net Loss Per Share

Basic net loss per share is computed using the weighted-average number of common shares outstanding during the year. Securities that could potentially dilute basic earnings per share in the future, but that have been excluded from the diluted net loss per share computation because their inclusion would have been anti-dilutive, were as follows:

	<u>Year Ended</u> <u>December 31, 2002</u>	<u>Six Months Ended</u> <u>December 31, 2001</u>	<u>Year Ended June 30,</u>	
			<u>2001</u>	<u>2000</u>
Stock options outstanding	4,144,488	4,009,817	3,905,559	2,355,313
Warrants to purchase common stock.....	<u>1,324,322</u>	<u>1,423,907</u>	<u>1,433,862</u>	<u>1,613,366</u>
	<u>5,468,810</u>	<u>5,433,724</u>	<u>5,339,421</u>	<u>3,968,679</u>

Impairment of Long-Lived Assets

Effective January 1, 2002, we adopted FAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." FAS 144 supersedes FAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of." We review long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. 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. The reclassifications had no impact on our financial position or results of operations.

Recently Issued Accounting Standards

In November 2002, the FASB issued FASB Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others," and interpretation of FASB Statements No. 5, 57, and 107 and rescission of FASB Interpretation No. 34. FIN 45 clarifies the requirements of FAS 5, "Accounting for Contingencies," relating to the guarantor's accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 are effective for financial statement of periods that end after December 15, 2002. However, the provision for the initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002. This interpretation does not currently have any impact on our financial position, results of operations or disclosure.

In December 2002, the FASB issued Statement No. 148, "Accounting for Stock-Based Compensation — Transition and Disclosure." FAS 148 amends FAS 123 "Accounting for Stock-Based Compensation" to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, FAS 148 amends the disclosure requirements of FAS 123 to require more prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The additional disclosure

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

requirements of FAS 148 are effective for fiscal years ending after December 15, 2002. We have elected to continue to follow the intrinsic value method of accounting as prescribed by APB 25 to account for employee and director stock options. See below in the "Stock Options and Stock Purchase Plan" note for the disclosures required by FAS 148.

In January 2003, the FASB issued FASB Interpretation No. 46, "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors 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. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applied in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. We do not believe there will be a material effect upon our financial condition or results of operations from the adoption of the provision of FIN 46.

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 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 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 share pursuant to FAS 123 is not likely to be representative of the effects on net loss and loss per 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.

No stock-based employee compensation is reflected in our net loss as all options granted had an exercise price equal to the market value of our underlying common stock on the date of grant. The following table illustrates the effect on our net loss and loss per share if we had applied the fair value recognition provisions of FAS 123 to our stock-based employee compensation:

	<u>Year ended December 31,</u>	<u>Six Months Ended December 31,</u>	<u>Year Ended June 30</u>	
	<u>2002</u>	<u>2001</u>	<u>2001</u>	<u>2000</u>
Net loss — as reported	\$(27,739)	\$(11,319)	\$(16,014)	\$(15,039)
Less: Total stock-based employee compensation expense determined under the fair value based method for all awards	<u>(14,968)</u>	<u>(8,918)</u>	<u>(12,340)</u>	<u>(2,206)</u>
Net loss — pro forma	<u>\$(42,707)</u>	<u>\$(20,237)</u>	<u>\$(28,354)</u>	<u>\$(17,245)</u>
Net loss per share basic and diluted — as reported	<u>\$ (1.38)</u>	<u>\$ (0.57)</u>	<u>\$ (0.85)</u>	<u>\$ (1.03)</u>
Net loss per share basic and diluted — pro forma	<u>\$ (2.13)</u>	<u>\$ (1.01)</u>	<u>\$ (1.51)</u>	<u>\$ (1.18)</u>

During the preparation of our notes to the financial statements for the year ended December 31, 2002, we determined that the calculation of the total stock-based employee compensation expense determined under the fair value based method for the six months ended December 31, 2001 and the fiscal year ended June 30, 2001, as reported

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

in those respective years, inadvertently omitted certain options which vested during those periods. Accordingly, the amounts of the total stock-based employee compensation expense determined under the fair value method reported under SFAS 123 for the six months ended December 31, 2001 and the year ended June 30, 2001 presented in the table above have been revised, resulting in increases in the previously reported amounts of \$4.9 million and \$3.9 million, respectively. This revision had no effect on our previously reported results of operations or financial condition.

