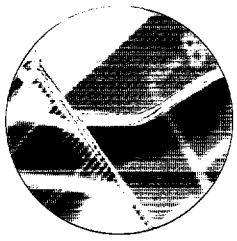
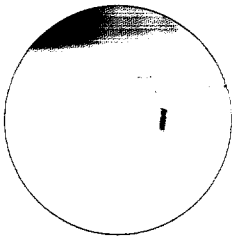
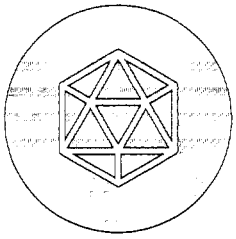
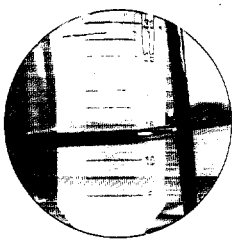
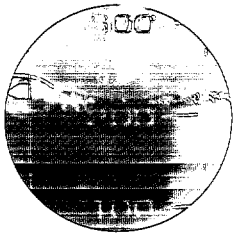








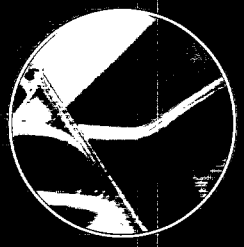


2001 ANNUAL REPORT

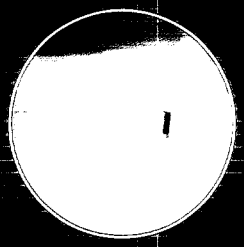
Ar/s
P.E. 12/31/01

AVIGEN Inc

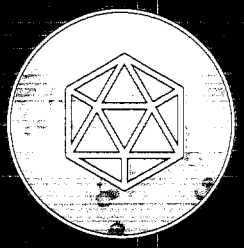
Avigen's 143 employees are committed to developing an effective gene delivery platform technology based on the Adeno-Associated Virus (AAV).



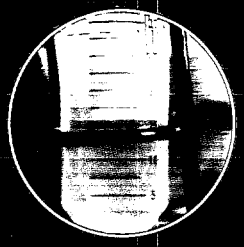
The first company to focus exclusively on AAV, Avigen has developed a formidable intellectual property portfolio, with 25 issued patents and 34 pending applications in the United States.



Preclinical studies have shown Avigen's AAV vector to be safe, effective and capable of delivering many different genes to a variety of cell types, producing long-term gene expression.



Avigen's patent-protected AAV manufacturing process is highly scalable and can efficiently produce significant quantities of commercial-grade vector.



The broad applicability of Avigen's AAV technology gives rise to multiple research, product and corporate partnering opportunities.

Avigen, Inc. is a leader in the development of gene therapy products using adeno-associated virus (AAV) vectors. In preclinical studies, the company's proprietary AAV technology has been shown to be both safe and effective in delivering a wide variety of genes to cells resulting in long-term gene expression, making it particularly appropriate for the treatment of many chronic conditions. Avigen is currently developing treatments for hemophilia and Parkinson's and has a range of ongoing research programs in areas such as congestive heart failure and metabolic disorders. The company has collaborated with Bayer Corporation to support late stage clinical trials for its leading product prospect, Coagulin-B for the treatment of hemophilia B. Avigen's collaborators include leading researchers at Stanford, Harvard, the University of California, the Children's Hospital of Philadelphia and others.

Important Notice to Investors:

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, trends in operating or financial performance, the potential efficacy of our AAV vector technology, market growth, competition, 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 I of our Transition Report on Form 10-K, which is included in this report.

Strategic Vision

To Our Stockholders

Avigen was organized to develop and commercialize therapeutic products based on the application of gene therapy techniques. During 2001, Avigen continued to apply its proprietary gene delivery technology using adeno-associated virus (AAV) vectors to advance these efforts in the fields of hemophilia, Parkinson's disease, and congestive heart failure. Avigen achieved important scientific and production milestones in each of these areas.

Clinical Developments

In late 1999, Avigen established the first human gene therapy trial for factor IX using AAV to treat patients suffering from hemophilia B. The trial was designed to test the safety of intramuscular delivery of Avigen's product, Coagulin-B™. The results from the initial patient group showed Avigen's treatment to be safe and well tolerated, and confirmed the successful transfer of the gene for factor IX as well as subsequent production of factor IX protein, in all patients treated. Based on this initial success, Avigen expanded the trial to assess the delivery of the gene directly to the liver, the body's natural site for the production of factor IX protein. Preliminary analysis of the data from the liver trial also suggests this route of administration to be safe and well tolerated. During the course of the liver trial, and in compliance with the clinical protocol, Avigen halted the study upon detection of DNA fragments related to its AAV vector in one of the patient's fluids.

PHILIP J. WHITCOME, PH.D.
Chairman of the Board

JOHN MONAHAN, Ph.D.
President and Chief Executive Officer

After further evaluation and analysis, and consultation with both the FDA and the Recombinant DNA Advisory Committee of the National Institutes of Health, Avigen received clearance from the FDA for the trial to continue. Avigen resumed the trial and began to enroll patients again in January 2002.

During the coming year, Avigen intends to treat additional patients at increasingly higher dosages of Coagulin-B with the goal of achieving sufficient levels of factor IX

Scientific Progress

protein in each patient's blood necessary to decrease or eliminate their need for traditional factor IX concentrate injections. In similar studies in hemophilic dogs, Avigen has been able to achieve factor IX levels well into the therapeutic range. However, results in dog models are not necessarily indicative of results that will be obtained in human trials, so we are cautious in our optimism.

Scientific Progress

Results from Avigen's preclinical research in other areas continue to support the potential utility of AAV vectors as a platform technology capable of effectively delivering a wide variety of genes to different target tissues. Studies to date have resulted in a number of patentable discoveries using AAV. Patents and patent applications form the cornerstone of Avigen's intellectual property portfolio, and serve as a driving force behind Avigen's ongoing research and development activities.

Avigen's commercial strategy focuses on diseases where the biological role of a specific gene is well understood, where a therapeutic protein has already been identified, and where long-term production of that protein is critical for effective therapy. Avigen also targets diseases where a clear cost and clinical benefit exists for patients and providers, and where clinical testing can be conducted on a relatively small patient population.

Current preclinical research studies include:

Parkinson's Disease is a devastating neurological disease that impacts an estimated 1.5 million mostly older patients in the United States and Europe. It results from a decline in the production of the neurotransmitter dopamine. Preclinical research in animal models has demonstrated success with AAV vectors in delivering a gene to a specific region of the brain in order to produce an enzyme that can restore neurotransmitter activity and provide clear therapeutic benefits. Avigen received a patent for this potential treatment in October 2001.

Corporate Development

Encouraged by results to date, Avigen is expanding its internal efforts, and has established research relationships with leading university collaborators to further its efforts in this area. If the preclinical trials currently underway progress as expected, Avigen believes that data from the studies could support the filing of an investigational new drug (IND) application within the next 12 months.

Hemophilia A is similar to hemophilia B, in that it is a blood clotting disorder characterized by the absence of a protein, in this case factor VIII. The gene involved in hemophilia A is significantly larger than that involved in hemophilia B, presenting a technical challenge for delivery; however, researchers at Avigen have developed a single-gene AAV vector which has demonstrated success in delivering the factor VIII gene to mice and to hemophilic dogs.

Preliminary results in the dog studies are encouraging, with no adverse side effects observed to date. Some of the treated dogs have exhibited therapeutic levels of factor VIII in their blood for more than six months. Avigen is continuing its investigation of factor VIII in order to demonstrate the potential and practicality of using its AAV-based approach in a human clinical study for the treatment of hemophilia A.

Congestive Heart Failure is a life-threatening disorder affecting almost 5 million people in the United States. Researchers have identified a number of important proteins that are believed to play a critical role in the heart's ability to pump blood. Work by Avigen and academic researchers suggests that AAV vectors can achieve efficient, high-level expression of such proteins in cardiac tissue and may provide advantages over other methods of delivery. Avigen is encouraged by these preliminary results and intends to extend its studies in large-animal models with its collaborators during 2002.

Financial Results

To adopt a reporting period consistent with that of other companies in its industry, Avigen changed its fiscal year end from June 30 to December 31. Consequently, the financial results discussed in this report are for the shortened transition period. For the six months ended December 31, 2001, Avigen reported a net loss of $11.3 million compared with $6.5 million in the same six-month period of 2000. This loss was consistent with management's expectations and was due to higher spending on clinical trials, additional research and development programs, and the expansion of production facilities. At December 31, 2001, Avigen had approximately $148 million in cash, cash equivalents, and short-term investments compared with approximately $158 million at June 30, 2001. Avigen believes that this strong financial position will provide a solid foundation from which to fund research and development and expanding clinical programs as Avigen moves toward the commercialization of its products.

Looking Ahead

Manufacturing

Recognizing the importance of manufacturing and production to the successful commercialization of it products, Avigen has committed its resources to the development of proprietary production capabilities and processes to meet the requirements for commercial-stage manufacturing. Avigen's ability to achieve superior yields and economies of scale with a safe and controlled manufacturing process that can accommodate the development and production of vectors containing numerous therapeutic genes, is one of the characteristics that distinguishes the company from its competition. Avigen continued to refine and improve its production processes during the last year and increased production capacity almost 20 fold within its current facility, enabling Avigen to meet the growing demands of its research and clinical programs.

Patents

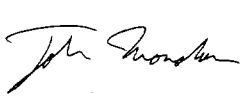
The ability to protect and safeguard its discoveries and inventions has always been a critical component of Avigen's commercialization strategy. To that end, Avigen has focused on developing a strong patent portfolio that includes 25 issued patents and 34 pending patent applications in the United States, and more than 270 pending patent applications worldwide. These patents cover various applications relating to using AAV vectors, including types of vectors, methods of production and manufacturing, methods of tissue administration, and several disease indications.