For equity awards to non-employees, including lenders, lessors and consultants, we apply the Black-Scholes method to determine the fair value of such investments. The options and warrants granted to non-employees are re-measured as they vest and the resulting value is recognized as an expense over the period of services received or the term of the related financing.

2. Available for Sale Securities

The following is a summary of cash 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	<u>23,307</u>	<u>301</u>	<u>—</u>	<u>23,608</u>
Total	117,642	1,593	(11)	119,224
Amounts reported as Cash and cash equivalents	<u>7,879</u>	<u>—</u>	<u>—</u>	<u>7,879</u>
Available for sale securities and restricted investments	<u>\$109,763</u>	<u>\$1,593</u>	<u>\$(11)</u>	<u>\$111,345</u>

The weighted average maturity of investments held at December 31, 2002 was 421 days, with \$56.3 million carrying a weighted average maturity of less than twelve months, and \$62.9 million carrying a weighted average maturity between one and three years.

The following is a summary of available for sale securities as of December 31, 2001 (in thousands):

	<u>Cost</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Fair Value</u>
Cash	\$ 10,571	\$ —	\$ —	\$ 10,571
Corporate debt securities	75,402	1,133	(39)	76,496
Federal agency obligations	45,732	996	(29)	46,699
Asset-backed and other securities	<u>14,336</u>	<u>174</u>	<u>(22)</u>	<u>14,488</u>
Total	146,041	2,303	(90)	148,254
Amounts reported as Cash and cash equivalents	<u>13,211</u>	<u>—</u>	<u>—</u>	<u>13,211</u>
Available for sale securities and restricted investments	<u>\$132,830</u>	<u>\$2,303</u>	<u>\$(90)</u>	<u>\$135,043</u>

Net realized gains were approximately \$820,000 for the year ended December 31, 2002, \$650,000 for the six months ended December 31, 2001 and were not material for the years ended June 30, 2001 and 2000.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

3. Property and Equipment

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

	December 31,	
	2002	2001
Leasehold improvements	\$18,450	\$ 9,428
Laboratory equipment	6,406	5,675
Furniture and fixtures.....	2,011	1,702
	26,867	16,805
Less accumulated depreciation and amortization	(8,141)	(5,056)
	18,726	11,749
Construction in progress	—	5,063
Property and equipment, net.....	<u>\$18,726</u>	<u>\$16,813</u>

Total depreciation and amortization expense for the fiscal year ended December 31, 2002, the six-month transition period ended December 31, 2001, and the fiscal years ended June 30, 2001 and 2000, was \$3.1 million, \$1.2 million, \$1.2 million, and \$0.4 million, respectively.

In the normal course of business, we have entered into contracts for the construction and improvement of our research and manufacturing facilities. While these contracts are typically cancelable, we expect the work described in such contracts to be completed and all amounts paid when due. At December 31, 2002, there were no longer any construction projects in progress, and all completed leasehold improvements were placed in service before such date.

4. 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 million through June 1, 2003. This revolving line of credit 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 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, 2002 and 2001, 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, 2002.

5. 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.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

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.

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 during 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.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

At December 31, 2002, 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
101,754	\$ 2.47 – \$ 3.67	1998	2003
209,903	\$ 4.19 – \$ 6.09	1998	2003
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>1,324,322</u>	\$ 2.47 – \$82.00		2003 – 2005

Shares Reserved for Future Issuance

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

	<u>December 31, 2002</u>
Stock options outstanding	4,144,488
Stock options available for grant	4,571,323
Warrants to purchase common stock	1,324,322
Shares available for Employee Stock Purchase Plan	<u>360,000</u>
	<u>10,400,133</u>

6. 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 and adopted the 1996 Equity Incentive Plan. At December 31, 2002, 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, as of December 31, 2002, 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, 2002, there were options to purchase approximately 1,546,000 shares outstanding under the 1996 Plan and approximately 1,339,000 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,

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

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, 2002, there were options to purchase approximately 1,860,000 shares outstanding under the 2000 Plan and approximately 3,140,000 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, 2002, 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. The shares vested in equal monthly installments over a period of three years beginning with the grant date. At December 31, 2002, 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. As of December 31, 2002, nonqualified options to purchase approximately 207,000 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 187,000 shares remained outstanding. At December 31, 2002, there were approximately 93,000 shares available for grant under the Directors' Plan.