Looking Ahead

The successes of the past year serve as the foundation for achieving Avigen's objectives in the coming year. Avigen continues to conduct its clinical trial for Coagulin-B for the treatment of hemophilia B and looks to invest further in earlier development programs for both Parkinson's disease and congestive heart failure. Avigen also anticipates continuing its efforts to bring Coagulin-A™, Avigen's gene therapy product for the treatment of hemophilia A, to the clinic. Avigen will continue to seek protection of its intellectual property through its aggressive patent strategy, and will continue its efforts to improve its production and manufacturing processes as it moves toward commercialization.

For all of Avigen's long-time stockholders, as well as for those of you who became Avigen stockholders during the past year, we thank you for your support and confidence as we enthusiastically take on the challenge of commercializing the first gene therapy products and providing relief to those patients whose illnesses are not well addressed by conventional modes of medical treatment.

PHILIP J. WHITCOME, PH.D.
Chairman of the Board



JOHN MONAHAN, PH.D.
President and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

(Mark One)

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

OR

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

For the transition period from July 1, 2001 to December 31, 2001.

Commission file number 0-28272

AVIGEN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-3647113**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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

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

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

Title of each class	Name of each exchange on which registered
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 of 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. ☒

The aggregate market value of the voting stock held by non-affiliates of the registrant as of March 8, 2002, was approximately $158,990,000 based upon the closing sale price of the registrant's Common Stock as reported on the Nasdaq National Market System on such date*. The number of outstanding shares of the Registrant's Common Stock as of March 8, 2002 was 20,068,139.

DOCUMENTS INCORPORATED BY REFERENCE

Parts of the following documents are incorporated by reference into Part III of this Form 10-K Report: The definitive Proxy Statement for the Registrant's Annual Meeting of Stockholders scheduled to be held on May 20, 2002.

* Excludes approximately 4,009,000 shares of common stock held by Directors, Officers and holders of 5% or more of the registrant's outstanding Common Stock at March 8, 2002. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, 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.

TRANSITION REPORT ON FORM 10-K

FOR THE TRANSITION PERIOD ENDED DECEMBER 31, 2001

TABLE OF CONTENTS

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

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Transition 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™ ;
- developments with respect to clinical development of drug candidates, clinical trials and the regulatory approval process;
- our expectations as to the various products that we are developing;
- our estimates regarding our capital requirements and our needs for additional financing; and
- developments relating to our selection and licensing of targets.

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 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*

The Company

Avigen is focused on the development of gene therapy products for the treatment of disease. We have developed a proprietary technology based on adeno-associated virus vectors, known as "AAV vectors". This technology is designed to deliver DNA into cells of patients in order to produce therapeutic results 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, hold great promise for treating a wide variety of diseases and conditions that are not adequately addressed by current medical science. We believe our AAV vectors can be used to deliver genes that promote therapeutic responses in patients suffering from many types of illnesses, including genetic diseases such as hemophilia and certain metabolic diseases, and many non-genetic diseases such as Parkinson's disease, congestive heart failure, anemia and cancer.

Gene Therapy and Gene Delivery

Living organisms consist of cells that contain thousands of different proteins essential for cell structure, growth, and function. Proteins are made of building blocks called amino acids. Together amino acids define the structure and function of proteins. The specific order of amino acids in the protein is determined by genetic instructions encoded by DNA. DNA is a commonly used acronym for the chemical that codes for the order

and length of amino acid chains and contains all the information necessary to control a cell's biological processes.

DNA is organized into segments called genes. Each gene contains the information required to produce a specific protein. Each human cell contains thousands of genes. Gene expression is the process by which genes use DNA as a blueprint to produce proteins. In genetic diseases, one or more genes can be defective, resulting in the complete lack of or insufficient levels of production of a necessary protein in the cell. Improper expression can also alter a cell's normal function and can frequently lead to disease.

Gene therapy typically uses genes to regulate cellular function or to correct cellular dysfunction through the introduction of therapeutic genes into cells to restore missing gene functions, correct aberrant gene functions, or augment normal gene activity. In some of these cases, the therapeutic gene will simply act to replace a missing protein or to augment the level of expression of a protein that is otherwise inadequate to prevent disease.

There are several different ways of delivering genes to cells. Each of the methods of delivery uses carriers, called "vectors," to transport the genes into cells. These carriers can be either man-made components or modified viruses. The use of viruses takes advantage of their natural ability to introduce DNA into cells. Gene therapy takes advantage of this property by replacing viral DNA with a specific gene. Once the gene is in the cell, it acts as a blueprint directing the cell to produce the therapeutic protein.

There are four major approaches to gene delivery currently under investigation in human clinical trials:

- *Retroviral vectors.* These were the first vectors used in human gene therapy trials. Retroviral vectors are considered to be well understood and are quite efficient at getting genes into cells. However, they have only been proven to work effectively in actively growing cells, which typically requires that the cells be removed from the patient, grown outside the body, exposed to the retroviral vector and later re-implanted back into the patient. This process limits the commercial viability of these vectors as a generalized approach to gene therapy.
- *Adenoviral vectors.* These vectors do not require that the cells be removed from the patient's body in order for the gene transfer process to take place. However, adenovirus can cause disease in humans, creating safety concerns about the use of adenovirus vectors. Also, although gene transfer using adenovirus can be efficient, common immune responses typically limit the duration of the production of the protein.
- *Non-viral vectors.* These vectors consist of either DNA or DNA mixed with other chemical compounds. These vectors are much less efficient than viral vectors at getting DNA into cells and are generally not capable of producing large amounts of the intended protein expression for extended periods of time.
- *Adeno-associated virus vectors.* AAV is a common human virus present in over 80% of the human population and has not been associated with a human disease or illness of any kind. We believe that AAV is emerging as a superior gene delivery approach, as it offers effective gene delivery characteristics, has a superior safety profile, and enables *in vivo* administration which has been shown to produce long-term gene expression.

Avigen's AAV Vector Technology

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 vectors have many advantages over other types of gene therapy vector systems. However, methods of producing large amounts of high quality, contaminant-free AAV vectors have been very challenging to overcome, which we believe may have deterred others from pursuing this technology. Avigen has dedicated significant resources to advancing its production methods, and has developed effective and scalable techniques that meet these quantity and quality objectives. For example, production of AAV vectors normally requires the use of a potentially

threatening helper virus, usually adenovirus, that could contaminate the final product. We have developed a proprietary method that does not require a helper virus, but rather selective reproductive genes, which we believe results in a safer product. 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. Our success in resolving many production limitations sets us apart from others, and we believe will enable us to manufacture 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.

Favorable Characteristics of Avigen's AAV Vector Technology

We believe our AAV vector gene therapy approach offers novel treatment alternatives for diseases that are currently poorly addressed. We believe our AAV vector gene therapy technology includes favorable characteristics such as:

- *Safety.* Our AAV vectors are based on a virus that has never been associated with a human disease of any kind and avoids the risk of contamination from other viral particles through our proprietary manufacturing process.
- *Efficient delivery of genes to cells which result in high levels of gene expression.* AAV by its nature is very efficient at getting into cells. Consequently, our AAV vectors have been shown to be very effective at delivering genes to cells. Once in the cell, genes delivered by AAV vectors in animal models have been shown to produce large amounts of protein on a continuous basis, often for years from a single administration.
- *Effective delivery to a wide range of types of cell targets.* Research has shown that AAV can be used to transfer genes to a wide variety of cell types, including dividing cells, such as liver, skin and cancer cells, and non-dividing cells, such as those found in skeletal muscle tissue, certain organs like the heart, and the central nervous system and brain. This versatility could allow us to target a broad range of treatments targeted at a wide variety of cell types.
- *AAV vectors can deliver many different genes.* Many genes fit into AAV vectors without modification of the basic vector structure, and have been successfully delivered to cells *in vivo*. Consequently, AAV vectors have the potential to treat many different diseases with a common technology platform.
- *Stability.* AAV appears to be stable under a wide range of conditions. We currently take extra precautions to store and ship all manufactured products in a frozen state; however, we believe that due to their proven stability under other conditions, our AAV vectors may be able to be handled with minimal refrigeration like many traditional pharmaceutical products, thereby lending themselves to fairly standard shipping and storing procedures.

Research and Development Programs

We are currently involved in a number of early research and product development programs that we feel can benefit from our experience with AAV and our advances in high quality, scalable production methods. All of our current projects reflect some combination of characteristics that we feel comprise a desirable profile for gene therapy research and development programs, including:

- involvement of a well understood gene function;
- requirement to produce long-term expression of a therapeutic protein;
- replacement of existing recombinant protein treatments that currently provide a partial correction of a disease; and
- demonstration of clear clinical benefits and measurable end points.

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. We characterize our product development programs in two stages: the first is as preclinical, which involves safety and efficacy studies in large animal models which are designed to provide data that would support the progression into human studies; and the second is human clinical trials, which typically include multiple phases designed to evaluate safety first, referred to as "Phase I", followed by phases for evaluations of 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

Program	Disease	Protein/Enzyme	Target Cell	Status
Blood Disease	Hemophilia B	Factor IX	Liver/Muscle	Phase I
Blood Disease	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 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.

Hemophilia B affects approximately one in every 30,000 males, afflicting an estimated 10,000 - 15,000 individuals in developed countries worldwide, with an estimated 40%-50% of those affected having a severe form of the disease. The cost of currently available protein factor IX can exceed $100,000 per year per patient. Because this protein therapy cannot prevent bone and joint damage, each patient may also require an additional $100,000 - $150,000 in other medical treatment costs annually. We believe the current market for providing recombinant protein factor IX to patients with the severe form of the disease exceeds $200 million per year, and that the aggregate cost of treating hemophilia B patients with replacement protein factor IX and other collateral disease treatments exceeds $450 million per year worldwide.

Extensive experience with factor IX over the last 25 years has established that 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 can often 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 and 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. 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.

Preclinical Studies

Prior to 1999, in our initial preclinical studies to evaluate gene delivery, we treated dogs suffering from hemophilia B with a single administration into muscle of our AAV vector containing the gene for factor IX. These early studies demonstrated that our AAV vector could produce sustained levels of factor IX protein in the dogs for over three years with a corresponding improvement in blood clotting. In the dogs receiving the greatest quantities of our AAV vector, factor IX protein levels were above 1% of the normal level, a level that is known to be beneficial to humans.

Additional preclinical studies were also designed to evaluate gene delivery into the liver, the normal site of clotting factor production. In these studies we have treated several species of animals to assess the safety and efficacy of a single administration of an AAV vector containing the gene for factor IX to the liver. Safety studies were conducted in rats and normal dogs, and efficacy studies were carried out in rats, mice and hemophilia B dogs. All of these studies showed that liver delivery of AAV vector is safe at doses significantly higher than planned for clinical studies in humans, and that the levels of factor IX protein expression that can be achieved by this vector and route of administration are significantly higher than could be achieved by the intramuscular route. For example, the efficacy studies demonstrated that when delivered to the liver, the AAV vector produced sustained levels of factor IX protein expression in three hemophilia B dogs for over one year, and that the levels of expression ranged between 5% and 14% of normal levels.

Data from these studies provided strong support for the feasibility of using the same approaches to treat human hemophilia patients and formed the basis for our investigational new drug, or "IND," applications, the first of which was submitted to the U.S. Food and Drug Administration, or FDA, in early 1999 and the second of which was submitted to the FDA in early 2001.

Clinical Trials

In June 1999, we began treating human subjects with a version for administration to muscle tissue of our product candidate, Coagulin-B, in a Phase I clinical trial with dose escalations. The design and goal of this initial trial was primarily to address the safety of the product in humans. A total of eight patients in three different dosage groups received a single treatment of Coagulin-B injected into their muscle tissue. Data from all patients showed the vector to be safe and well tolerated with no serious adverse events noted. Although the study was designed primarily to evaluate the safety of the product in humans, the data collected also showed that all patients experienced a successful delivery of the factor IX gene into the targeted cells and demonstrated measurable levels of protein expression. There was a diverse range of factor IX protein levels in this small trial population, with two of the patients continuing to exhibit a significant reduction in factor IX usage for more than two years. In light of the success of the safety measurements of our muscle study in humans, and the stronger efficacy results observed in a preclinical study that treated a small group of dogs with a liver construct of an AAV vector containing the gene for factor IX, we submitted a second IND and second clinical trial protocol using the liver as the target for gene delivery in June 2001.

This second phase I clinical trial with dose escalations is designed to test the safety of treating patients with a single administration of a version of Coagulin-B modified for liver tissue via infusion into the hepatic (liver) artery. The liver is the normal site of clotting factor production. This trial is also designed to treat patients representing three escalating dosage groups. In August 2001, the first patient in this second phase I clinical trial was treated and reported no immediate adverse reactions. The trial was temporarily suspended when tests using sensitive assays identified trace amounts of DNA from the gene therapy in the patient's seminal fluid. Existing FDA protocols for gene therapy clinical trials required a temporary suspension from treating additional patients until subsequent tests could confirm that the trace amounts of DNA had cleared the patient's body. In October 2001, we announced that the trial was on clinical hold until such additional test results could be established.

In December 2001, our representatives met with representatives of the FDA and the National Institutes of Health's Recombinant DNA Advisory Committee (RAC) to discuss in an open scientific forum issues surrounding the potential impact of gene therapy on germ-line transmission, and how best to gather additional vital clinical data. At the meeting we reported that subsequent testing on this first patient had confirmed that

the trace amounts of DNA had cleared the patient's body and that the patient remained in good health with no reportable side effects from the therapy. These discussions resulted in plans for us to initiate new research studies to provide additional data that may be used to answer future questions about these issues, but did not place additional limitations on the clinical trial protocol. In December 2001, we announced that we had received notice from the FDA giving us clearance to continue human clinical testing of our Coagulin-B product.

In February 2002, we announced that we had treated a second patient in the liver delivery clinical trial, and that upon confirming the necessary safety data from this subject, we plan to begin increasing the dosage levels for subsequent patients. We remain confident that the risk of germ-line transmission is low and are continuing to perform additional studies to gather more data so that we might better be able to respond to questions that may arise from future test results.

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 patients in these or other studies will demonstrate the same results or that these treated patients will continue to exhibit beneficial results over a longer period of time.

Hemophilia A

We are also 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 an estimated 40,000 - 50,000 individuals in developed countries worldwide. The cost of currently available replacement protein factor VIII can exceed $100,000 per year per patient. Because protein therapy has not proven effective at preventing bone and joint damage that is common among hemophilia patients, each patient may require $100,000 - $150,000 in additional medical treatment costs annually. We believe the current worldwide market value 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 collateral disease treatments is over $3 billion per year.

Preclinical Studies

The factor VIII gene is much larger than the factor IX gene, and therefore poses an additional challenge for using AAV vectors as a delivery mechanism. However, in our preclinical studies, which have investigated two different approaches for delivering this larger gene to the liver, we have been successful in delivering the factor VIII gene into animals, including with a single-vector construct. Similar to the progression in the hemophilia B program, we migrated our preclinical research studies from small animal models into larger animal models and began working with dogs in the second-half of 2001. These studies are still in progress.

Assuming these studies 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. This disease is commonly characterized by an increase in spontaneous movements, gait difficulty, postural instability, rigidity and tremor. Parkinson's disease is a complex illness, one theory of which suggests that its symptoms result from a decrease in the levels of dopamine, a chemical which is essential to the transmission of nerve impulses, in certain parts of the brain. These nerve impulses are critical to movement and motor control. Research suggests that dopamine levels decline because there is a slow degeneration or loss of the small population of nerve cells in the brain that produce it; however, the underlying cause of this nerve cell degeneration is not known.

Dopamine cannot be administered directly, as it cannot pass from the bloodstream into the cells in the brain. Currently, the primary treatment for Parkinson's disease is a replacement strategy in which a dopamine precursor known as L-dopa, which can be converted into dopamine once inside the brain, is given orally to the patient. Unfortunately, while this approach can help relieve symptoms for up to several years, it eventually tends to become ineffective and can result in serious side effects as the dosage levels are increased. 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 a gene into certain parts of the brain that will stimulate higher levels of an enzyme known as aromatic amino acid decarboxylase, or AADC, which is needed to convert L-dopa into dopamine. This approach targets only the affected region of the brain and we believe 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 gene therapy for Parkinson's disease may be effective in supplementing existing therapies. 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 the 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 pre-clinical studies in order to assess the safety and efficacy of this approach prior to seeking to initiate human clinical studies.

Research Programs

We believe our technology can be used to reach a broad array of 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 in areas including Gaucher disease, anemia, and thallasemia. These studies advanced our understanding of AAV and produced intellectual property that has supported research in other areas and may support future research for these 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 our active internal and collaborative research programs, which are engaged in the exploration of promising new disease targets that we believe have the potential to become future development programs include:

AAV Vector-Based Gene Therapy Research Programs

Program	Disease	Target Cell
Heart Disease	Congestive Heart Failure	Heart
Metabolic Disorders	Phenylketonuria	Liver

Congestive Heart Failure

Congestive heart failure (CHF) describes a condition in which the ability of the heart to pump blood effectively is adversely affected. This can have a negative impact on all major functions in a patient's body and often includes symptoms such as shortness of breath, as blood supply to the lungs decreases, swelling in the

lower extremities, as blood circulation is reduced, general feeling of tiredness, as muscles throughout the body are undersupplied with blood and the functions of vital organs deteriorate, and death.

Almost 5 million Americans have some form of CHF today, with an estimated 500,000 new cases diagnosed each year. CHF is the leading cause of hospitalizations for patients over 65 and the number of annual deaths linked to heart failure is rising rapidly. It has been reported that more than $20 billion is spent each year on CHF patients in the form of institutional care and medications.

Currently, there are a number of drug-based and surgical treatments that can be effective in treating many of the symptoms of CHF, and in some cases reducing the need for hospitalization and improving survival. However, with survival for more than half of patients with severe CHF limited to two years, eventually, many patients reach a state in which medical therapy is no longer effective and heart transplantation, which is limited by the availability of organ donors, is their only alternative.

Researchers have shown that certain proteins in heart cells can improve the heart's ability to pump blood. Genes that control the expression of certain of these proteins have been identified. Based on our own past research, which created intellectual property for methods of AAV-based gene delivery to cardiac muscle and certain related cardiac infusion techniques, we are currently working with external collaborators to explore ways to treat this disease by using our AAV vectors to deliver genes to cardiac muscles to affect protein expression.

Phenylketonuria

Phenylketonuria (PKU) is an example of a metabolic disorder, that if left untreated, can lead to severe mental retardation, seizures, delayed speech, and behavior abnormalities. PKU is caused by a defect in the gene encoding phenylalanine hydroxylase (PAH), which is responsible for the conversion of the amino acid phenylalanine to tyrosine. Patients with PKU are unable to metabolize phenylalanine effectively, which results in elevated levels of the amino acid in their blood and tissues. It is estimated that approximately 1 in 10,000 infants in the United States suffer from PKU.

Current treatment for PKU is limited to strict metabolic control requiring a highly specialized diet, which avoids protein-rich foods such as meat, and which must be implemented soon after birth in order to prevent the development of many PKU symptoms. For many patients, maintenance of this strict diet leads to an extremely altered lifestyle and non-compliance is very common, which can result in complications such as reduced cognitive abilities and neuropsychological dysfunction. Using AAV vectors to deliver the gene for PAH, we are investigating whether a patient's own cells can be corrected to produce the normal missing protein, thus allowing the patient to metabolize phenylalanine in their diet.