AVIGEN, INC.
(a development stage company)

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 June 30, 1999.....	1,856,700	\$ 3.10
Granted	980,344	32.04
Canceled	(42,693)	4.16
Exercised	<u>(439,038)</u>	3.49
Outstanding at June 30, 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.....	<u>4,144,488</u>	14.31

The following table summarizes information with regard to total stock options outstanding under all stock option plans at December 31, 2002:

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>		<u>Options Exercisable</u>		<u>Weighted-Average Exercise Price</u>
	<u>Number of Shares</u>	<u>Weighted-Average Remaining Contractual Life</u>	<u>Weighted-Average Exercise Price</u>	<u>Number of Shares</u>	
\$ 0.44 – \$ 0.49	525,406	2.56	\$ 0.49	525,406	\$ 0.49
0.71 – 4.00	268,367	4.68	2.91	268,367	2.90
5.00 – 6.83	540,707	7.41	8.47	306,277	5.72
6.96 – 8.53	542,273	9.44	8.06	48,497	8.34
8.62 – 11.05	177,073	9.11	9.81	39,493	9.81
11.20 – 14.63	1,043,953	8.20	14.48	380,559	14.42
14.77 – 20.06	140,080	7.90	17.40	72,899	17.37
21.47 – 28.00	94,655	7.47	25.58	66,155	25.22
29.00 – 29.00	242,983	7.38	29.00	138,568	29.00
30.14 – 38.19	505,398	7.46	37.38	303,020	37.22
\$38.88 – 56.00	63,593	7.47	44.75	43,448	44.87
	<u>4,144,488</u>	7.18	14.31	<u>2,192,689</u>	13.33

The numbers of options exercisable at December 31, 2001, June 30, 2001 and 2000 were 1,569,789, 1,217,656, and 875,787 respectively, with a weighted average exercise price of \$12.13, \$9.25, and \$2.31 respectively.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

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 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 with the following assumptions:

	Year ended December 31, 2002	Six months ended December 31, 2001	Year ended June 30,	
			2001	2000
Expected volatility.....	2.0901	2.2492	2.3453	2.5884
Risk free interest rate.....	4.00%	4.50%	5.50%	6.50%
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 require the input of highly subjective assumptions, including the expected stock price volatility. Because our employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in our opinion the existing models do not necessarily provide a reliable single measure of the fair value of our employee stock options.

7. 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 year ended December 31, 2002 and the six months ended December 31, 2001 were approximately \$134,000 and \$65,000, respectively.

8. 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.

9. Commitments

We lease our laboratory, manufacturing, and office facilities under multiple non-cancelable operating lease agreements, which expire at various times through November 2010. Under one operating lease, we have pledged \$2.0 million of our available for sale securities to secure a letter of credit required under the terms of the lease and under a separate operating lease, we have pledged \$1.5 million of our investment portfolio as collateral for the lease. These amounts are included in restricted investments on the balance sheet at December 31, 2002 and December 31, 2001. 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.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

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

	<u>Operating Lease</u>
Year ending December 31:	
2003.....	\$ 2,343
2004.....	2,503
2005.....	2,586
2006.....	2,654
2007.....	2,544
Thereafter	<u>5,262</u>
Total non-cancelable lease payments.....	<u>\$17,892</u>

Rent expense for the year ended December 31, 2002, six months ended December 31, 2001, and years ended June 30, 2001 and 2000, was \$2,308,668, \$1,147,462, \$1,923,000, and \$551,000, respectively.

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, 2002 the estimated costs related to these commitments totaled \$876,000, all of which is expected to be paid within the next twelve to eighteen months.

10. Income Taxes

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

	<u>December 31, 2002</u>	<u>December 31, 2001</u>
Net operating loss carryforward	\$ 36,700	\$ 27,500
Research and development credit carryforwards	5,300	3,800
Capitalized research and development	5,200	3,700
Capitalized patents	1,300	1,700
Other	<u>600</u>	<u>400</u>
Gross deferred tax assets	49,100	37,100
Unrealized gain on investment	(600)	(800)
Valuation allowance	<u>(48,500)</u>	<u>(36,300)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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 \$12,200,000, \$4,620,000, and \$8,860,000 for the year ended December 31, 2002, six months ended December 31, 2001 and the year ended June 30, 2001, respectively.