Patents and Intellectual Property

Patents and other proprietary rights are important to our business. Our goal 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 2002, we owned, co-owned, or held licenses to 25 issued U.S. patents and 34 pending U.S. patent applications, most of which have also been filed internationally. The patents in which we own or hold as licensees protect rights to specific vectors, methods of vector production, methods of tissue administration, and 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

Examples of the intellectual property rights these patents cover, include:

- specific AAV vectors such as those containing erythropoietin, or Epo, and enzymes associated with lysosomal storage diseases;

- methods of producing AAV that result in wild-type free vectors, adenovirus-free vectors, and certain large-scale manufacturing and purification processes;
- methods of administering AAV vectors, including to skeletal muscle, cardiac muscle, and smooth muscle, as well as delivery to the bloodstream, including intravenous (IV) and intraarterial (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.

We wholly own or co-own the rights to 48 of the patents and patent applications in our portfolio and hold licenses to 11 patents and patent applications. With regard to shared rights to co-owned intellectual property, although we always have the right to use the technology ourselves, we may not be able to exclude others from using the same technology without licensing the shared rights of the co-owner. As a result, we regularly seek to acquire exclusive licenses to such rights from those collaborators. As of February 2002, we did not have exclusive licenses to 7 co-owned patents and patent applications within our portfolio, however, we have options which have not yet been exercised to negotiate exclusive licenses for the respective collaborator's rights to each of these pieces of co-owned intellectual property.

When we identify technologies that have been previously patented, which we believe are critical to the development and future commercialization of our gene therapy products, we seek opportunities to license-in such rights under the most favorable terms. As of February 2002, our intellectual property portfolio included 3 exclusive licenses and 8 non-exclusive licenses to patented rights held by research institutions and their representatives. All licenses provide for a term that extends for the life of the underlying patent. Although specific terms of the licenses vary, some licenses require us to exercise our best efforts to achieve research, clinical, and commercial milestones. All licenses 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 also require us to make additional payments upon the completion of clinical and regulatory milestones, and in some cases, 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 license, could have a material adverse effect on our financial position.

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

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 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 approximately 2017.

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 IV and IA injection. This license excludes use to such methods to treat Pompe disease and alpha-1-antitrypsin. The license is for the duration of the underlying patents, or approximately 2016.

BTG International. 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 approximately 2008.

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 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.

In February 2002, we terminated a license with Research Corporation Technologies ("RCT") that we had entered into in May 1992 that had included rights to patents and patent applications related to cell-specific promoters in AAV vectors. Subsequent to the termination of the license, we also filed suit against RCT for breach of contract, which is described in Item 3 Legal Proceedings.

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, but 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.

We cannot be assured that other patents will be issued from any of the applications by or licensed to Avigen, 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 technology. The patent application process takes several years and entails considerable expense. In addition, with respect to each of our co-owned patent applications, we have executed an exclusive license or are in discussions with the co-inventors to execute a license or option to obtain an exclusive, worldwide, transferable, royalty-bearing license to the technology. In the event we are unable to negotiate exclusive rights to the 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. The failure to exclude others from using these technologies or proposed products may harm our competitive position and business prospects.

The patent positions of pharmaceutical and biotechnology firms are generally uncertain and involve complex legal and factual questions. To date, there has emerged no consistent policy regarding the breadth of claim allowed in biotechnology patents. Patent applications in the United States are maintained in secrecy until a patent issues, and we cannot be certain that others have not filed applications for technology covered by our patent applications or that we were first to file patent applications for the technology. Competitors may have filed applications for, or may have received, patents and may obtain additional patents and proprietary rights relating to compounds or processes that block or compete with our patents.

We cannot ensure that third parties will not assert patent or other intellectual property infringement claims against us with respect to our products or technology or other matters. There may be third-party patents and other intellectual property relevant to our products and technology that are not known to us. A number of the gene sequences or proteins encoded by certain of those sequences that we are investigating or may use in our products are or may become patented by others. As a result, we may be required to obtain licenses to the gene sequences or other technology in order to test, use or market products that contain proprietary gene sequences or encode proprietary proteins. For example, in connection with our hemophilia B program, we obtained a license to the gene for factor IX. We cannot ensure that we will be able to obtain any other licenses on terms favorable to us, if at all.

Patent litigation is becoming more widespread in the biotechnology industry. Litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to us, to protect trade secrets owned by us, or to determine the scope and validity of proprietary rights of third parties. Although no third party has asserted that we are infringing the third party's patent rights or other intellectual property, we cannot ensure that litigation asserting these 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. 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 to resolve. 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 the 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 of our trade secrets, know-how or other proprietary information. 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.

Collaboration Agreements

In the normal course of operations, we may enter into collaborative research agreements with independent researchers that could involve reimbursements of some of our research and development expenses. In 1998, we entered into an agreement with John Hopkins University (JHU) under which JHU agreed to provide research funding to Avigen through a National Institutes of Health Grant. The funded project consisted of researching Capsid-Targeted Viral Inactivation in the treatment of HIV.

Research and development expense for the six-months ended December 31, 2001 and 2000 were $11.5 million and $6.2 million, respectively, and in the fiscal years ended June 30, 2001, 2000 and 1999 for Avigen-sponsored research was $17.0 million, $8.0 million and $6.5 million, respectively. Of that, $86,000, $58,000 and $185,000, respectively, were reimbursed by JHU during the fiscal years ended June 30, 2001, 2000 and 1999, and reflected as grant and other revenues on our statements of operations. This agreement expired in March 2001.

No reimbursements by third parties were received for the six-months ended December 31, 2001 and we are not currently party to any collaborative agreements that would reimburse any future research and development expenses by a third party.

We may also consider entering into collaboration agreements that we feel could enhance our potential success with regard to future commercialization of our products. Our strategy is to retain most of the rights to the future commercialization of our products, thereby capturing a larger portion of their potential commercial value. However, we have taken part, and may in the future engage, in discussions with other gene therapy or large pharmaceutical companies concerning collaborations that may involve exchanging a portion of these rights for financial consideration and 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 with regard to Coagulin-B, our product for hemophilia B.

Bayer Corporation. In November 2000, we announced a collaboration agreement with Bayer Corporation, a worldwide health care and life sciences company and leader in the development, manufacture, and distribution of hemophilia treatments. Under the terms of the agreement, Bayer, in collaboration with Avigen, will conduct the planned Phase II/III clinical trials for our Coagulin-B™ gene therapy treatment for hemophilia B, and 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 a royalty on net sales of the product for its intellectual property. 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 trials. Under the terms of the deal, Bayer AG, an affiliate of Bayer Corporation, 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 AG was completed in February 2001.

Vector Production and Manufacturing

In nature, AAV virus lacks the genes needed to reproduce itself. As a result, in order to reproduce, AAV must borrow certain genes from other viruses, typically referred to as "helper viruses". The most common helper viruses are adenovirus and herpes virus.

In the laboratory, most researchers producing AAV vectors for gene therapy use adenovirus and herpes virus 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 consist of toxins which do cause disease in humans. The presence of pathogenic helper viruses in the production process — either alive or inactive — can compromise the safety of AAV vectors produced with these helper viruses.

In order to minimize the risk of illness to the patient, the 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 spent several years developing a production process for making AAV vectors without helper viruses by means of a proprietary transfection process. Our patented transfection process does not add helper viruses at all. Instead we use only a select handful of helper-virus genes to cause reproduction of AAV 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 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 through 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 genes desired.

Modular transfection 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.

The modular nature of our process also has considerable scaleability potential. To date, all vectors produced for clinical testing were grown in tissue-culture flasks and purified using high-speed centrifugation with cesium chloride. High-speed centrifugation is a lab-scale process, and is inherently not scalable. Over the last year or so we achieved significant enhancements to our production process that we expect will allow us to increase the scale of our production capacity to what we expect will be needed to support commercial levels.

Our new production process uses roller bottles to produce AAV vectors in large quantities and 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 began using chromatographic purification techniques to increase the final yield and scale of our process for separating AAV from other cellular material. Together, these enhancements are highly scalable, and easily transferable to clinical and commercial grade manufacturing levels.

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 manufacturing facilities make use of the automation and chromatographic processes developed during our product development stages, and benefit from the many advantages of our proprietary transfection process. In particular, manufacturing will benefit from the favorable characteristics of our transfection process which isolate and standardize many of the materials and steps during production and increase the ease of changeover to new products.

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 which is outside of the scope of our collaborative agreement, Baxter Healthcare Corporation, and Wyeth. Many of our competitors or 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. We are aware that other companies or institutions are actively engaged in gene therapy product development programs which currently target gene therapy products that could compete directly with our current development and research programs, including: Cell Genesys, Inc., Collateral Therapeutics, Inc., Genstar Corporation, GenVec, Inc., Targeted Genetics Corporation and Transkaryotic Therapies, Inc. Furthermore, it is our understanding that certain of these competitors are currently conducting clinical trials to treat Hemophilia A patients, including Genstar, which is conducting a Phase I clinical trial using adenovirus, and Transkaryotic Therapies, which is conducting a Phase I/II clinical trial using a nonviral vector-based system, and clinical trials to treat certain forms of heart failure, including Collateral Therapeutics and GenVec, each of which is in a Phase II clinical trial.

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 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 are subject to rigorous regulation by the FDA under the Federal Food, Drug, and Cosmetic Act. Biological products, in addition to being subject to certain provisions of this act, are also regulated under the Public Health Service Act. These laws and the regulations promulgated thereunder govern, among other things, testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotional practices, and import and export of drugs and biological products. In general, the Center for Biologics Evaluation and Research holds primary responsibility for the regulation of biological products and has handled the IND applications of most gene therapy products to date. At the present time, we

believe that our 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.

Under the National Institutes of Health ("NIH") guidelines for research involving recombinant DNA molecules, clinical protocols involving human gene transfer conducted at institutions receiving NIH funds cannot be initiated without simultaneous submission of information describing the proposed clinical protocol to both the NIH and the FDA. However, the FDA is the regulatory body with statutory authority over gene therapy products. Submission to the FDA will be in the form of an IND application or IND amendment, while submission to the NIH shall be for scientific and ethical review purposes and determination regarding the necessity of full review by the Recombinant DNA Advisory Committee, or "RAC," of the NIH. Full RAC review of an individual human gene transfer protocol can be initiated by the NIH director or recommended to the NIH director by three or more RAC members or other federal agencies. An individual human gene transfer protocol that is recommended for full RAC review should represent novel characteristics deserving of public discussion. Prior to submission of a human gene transfer experiment to NIH, the principal investigator must obtain Institutional Biosafety Committee approval from each institution that will handle recombinant DNA material that is to be administered to human subjects and institutional review board, or "IRB," approval from each institution in which human subjects will undergo gene transfer. The review process conducted by the NIH and the FDA can be unpredictable and may result in considerable time and expense to us.

The steps required before a new drug, including a biological product, may be marketed in the United States generally include:

- preclinical laboratory tests and preclinical animal studies;
- the submission to the FDA of an IND application for human clinical testing, which must become effective before human clinical trials commence;
- 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 maintain a drug manufacturing license from the State of California for any of our products administered to humans, including products used in clinical trials.

Preclinical studies include laboratory evaluation of the product, as well as animal studies to assess the potential safety and, if possible, efficacy of the product. Preclinical safety studies must be conducted by laboratories that comply 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, which must become effective before human clinical trials may be commenced. The IND will become automatically effective 30 days after its receipt by the FDA unless the FDA indicates prior to the end of the 30-day period that it does not wish the trials to proceed as outlined in the IND. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. We cannot assure you that submission of an IND will result in FDA authorization to commence clinical trials.

Clinical trials must be conducted in accordance with the FDA's good clinical practice guidelines and must be approved by the IRB at each respective institution participating in the clinical study. The IRB will

consider, among other things, safety, and ethical issues, proper informed consent of the human subjects, possible issues relating to health care costs and potential liability of the institution. The IRB may require changes in a protocol, and we cannot assure you that the IRB 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 determine the drug's safety, metabolism, pharmacokinetics and pharmacological actions in humans, and the side effects associated with increasing doses. Phase II typically involves studies in a limited patient population:

- to further identify possible adverse effects and safety risks;
- to determine the efficacy of the drug for specific diseases; and
- to determine dosage tolerance and optimal dosage.

If the drug appears to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to evaluate efficacy and safety within an expanded patient population typically at geographically dispersed clinical study sites. We cannot assure you that Phase I, Phase II, or Phase III testing will be completed successfully within any specific time period, if at all, with respect to any of our products subject to this testing. Furthermore, the FDA may suspend clinical trials at any time on various grounds, including a finding that patients are being exposed to an unacceptable health risk. The FDA also views gene therapy as a relatively new technology, with no experience as to long-term safety. As a result, the FDA is requiring long-term monitoring of all patients that participate in each phase of clinical trials. FDA regulations also subject sponsors of clinical investigations to numerous regulatory requirements related to, among other things, selection of qualified investigators, proper monitoring of investigations, record keeping and record retention and notice to investigators and the FDA of any death or serious unexpected adverse reaction. In addition, the FDA may require post marketing clinical studies, sometimes referred to as Phase IV clinical trials, which will require extensive patient monitoring and record keeping and may result in restricted marketing of the product for an extended period of time.

The results of the pharmaceutical development, preclinical studies, and clinical trials are submitted to the FDA in the form of a BLA for approval of the manufacture, marketing, sale, and commercial shipment and distribution of the biological product. The testing and approval process is likely to require substantial time and effort, and we cannot assure you that any approval will be granted on a timely basis, if at all. The FDA may deny a BLA if applicable regulatory criteria are not satisfied, require additional testing or information, or require post marketing testing and surveillance to monitor the safety or efficacy of a product. Moreover, if regulatory approval of a biological product is granted, this approval may entail limitations on the indicated uses for which it may be marketed. Finally, product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur following initial marketing. Among the conditions for BLA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures conform to good manufacturing practices, which must be followed at all times. In complying with standards set forth in these regulations, manufacturers must continue to expend time, financial resources, and effort in the area of production and quality control.

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.

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.

Product Liability Insurance

The manufacture and sale of medical products entail significant risk of product liability claims. We have established product liability insurance prior to beginning our clinical trials; however there can be no assurance that this coverage will be adequate to protect us from any liabilities we might incur in connection with the testing of our products in clinical trials or future sale of our products upon commercialization. In addition, we may require increased product liability coverage as additional products are used in clinical trials and commercialized. This insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage could have a material adverse effect on our business and results of operations.

Employees

As of February 28, 2002, Avigen had 143 full-time employees, 30 of whom have Ph.D. or M.D. degrees. Of this amount, approximately 119 employees are involved in our research and development activities, including manufacturing, quality assurance and quality control, regulatory affairs and clinical affairs, and 24 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.

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 consists of the following individuals:

Alan McClelland, Ph.D. (Chairman), is Vice President, Research and Development, of Avigen. Dr. McClelland previously held senior level research positions at Novartis and Bayer. He holds a Ph.D. in biochemistry from the University of London and received postdoctoral training at Yale University.

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. He has authored more than 150 publications.

Katherine A. High, M.D., is the William H. Bennett Associate Professor of Pediatrics at the University of Pennsylvania in Philadelphia and the Director of Research of the Hematology Division at The Children's Hospital of Philadelphia. Dr. High is an expert in both basic and clinical aspects of blood coagulation and is a well-recognized authority on gene transfer for bleeding disorders. She is an officer of the American Society of Gene Therapy and on the editorial board of *Molecular Therapy,* the journal of ASGT.

Mark A. Israel, M.D., is Professor of Pediatrics and Genetics at Dartmouth Medical School. He is 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.

Yuichi Iwaki, M.D., Ph.D., serves as a director of Avigen, and is a Professor of the Departments of Urology and Pathology at the University of Southern California. He is currently Director of the Transplantation Immunology and the Immunogenetic Laboratory. Dr. Iwaki also holds visiting professorships at Nihon University School of Medicine in Japan, at the University of Pittsburgh School of Medicine, and at the University of California, Irvine.

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 is 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 lab has characterized the molecular defects in hemophilia A and developed a small animal model of the disease.

Keiya Ozawa, M.D., Ph.D., is a professor and chairman of the Department of Hematology, 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 200 publications regarding hematology, virology and gene therapy.

Jeffrey M. Rosen, Ph.D., is the C.C. Bell Professor of Molecular and Cellular Biology 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 *NucleicAcids 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, 2001, we had an accumulated deficit of $79.1 million. The process of 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 for Coagulin-B for the treatment of Hemophilia B are 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, which could be less favorable. Also, since our Coagulin-B clinical trial studies to date are still in very early stages, 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. In addition, any report of clinical trial results that are below the expectations of financial analysts or investors would most likely cause our stock price to drop dramatically.

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 in both dogs and mice, the measured levels of factor IX gene expression for comparable dosage sizes relative to body mass were different between the two animals. 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.

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

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. All of our product candidates are in early stages of development. 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 for the treatment of hemophilia 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 potential products.

Technological change may make our potential products and technologies less attractive or obsolete

Gene therapy is new and rapidly evolving and is expected to continue to undergo significant and rapid technological change. Rapid technological development could result in our actual and proposed technologies, products or processes becoming less attractive or obsolete.

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.

Deaths and other potential adverse events in the field of gene therapy, as well as any potential adverse events from other types of drug development clinical trials, that may occur in the future could result in greater governmental regulation of our potential products and potential regulatory delays relating to the testing or approval of our potential products.

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 developmental progress of our potential products is dependent upon collection of sufficient amounts of data from human clinical trials to demonstrate safe and effective results. This data can only be collected by testing our development products on patients in these trials. We have in the past experienced difficulties in enrolling patients in our clinical trials, and may in the future experience similar difficulties. 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

The clinical trial progress is complex, uncertain and expensive. Positive results from preclinical studies and early clinical trials do not ensure positive results in clinical trials designed to permit application for regulatory approval. 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. The FDA approval process is typically lengthy and expensive, and approval is never certain. 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. We may encounter significant delays or excessive costs in our efforts to secure regulatory approvals. Factors that raise uncertainty in obtaining these regulatory approvals include:

- gene therapy is a new, largely unproven, and rapidly evolving technology;
- to date, there has been only limited research and development in gene therapy using AAV vectors, which we believe will cause clinical trials to proceed more slowly than clinical trials involving traditional drugs;
- FDA approval, which may be withheld, is required to begin clinical trials of our potential products;
- we must demonstrate through clinical trials that the proposed product is safe and effective for its intended use;
- we are not aware of any gene therapy products that have obtained marketing approval from the FDA;
- whether or not our product candidates cause patients to develop antibodies to these potential products or the proteins produced by these potential products;
- the regulatory requirements governing gene therapy products are uncertain and are subject to change;
- none of our proposed products have yet been involved in tests designed to measure their effectiveness in humans; and
- data obtained from preclinical and clinical activities are susceptible to varying interpretations which could delay, limit or prevent regulatory approvals.

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 useful, as demonstrated through clinical trials.

AAV technology is still new and developing rapidly; very little clinical data results exist and new information may arise which may cause us 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. 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. 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 suspend clinical trials at any time if it believes the subjects participating in trials are being exposed to unacceptable health risks or if it finds deficiencies in the clinical trial process or conduct of the investigation.

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 also 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 health authorities of any other country.

We have limited experience in manufacturing our potential products, 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, would be revoked. Although we may be able find third-party manufacturers with greater experience and the proper licensing requirements from the FDA, we may not be able to negotiate favorable terms regarding costs or a long-term commitment to manufacture our products.

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 critical materials according to GMP regulations. If we were to lose access to critical materials from any of our 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 have no experience in marketing or selling our potential products, which raises uncertainty about our ability to commercialize our potential products cost-effectively

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 do not anticipate establishing our own sales and marketing capabilities for any of our potential products in the foreseeable future. We have entered into an agreement with Bayer Corporation, a worldwide health care and life sciences company and a leader in the development, manufacture, and distribution of hemophilia treatments, which grants Bayer Corporation exclusive worldwide marketing and distribution rights for Coagulin-B. If Bayer Corporation does not perform under this agreement, then 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.