Deferred tax assets related to carryforwards at December 31, 2002 include approximately \$1,300,000 associated with stock option activity for which any subsequently recognized tax benefits will be credited directly to stockholders' equity.

At December 31, 2002, we have net operating loss carryforwards for federal and state income tax purposes of approximately \$105,000,000 and \$16,000,000, respectively, which expire in years ended December 31, 2005 through December 31, 2022. At December 31, 2002, we have research and development credit carryforwards for federal tax purposes of approximately \$3,500,000, which expire in fiscal years ended December 31, 2009 through December 31, 2022.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

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.

11. Condensed Quarterly Financial Information (Unaudited)

	Year ended December 31, 2002			
<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)
			Six months ended December 31, 2001	
<u>(amounts in thousands except per share data)</u>			<u>First Quarter</u>	<u>Second Quarter</u>
Total revenue			\$ —	\$ 8
Net loss			(5,392)	(5,927)
Net loss per share basic and diluted			\$ (0.27)	\$ (0.30)
			Year ended June 30, 2001	
<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	\$ —	\$ —	\$ 86
Net loss	(3,052)	(3,432)	(4,896)	(4,634)
Net loss per share basic and diluted	(0.18)	(0.19)	(0.25)	(0.23)

12. Subsequent Events — (Unaudited)

Collaboration Milestone Payment

In March 2003, we received a \$2.5 million milestone payment from Bayer Corporation under the terms of our collaboration agreement in recognition of the clinical progress to date in our Coagulin-B liver trial. This milestone payment is expected to be recorded as revenue in 2003.

Legal proceedings

On February 12, 2003, we settled a lawsuit that we had initiated on February 21, 2002 in the United States District Court for the Northern District of California alleging that Research Corporation Technologies, Inc. (RCT), engaged in a breach of contract as a result of RCT’s failure to disclose material information to the Patent and Trademark Office in connection with the prosecution of a U.S. patent application which subsequently issued as a U.S. patent. In May 1992, we entered into a license agreement with RCT for rights to the invention that was described by this patent application and other related patent applications. On June 20, 2002, RCT filed an answer to the complaint and a counterclaim alleging our failure to pay royalties under the license agreement and seeking \$100,000 in damages. The parties agreed to a dismissal of both our complaint and RCT’s counterclaim with prejudice except that the dismissal does not affect our rights to assert unenforceability and/or invalidity of any RCT patent, including U.S. Patent No. 6,261,834 (and any co-pending applications, continuations, continuations in part, reexaminations, reissues, and divisionals thereof, and any foreign counterparts thereof, if applicable) in any future proceeding or suit.

AVIGEN, INC.
(a development stage company)

NOTES TO FINANCIAL STATEMENTS — (Continued)

As of March 15, 2003, we were not involved in any legal proceedings. While we may become subject to legal proceedings in the ordinary course of business, we are not currently aware of any matters that might require us to incur costs to resolve such matters that could have a material adverse effect on our financial position, results of operations, or cash flows.

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

None.

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 Company" at the end of Part I of this Annual Report on Form 10-K. The information required by this Item with respect to Directors 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 2003 Annual Meeting of Stockholders to be held on May 22, 2003 (the "Proxy Statement").

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.

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 below.

EQUITY COMPENSATION PLAN INFORMATION

<u>Plan Category</u>	<u>(a)</u>	<u>(b)</u>	<u>(c)</u>
	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,769,341	\$14.62	1,791,222
Equity compensation plans not approved by security holders	<u>2,375,147</u>	<u>14.07</u>	<u>3,140,101</u>
Total	<u>4,144,488</u>	<u>\$14.31</u>	<u>4,931,323</u>

Avigen's 2000 Equity Incentive Plan (the "2000 Plan") was in effect as of December 31, 2002 and was adopted without the approval of our security holders. The essential features of the 2000 Plan are outlined below:

General

The 2000 Plan provides for the grant of nonqualified stock options, stock bonuses and restricted stock purchase awards (collectively, "stock awards"). To date, we have 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 us or our 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. We 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.

In addition to the 2000 Plan, the Chairman’s Grant was in effect as of December 31, 2002 and was adopted in July 1995 without the approval of our security holders. The Chairman’s Grant is comprised of a single stock option granted to Philip J. Whitcome, Ph.D. to purchase 515,248 shares of our 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. 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, 2002; 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.