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. 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.

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

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

If we are unsuccessful in our litigation concerning the terminated RCT license, we may not be able to retain rights to certain formulation technologies, which may prevent or delay us from commercializing our Coagulin-B product

We have sued Research Corporation Technology (RCT) of Tucson, Arizona, for breach of contract in connection with a license agreement we entered into in May 1992 for rights to a patent application related to a cell-specific promotor in AAV vectors. Two patents have since issued: USP No. 5,252,479 and No. 6,261,834. We are seeking financial damages and a determination by the court that RCT's actions have rendered the patents' claims unenforceable. If our claims of breach of contract against RCT are unsuccessful, and the court does not determine that RCT's actions have rendered its patents' claims unenforceable, we may be forced to develop alternative technologies to replace the functions of 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.

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 the following:

- research and development;
- preclinical studies and 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 directly with products we are developing. See "Item 1. Business — Competition" for a more detailed discussion of the competition we face.

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. Under the terms of the agreements with the co-inventors, we have obtained or have an option to obtain an exclusive, worldwide, transferable, royalty-bearing license for the technology. To date, we have negotiated exclusive licenses for many of our co-invented technologies. 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 the event of any unauthorized use, misappropriation or disclosure 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 or technology 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 to 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.

If our products are not accepted by physicians and insurers, we will not be successful

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. We believe that recommendations by physicians and health care payors will be essential for market acceptance of our gene therapy products. In the past, there has been concern regarding the potential safety and efficacy of gene therapy products derived from pathogenic viruses such as retroviruses and adenoviruses. While our proposed gene therapy products are derived from AAV, which is a non-pathogenic virus, we cannot be certain that physicians and health care payors will conclude that the technology is safe.

Even if we bring our products to market, we may be unable to effectively price our products or obtain adequate reimbursement for sales of our products, which would prevent our products from becoming profitable

If we succeed in bringing our proposed products to the market, 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 competitive 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. Our business and financial condition is affected by the efforts of government and third-party payors to contain or reduce the cost of health care through various means. In the United States, there have been and will continue to be a number of federal and state proposals to implement government controls on pricing. In addition, the emphasis on managed care in the United States has increased and will continue to increase the pressure on the pricing of pharmaceutical products. We cannot predict whether any legislative or regulatory proposals will be adopted or the effect these proposals or managed care efforts may have on our business.

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

We are highly dependent on members of our senior management, as well as members of our staff that lead or play critical roles in our research and development efforts. The loss of any of these persons, or our inability to recruit additional personnel necessary to our business, could substantially impair our research and development efforts and impede our ability to develop and commercialize any of our products. Recruiting and retaining qualified technical and managerial personnel will also be critical to our success. Our business is located in the San Francisco Bay Area in California, where demand for personnel with these skills is extremely high and is likely to remain high. 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 employers other than us and some have consulting or other advisory arrangements with other entities that may conflict or compete with their obligations to us.

We must secure additional financing, otherwise we will not be able to develop our products

We will require substantial additional funding to complete the research and development activities currently contemplated and to commercialize our products. If we do not obtain these funds, we will not be able to develop our products. We anticipate that our existing capital resources as of December 31, 2001, will be adequate to fund our needs for at least the next three years. 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;
- competing technological developments;
- the cost of manufacturing scale-up;
- the cost of commercialization activities; and
- other factors which may not be within our control.

We intend to seek additional funding through public or private equity or debt financing, when market conditions allow. If we raise additional funds by issuing equity securities, there will be further dilution to existing stockholders. However, we cannot assure you that we will be able to enter into financing arrangements on acceptable terms, if at all. Without 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 material 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

Because we use radioactive materials and other hazardous substances in our research and development and manufacturing operations, we are potentially subject to material liabilities related to personal injuries or property damages that may be caused by the spread of radioactive contamination or by other hazardous substance releases or exposures at, or from, our facilities. Decontamination costs associated with radioactivity releases, other clean-up costs, 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, including requirements governing the handling, storage and disposal of radioactive and other hazardous substances and wastes, and laboratory operating and safety procedures. These laws and regulations can impose substantial fines and criminal sanctions for violations. Maintaining in compliance with these laws and regulations with regard to the operation of our own commercial manufacturing facility could require substantial additional capital. These costs could decrease our ability to conduct manufacturing operations in a cost-effective manner.

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. 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

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;
- our 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.

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***

As of February 28, 2002, we were involved in one legal proceeding. On February 21, 2002, we filed a complaint in the United States District Court for the Northern District of California alleging that Research Corporation Technologies, ("RCT"), engaged in a breach of contract and breach of the implied covenant of good faith and fair dealing 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 and U.S. Patent Application No. 07/982,193 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 patent applications relating to a cell-specific promoter in AAV vectors. The license was exclusive and worldwide. In consideration for the license, we paid an initial license fee and issued 247,949 shares of our common stock. We believe that RCT's actions have

made the patents and patent applications covered by the license agreement unenforceable, and in so doing have destroyed the value of the exclusive patent license. We are seeking financial damages and a determination by the court that RCT's actions have rendered the patents' claims unenforceable.

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

(a) The Annual Meeting of Stockholders of Avigen, Inc. was held on November 16, 2001.

(b) - (e) The matters voted upon at the meeting and the voting of stockholders with respect thereto are as follows:

1. Dr. John Monahan was elected as Class III director of Avigen to hold office until the 2004 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until such directors' earlier death, resignation or removal. The voting results, with approximately 68.2% of the shares voting, was as follows:

For	13,144,880
Withhold	472,428
Abstain	-0-
Broker nonvotes	-0-

Class I directors, Zola Horovitz, Ph.D. and Yuichi Iwaki, M.D., Ph.D., will each continue to serve on the Board of Directors until the 2002 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal. Class II directors, Philip Whitcome, Ph.D. and John K.A. Prendergast, Ph.D., will each continue to serve on the Board of Directors until the 2003 Annual Meeting of Stockholders and until his successor is elected and has qualified, or until his earlier death, resignation or removal.

2. The amendment to Avigen's 1996 Non-Employee Directors' Stock Option Plan to increase the number of shares of common stock subject to automatic annual grants from 7,500 shares to 10,000 shares was approved. The voting results were as follows:

For	12,290,232
Against	1,318,567
Abstain	8,509
Broker nonvotes	-0-

3. The selection of Ernst & Young LLP as our Auditors for its transition period ended December 31, 2001 was ratified. The voting results were as follows:

For	13,609,804
Against	4,995
Abstain	2,509
Broker nonvotes	-0-

PART II

Item 5. *Market for Registrants 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 8, 2002, there were approximately 188 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 sale prices available for the fiscal years 2000 and 2001, and the transition period ended December 31, 2001.

Fiscal 2000	High	Low
Quarter End 9/30/99	$13.25	$ 5.63
Quarter End 12/31/99	$37.00	$12.25
Quarter End 3/31/00	$89.00	$28.00
Quarter End 6/30/00	$46.75	$25.00

Fiscal 2001	High	Low
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

Transition Period ended December 31, 2001	High	Low
Quarter End 9/30/01	$20.13	$9.10
Quarter End 12/31/01	$14.88	$8.90

Item 6. *Selected Financial Data*

	Six Months Ended December 31,		Fiscal Years Ended June 30,					October 22, 1992 (Inception) to December 31,
	2001	2000 (unaudited)	2001	2000	1999	1998	1997	2001
			(in thousands, except per share data)					
Statement of Operations Data:								
Grant and other revenue	$ 8	$ 30	$ 116	$ 58	$ 185	$ –0–	$ 98	$ 730
Expenses:								
Research and development	11,465	6,173	17,041	7,953	6,490	6,235	4,033	61,547
General and administrative	3,957	3,159	6,761	4,516	3,445	2,990	2,352	28,278
In-license fees	–0–	–0–	–0–	5,034	–0–	–0–	–0–	5,034
	15,422	9,332	23,802	17,503	9,935	9,225	6,385	94,859
Loss from operations	(15,414)	(9,302)	(23,686)	(17,445)	(9,750)	(9,225)	(6,287)	(94,129)
Interest income, net	4,112	2,822	7,727	2,419	148	365	710	14,911
Other income, net.....	(17)	(4)	(55)	(13)	(9)	(17)	(1)	75
Net loss	$(11,319)	$(6,484)	$(16,014)	$(15,039)	$(9,611)	$(8,877)	$(5,578)	$(79,143)
Net loss per share.....	$ (0.57)	$ (0.37)	$ (0.85)	$ (1.03)	$ (0.99)	$ (1.22)	$ (0.77)	

	December 31, 2001	June 30,				
		2001	2000	1999	1998	1997
		(in thousands)				
Balance Sheet Data:						
Cash, cash equivalents and available for sale securities	$148,254	$157,737	$ 77,953	$ 14,881	$ 4,477	$ 13,039
Working capital	147,486	158,341	76,732	13,471	4,635	11,936
Total assets	168,409	174,946	85,287	16,183	5,997	14,760
Long-term obligations	8,558	5,391	4,113	265	1,052	1,316
Deficit accumulated during development stage ..	(79,143)	(67,823)	(51,810)	(36,771)	(27,160)	(18,283)
Stockholders' equity	157,350	167,182	79,013	14,323	3,583	12,341

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" in 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, 2001 we had an accumulated deficit of $79.1 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 estimates and assumptions 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 from those estimates. We consider certain accounting policies that involve complex judgments and uncertainties to be critical policies.

Valuation of investments in financial instruments

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 are subject to credit risk. Despite the conservative nature of our investment policy, certain investments could be subject to write-down for impairment whenever events or changes in circumstances indicate that the carrying amount of these investments may not be fully recoverable. Our management reviews the securities within our portfolio for other than temporary declines in value with our investment advisor, at a minimum, on a semi-annual basis.

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.

Impairment of property and equipment

We have invested, and plan to continue to invest, significant amounts on construction for improvements to our manufacturing facilities in order 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, which could have a material effect on our balance sheet and our results of operations.

Results of Operations

Six months ended December 31, 2001 (transition period) and December 31, 2000, and fiscal years ended June 30, 2001, 2000, and 1999.

Revenue

Since our inception, our revenue has consisted primarily of grant revenue. Total revenue for the six-months ended December 2001 and 2000 was $8,000 and $30,000, respectively, and represented other revenue. Total revenue for the years ended June 30, 2001, 2000, and 1999 was $116,000, $58,000 and $185,000, respectively, and included mostly grant revenue. All grant revenue for these years consisted of reimbursements under a grant from the National Institutes of Health, which expired on March 31, 2001.

Expenses

Research and development expenses

Our research and development expenses totaled $11.5 million for the six months ended December 31, 2001 and $6.2 million for the six months ended December 31, 2000. The increase was primarily because our staff levels dedicated to research and development activities at December 31, 2001 were 50% greater than at December 31, 2000, and the amount of square footage of our premises under lease doubled between December 31, 2000 and December 31, 2001. In addition, we experienced corresponding increases in materials usage and other operating activities.

Our research and development expenses totaled $17.0 million for the year ended June 30, 2001, an increase from $8.0 million for the year ended June 30, 2000, and $6.5 million for the year ended June 30, 1999. These increases reflected similar growth in personnel, premises, and operating activities as the comparable six-month periods described above. Also significant to the rise in research and development expenses in fiscal 2000 versus fiscal 1999 was an increase of over $650,000 for research fees paid to third-party collaborators in connection with our first clinical trial and other preclinical studies that occurred during the period. We expect research and development spending to continue to increase over the next several years as we continue to expand our research, product development and clinical trial efforts.

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. Clinical development costs include activities associated with maintaining regulated and controlled processes, manufacturing vector for use in human clinical trials, and supporting patient accrual and patient administration within clinical trials. We estimate that the split in costs associated with these two functions approximate the following (in thousands):

	Six Months Ended December 31, 2001	Fiscal Year Ended June 30, 2001	Fiscal Year Ended June 30, 2000	Fiscal Year Ended June 30, 1999
Research and preclinical development	$ 6,024	$10,010	$6,112	$5,517
Clinical development	5,441	7,031	1,841	974
Total research and development expenses	$11,465	$17,041	$7,953	$6,490

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 annualized increase in our total research and development expenses for the six months ended December 2001 versus the fiscal year ended June 30, 2001 reflects balanced growth in both our research and preclinical development and clinical development activities. Between June 30, 2001 and June 30, 2000, the increase in total research and development expenses was most significantly impacted by the expansion of our clinical development activities, reflecting the increased demand for clinical-grade vector production as our Coagulin-B trials progressed, and to the growth in our research staff to diversify our projects and enhance our production techniques. The increase in total costs between June 30, 2000 and June 30, 1999 reflects the more modest growth associated with the very early stages of our first clinical trial.

General and administrative expenses

General and administrative expenses totaled $4.0 million for the six months ended December 31, 2001 and $3.2 million for the six months ended December 31, 2000. Increases in costs between the comparable six-month periods primarily include higher personnel costs, legal fees associated with intellectual property activities, and other corporate expenses such as insurances and taxes. General and administrative expenses totaled $6.8 million for the year ended June 30, 2001, up from $4.5 million for the year ended June 30, 2000, and $3.4 million for the year ended June 30, 1999. These increases between the comparable fiscal years also primarily reflect higher personnel costs, higher legal costs associated with intellectual property activities, and increases in other corporate expenses such as insurances and taxes. In general, we expect general and administrative expenses to continue to increase as the level of our operating activities increase, but should continue to decrease as a percentage of total expenses as we place more emphasis on the growth of our research and development efforts.

In-license fees

In the 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 full-year expense included cash payments to licensors of approximately $1.8 million and a non-cash charge for warrants issued to a licensor that were valued at approximately $3.2 million. These expenses are primarily initiation fees, and are not predictive of initial in-license fees to be incurred in future periods. No such in-license fees were incurred in either the six-months ended December 31, 2001 or the comparable period in 2000.

Interest Income

Interest income for the six months ended December 31, 2001 was $4.3 million compared to the comparable prior year period of $2.9 million. The rise in interest income between the two periods was directly related to increases in our balances of interest-earning cash and investments in available for sale securities in connection with equity transactions between November 2000 and December 31, 2001. These equity transactions raised approximately $108 million during the fourteen months ended December 31, 2001, and included sales of stock pursuant to a public offering in November 2000 and a collaborative agreement with Bayer Corporation in February 2001, and as a result of on-going exercises of previously issued warrants and options. Interest income for the year ended June 30, 2001 was $7.9 million, up from $2.5 million for the year ended June 30, 2000 and $326,000 in fiscal 1999. The rise in interest income between the comparable 2001 and 2000 fiscal years reflected the same increase in our cash and investments balances mentioned above. The rise in interest income between fiscal 2000 and fiscal 1999 also reflected the increase of approximately $75 million in our cash and investments balances that resulted from sales of stock pursuant to a private placement of common stock and warrants that was completed in November 1999, a public offering completed in April and May of 2000, and on-going exercises of previously issued warrants and options.

Liquidity and Capital Resources

Cash expenditures have significantly exceeded revenue since our inception. Our operations have principally been funded through public offerings and private placements of 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 completed a sale of common stock to Bayer Corporation pursuant to a collaborative 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 $12.0 million. The timing and size of 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, we have attempted to contain costs and reduce cash flow requirements by renting scientific equipment and facilities, contracting with other parties to conduct research and development and using consultants, where appropriate. We expect to incur additional future expenses, resulting in significant 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 expenses relating to the filing, prosecution, maintenance, defense and enforcement of patent and other intellectual property claims.

At December 31, 2001, we had cash, cash equivalents, available for sale securities, and restricted investments, including accrued interest, of approximately $150 million, compared to $160 million at June 30, 2001, and $79 million at June 30, 2000. Total capital resources declined between June 2001 and December 2001, primarily owing to the funding of operations. Total cash resources rose between June 2000 and June 2001 as a result of the previously mentioned sale of stock to Bayer AG in February 2001, and as a result of the November 2000 public offering of our common stock.

The following are contractual commitments at December 31, 2001 associated with debt obligations, lease obligations, and contractual commitments to fund third-party research and complete construction in progress (in thousands):

	Payments Due by Period				
Contractual Commitment	Total	Less Than 1 Year	2-3 Years	4-5 Years	After 5 Years
Revolving line of credit	$ 8,000	$ —	$ 8,000	$ —	$ —
Operating leases	19,988	2,096	4,846	5,240	7,806
Research funding for third-parties	1,757	1,567	190	—	—
Construction in progress funding	3,541	3,541		—	—
Total Contractual Commitments	$33,286	$7,204	$13,036	$5,240	$7,806

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 under these contracts are included in the table above under research funding for third-parties.

For the six months ended December 31, 2001, net cash used in operating activities was $8.3 million compared to $7.4 million for the comparable period in 2000. Excluding interest income earned on our cash, cash equivalents, and available for sale securities in each of these periods, cash used to cover operating expenses rose to $12.6 million for the six months ended December 31, 2001, up from $10.2 million for the same period in 2000, primarily due to the growth in staff, premises under lease, and expansion of other operating activities. For the year ended June 30, 2001, net cash used in operating activities was $15.2 million,

an increase over the same amounts for the years ended June 30, 2000 and 1999 of $11.7 million and $9.1 million, respectively. Excluding interest income earned on our cash, cash equivalents, and available for sale securities in each of these three years, cash used to cover operating expenses rose to $23.1 million for the year ended June 30, 2001, up from $14.2 million and $9.4 million, for the years ended June 30, 2000 and 1999, respectively.

In November 2000, we refinanced a $10 million revolving line of credit that had been put in place with Wells Fargo Bank in June 2000 to provide financial support for construction related activities. Under the terms of the agreement, the line of credit will expire on June 1, 2003, and 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. Also under the terms of the agreement, we pledged a portion of our portfolio of available for sale securities to secure this long-term obligation. The amount of pledged securities is equal to the amount of utilized borrowing capacity on the line of credit and is identified as restricted investments on our balance sheets. At December 31, 2001, 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, we have no more borrowing capacity under this facility at December 31, 2001.

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 anticipate that our capital resources at December 31, 2001 will be adequate to fund our needs through at least the next three 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. 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 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***

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 material market risk. We have also evaluated the risk associated with our Wells Capital Management investments in securities and owing to the short-term nature of our available for sale securities portfolio, have deemed this risk immaterial.

If market interest rates were to increase by 100 basis points, or 1%, from their December 31, 2001 levels, we estimate that the fair value of our securities portfolio would decline by approximately $1.8 million. The

modeling technique used estimates the 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.

Item 8. *Financial Statements and Supplementary Data*

The financial statements required by this item are set forth beginning at page F-1 of this report and are incorporated herein by reference. Condensed supplementary data for each of the quarters in transition period ended December 31, 2001, and the fiscal years ended June 30, 2001 and 2000 are set forth under Note 12 of the financial statements and are incorporated herein by reference. Additional supplementary data regarding the quarterly results of operations that would have been reported had we been previously following a December 31 year-end, are set forth under Note 13 of the financial statements and are unaudited.

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*

Information with respect to Directors and Executive Officers may be found in the sections entitled "Proposal 1 — Election of Directors," "Management — Executive Officers of the Company," and "Section 16(a) Beneficial Ownership Reporting Compliance" appearing in the definitive Proxy Statement to be delivered to stockholders in connection with the solicitation of proxies for Avigen's Annual Meeting of Stockholders to be held on May 20, 2002 (the "Proxy Statement"). Such information is incorporated herein by reference.

Item 11. *Executive Compensation*

The information required by this item is set forth in the Proxy Statement under the heading "Management — Executive Compensation," which information is incorporated herein by reference.

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

The information required by this item is set forth in the Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management," which information is incorporated herein by reference.