Item 13. *Certain Relationships and Related Transactions*

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

Item 14. *Controls and Procedures*

Within 90 days prior to the date of this report, our president and chief executive officer and our chief financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to the Securities Exchange Act Rules 13a-14. Based upon that evaluation, our president and chief executive officer, along with our chief financial officer, concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to Avigen that is required to be disclosed by us in this annual report. There have been no significant changes in our internal controls or in other factors that could significantly affect internal controls subsequent to the date we carried out our evaluation of these controls and there were no corrective actions undertaken with regard to significant deficiencies and material weaknesses.

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, Avigen is responsible for listing the non-audit services approved by Avigen’s Audit

Committee to be performed by Ernst & Young, Avigen's external auditor. Non-audit services are defined as services other than those provided in connection with an audit or a review of the financial statements of Avigen. The Audit Committee has approved our recurring engagements of Ernst & Young for the following non-audit services: (1) preparation of tax returns, and tax advice in preparing for and in connection with such filings; and (2) all work required to be performed by Ernst & Young in connection with preparing and giving consents required to be given in connection with Avigen's filings with the Securities and Exchange Commission.

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.
10.34(15)	Form of Common Stock Warrant Issued In August/September 1998 Private Placement.
10.35(15)	Form of Common Stock Warrant Issues In October 1998 Private Placement.
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

<u>Exhibit Number</u>	<u>Exhibits</u>
10.41(10)	Property Lease Agreement between ARE-1201 Harbor Bay, LLC and Avigen, dated February 29, 2000
10.42(10)	Property Sublease between Lucent Technologies, Inc. and Avigen, dated February 1, 2000
10.43(11, 13)	Agreement between Bayer Corporation and Avigen, dated November 17, 2000
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.
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney (included on the signature pages hereto)
99.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Keys to Exhibits:

- (1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 (No. 333-3220) 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.

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

None.

(c) ***Exhibits***

See Item 15(a) above.

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

See Item 15(a) 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/ JOHN MONAHAN

John Monahan, Ph.D.

President, Chief Executive Officer and Director

Dated: March 26, 2003

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints John Monahan 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/ John Monahan</u> John Monahan, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2003
<u>/s/ Thomas J. Paulson</u> Thomas J. Paulson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2003
<u>/s/ Philip J. Whitcome</u> Philip J. Whitcome, Ph.D.	Chairman of the Board	March 26, 2003
<u>/s/ Zola Horovitz</u> Zola Horovitz, Ph.D.	Director	March 26, 2003
<u>/s/ Yuichi Iwaki</u> Yuichi Iwaki, M.D., Ph.D.	Director	March 26, 2003
<u>/s/ John K.A. Prendergast</u> John K.A. Prendergast, Ph.D.	Director	March 26, 2003
<u>/s/ Daniel Vapnek</u> Daniel Vapnek, Ph.D.	Director	March 26, 2003

CERTIFICATION

I, John Monahan, certify that:

1. I have reviewed this annual report on Form 10-K of Avigen, Inc.;
2. Based on my knowledge, this annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:
 - a) designed such disclosure controls and procedures 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 annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 26, 2003

/s/ JOHN MONAHAN

John Monahan
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 annual 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 annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual 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-14 and 15d-14) for the registrant and have:
 - a) designed such disclosure controls and procedures 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 annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 26, 2003

/s/ THOMAS J. PAULSON

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

BOARD OF DIRECTORS

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

John Monahan, Ph.D.
President, Chief Executive Officer,
Avigen, Inc.

Zola Horovitz, Ph.D.
Pharmaceutical Consultant,
Former Vice President,
Business Development and 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.

SENIOR MANAGEMENT

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

John Monahan, Ph.D.
President, Chief Executive
Officer and Director

Kenneth G. Chahine, Ph.D., J.D.
Chief Operating Officer

Thomas J. Paulson
Vice President, Finance,
Chief Financial Officer and Secretary

Glenn Pierce, Ph.D., M.D.
Vice President, Research and
Clinical 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 regard-
ing 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

The Company's common stock is
traded on the Nasdaq National
Market under the symbol AVGN.
As of March 15, 2003 there were
approximately 162 stockholders of
record of the Company's common
stock and 20,124,765 shares of com-
mon stock outstanding. Avigen has
not paid dividends on its common
stock since the Company's inception,
and does not anticipate paying any
dividends in the foreseeable future.

INVESTOR RELATIONS

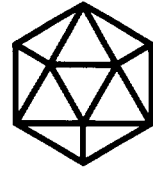
For additional information about
Avigen please see our web page at
www.Avigen.com. Investor inquiries
and requests for additional copies of
this report, free of charge, should be
directed to Investor Relations at
510-748-7150 or via e-mail at
ir@avigen.com

ANNUAL MEETING

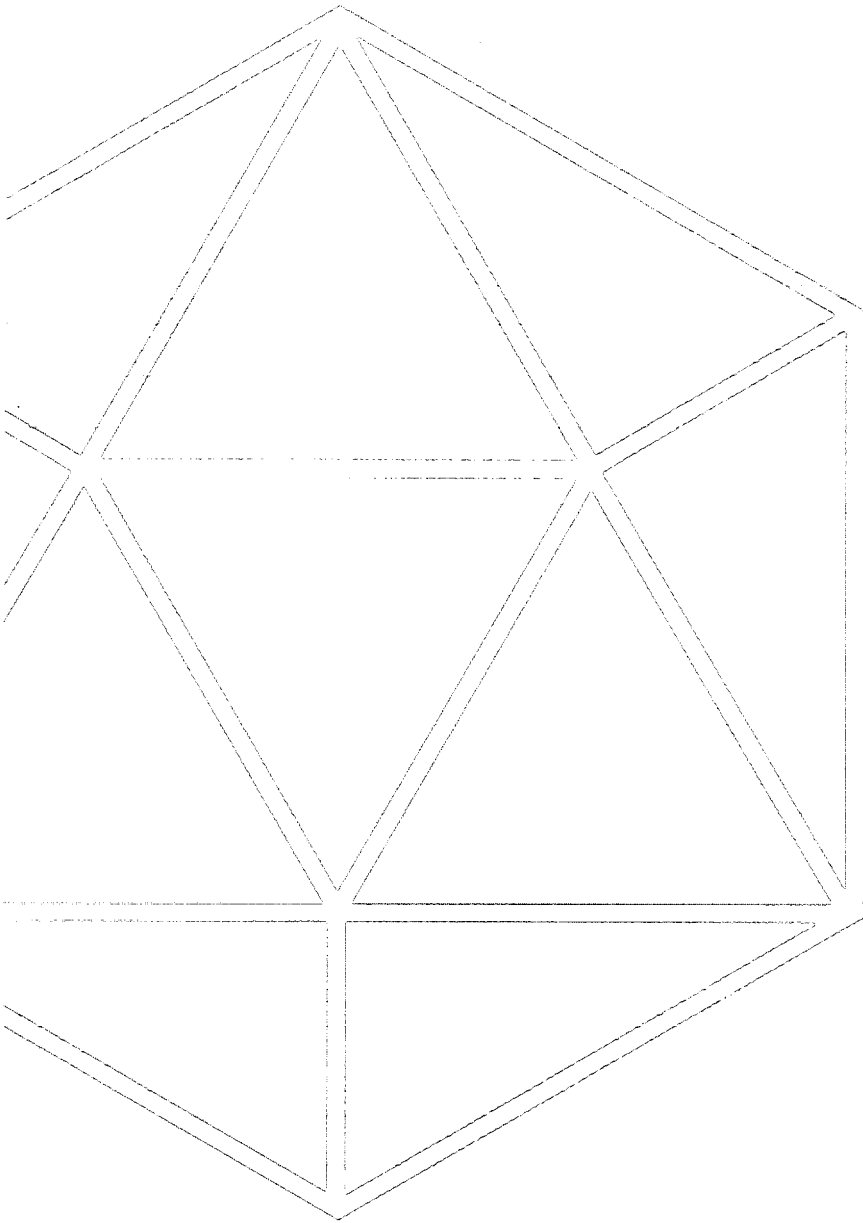
The annual meeting of stockholders
will be held on Thursday, May 22,
2003, at 10:00 a.m. PST, at Avigen's
corporate headquarters,
1301 Harbor Bay Parkway
Alameda, California 94502

TRADEMARKS

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



AVIGEN



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510-748-7155 fax
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