Item 13. *Certain Relationships and Related Transactions*

The information required by this item is set forth in the Proxy Statement under the heading "Certain Relationships and Related Transactions," which information is incorporated herein by reference.

Item 14. *Exhibits, Financial Statement Schedules, and Reports on Form 8-K*

(a) The following documents are filed as part of this Transition 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 Statements schedules have been omitted from this report because the information is provided in the Financial Statements or is not applicable.

(3) *Exhibits*

Exhibit Number	Exhibits
3.1(1)	Amended and Restated Certificate of Incorporation
3.1.1(13)	Certificate of Amendment of Certificate of Incorporation
3.2 (1)	Restated Bylaws of the Registrant
4.1(1)	Specimen Common Stock Certificate
10.1(7)	Nonstatutory Stock Option Outside of Plans to Philip J. Whitcome.
10.2(1, 2)	1993 Stock Option Plan
10.3(2, 14)	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)	1996 Non-Employee Director 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(15)	Form of Incentive Stock Option Grant for 1993 Stock Option Plan
10.15(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, 18)	Management Transition Plan
10.37(15)	Form of Common Stock Warrant Issued in February 1999 Private Placement.
10.38(4, 11)	Factor IX patent and know-how exclusive license agreement between The Children's Hospital of Philadelphia and Avigen, dated May 20, 1999.
10.39(9, 11)	License Agreement between Avigen and the University of Florida Research Foundation, Inc., dated November 13, 1992, and its First Amendment, dated March 25, 1996.
10.40(10, 11)	License Agreement, dated March 3, 2000, by and between BTG International Ltd., a British corporation and Avigen
10.41(10)	Property Lease Agreement between ARE-1201 Harbor Bay, LLC and Avigen, dated February 29, 2000
10.42(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.

Exhibit Number	Exhibits
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.
23.1	Consent of Ernst & Young LLP, Independent Auditors
24.1	Power of Attorney (Reference to the signature page herein)

(1) Filed as an exhibit to the Registrant's Registration Statement on Form -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.

(b) *Reports on Form 8-K*

On October 8, 2001, Avigen filed a report on Form 8-K reporting under Item 5 announcing that the clinical trial studying the safety of Coagulin-B™, its gene therapy treatment for hemophilia B, was on clinical hold.

On December 20, 2001, Avigen filed a report on Form 8-K reporting under Item 5 announcing that the U.S. Food and Drug Administration had given Avigen clearance to continue human clinical testing of Coagulin-B™, its gene therapy treatment for hemophilia B.

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 22, 2002

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 Report, 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.

Signature	Title	Date
/s/ JOHN MONAHAN John Monahan, Ph.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	March 22, 2002
/s/ THOMAS J. PAULSON Thomas J. Paulson	Chief Financial Officer (Principal Financial and Accounting Officer)	March 22, 2002
/s/ PHILIP J. WHITCOME Philip J. Whitcome, Ph.D.	Chairman of the Board	March 22, 2002
/s/ ZOLA HOROVITZ Zola Horovitz, Ph.D.	Director	March 22, 2002
/s/ YUICHI IWAKI Yuichi Iwaki, M.D., Ph.D.	Director	March 22, 2002
/s/ JOHN K.A. PRENDERGAST John K.A. Prendergast, Ph.D.	Director	March 22, 2002
/s/ DANIEL VAPNEK Daniel Vapnek, Ph.D.	Director	March 22, 2002

This page left intentionally blank

INDEX TO FINANCIAL STATEMENTS

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Avigen, Inc.

We have audited the accompanying balance sheets of Avigen, Inc. (a development stage company) as of December 31, 2001, June 30, 2001, and June 30, 2000 and the related statements of operations, stockholders' equity and cash flows for the six months ended December 31, 2001, for each of the three years in the period ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2001. 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, 2001, June 30, 2001 and June 30, 2000, and the results of its operations and its cash flows for the six months ended December 31, 2001, each of the three years in the period ended June 30, 2001 and for the period from inception (October 22, 1992) through December 31, 2001, in conformity with accounting principles generally accepted in the United States.

Palo Alto, California
January 31, 2002

AVIGEN, INC.
(a development stage company)

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

ASSETS

	December 31, 2001	June 30, 2001	June 30, 2000
Current assets:			
Cash and cash equivalents	$ 13,211	$ 6,092	$ 13,361
Available for sale securities	125,043	144,645	60,592
Restricted investments	10,000	7,000	4,000
Accrued interest	1,335	2,401	940
Prepaid expenses and other current assets	398	576	—
Total current assets	149,987	160,714	78,893
Property and equipment, net	16,813	12,488	4,025
Deposits and other assets	1,609	1,744	2,369
Total assets	$168,409	$174,946	$ 85,287

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:			
Accounts payable and other accrued liabilities	$ 1,643	$ 1,765	$ 1,656
Accrued compensation and related expenses	858	608	268
Current portion of capital lease obligations	—	—	237
Total current liabilities	2,501	2,373	2,161
Long-term loan payable	8,000	5,000	4,000
Deferred rent	558	391	113
Commitments			
Stockholders' equity:			
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding, in 2001 and 2000	—	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized at December 31, 2001 and June 30, 2001 and 30,000,000 shares authorized at June 30, 2000, 19,966,334, 19,945,097 and 17,000,267 shares issued and outstanding at December 31, 2001, June 30, 2001 and June 30, 2000, respectively	20	20	17
Additional paid-in capital	234,260	233,946	130,886
Accumulated other comprehensive income (loss)	2,213	1,040	(80)
Deficit accumulated during the development stage	(79,143)	(67,824)	(51,810)
Total stockholders' equity	157,350	167,182	79,013
Total liabilities and stockholders' equity	$168,409	$174,946	$ 85,287

See accompanying notes.

AVIGEN, INC.
(a development stage company)

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

	Six Months Ended December 31,		Year Ended June 30,			Period from October 22, 1992 (inception) through December 31, 2001
	2001	2000	2001	2000	1999	
		(unaudited)				
Grant and other revenue	$ 8	$ 30	$ 116	$ 58	$ 185	$ 730
Operating expenses:						
Research and development	11,465	6,173	17,041	7,953	6,490	61,547
General and administrative	3,957	3,159	6,761	4,516	3,445	28,278
In-license fees	—	—	—	5,034	—	5,034
	15,422	9,332	23,802	17,503	9,935	94,859
Loss from operations	(15,414)	(9,302)	(23,686)	(17,445)	(9,750)	(94,129)
Interest expense	(204)	(38)	(180)	(129)	(178)	(1,643)
Interest income	4,316	2,860	7,907	2,548	326	16,554
Other (expense) income, net	(17)	(4)	(55)	(13)	(9)	75
Net loss	$ (11,319)	$ (6,484)	$ (16,014)	$ (15,039)	$ (9,611)	$(79,143)
Basic and diluted net loss per share	$ (0.57)	$ (0.37)	$ (0.85)	$ (1.03)	$ (0.99)	
Shares used in basic and diluted net loss per share calculation	19,959,941	17,745,484	18,730,437	14,557,999	9,684,329	

See accompanying notes.

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY

Period from October 22, 1992 (inception) through December 31, 2001
(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
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

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

	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 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
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

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

	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 $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
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
Proceeds from exercise of options at $0.44 to $34.00 per share	—	—	165,700	—	—	—	869	—	—	869
Proceeds from exercise of warrants at $2.18 to $23.43	—	—	174,255	1	—	—	771	—	—	772
Compensation expense related to options granted for services	—	—	—	—	—	—	336	—	—	336
Issuance of common stock at $37.50 to $45.06 per share in November 2000 Public Offering (net of issuance cost of $4,622,188)	—	—	2,291,239	2	—	—	86,084	—	—	86,086
Issuance of common stock at $47.82 per share in February 2001 pursuant to a collaboration agreement	—	—	313,636	—	—	—	15,000	—	—	15,000
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(16,014)	(16,014)
Net unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	1,120	—	1,120
Comprehensive loss										(14,894)
Balance at June 30, 2001	—	—	19,945,097	20	—	—	233,946	1,040	(67,824)	167,182
Proceeds from exercise of options at $2.13 to $6.75 per share	—	—	11,282	—	—	—	60	—	—	60

AVIGEN, INC.
(a development stage company)

STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

	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 warrants $7.50 per share	—	—	9,955	—	—	—	75	—	—	75
Compensation expense related to options granted for services	—	—	—	—	—	—	179	—	—	179
Comprehensive loss:										
Net loss	—	—	—	—	—	—	—	—	(11,319)	(11,319)
Net unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	1,173	—	1,173
Comprehensive loss										(10,146)
Balance at December 31, 2001	—	$—	19,966,334	$20	—	$—	$234,260	2,213	$(79,143)	157,350

See accompanying notes

AVIGEN, INC.
(a development stage company)

STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended December 31,		Year Ended June 30,			Period from October 22, 1992 (inception) through December 31,
	2001	2000	2001	2000	1999	2001
		(unaudited)				
Operating activities						
Net loss	$(11,319)	$ (6,484)	$ (16,014)	$ (15,039)	$ (9,611)	$ (79,143)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization of fixed assets	1,167	309	1,203	394	473	5,591
Amortization of deferred compensation	—	—	—	5	41	164
Amortization of warrants issued in connection with the extension of the building lease	109	124	217	72	—	398
Amortization of deferred rent expense	167	—	278	—	—	445
Common stock, warrants, and stock options issued for services	179	209	336	89	—	1,193
Warrants issued for patent license	—	—	—	3,182	—	3,182
Changes in operating assets and liabilities:						
Accrued interest	1,066	(1,104)	(1,462)	(755)	—	(1,151)
Prepaid expenses and other current assets	178	—	(575)	—	(185)	(582)
Deposits and other assets	26	60	408	(636)	94	(343)
Accounts payable, other accrued liabilities and accrued compensation and related expenses	128	(468)	449	988	84	2,913
Net cash used in operating activities	(8,299)	(7,354)	(15,160)	(11,700)	(9,104)	(67,333)
Investing activities						
Purchases of property and equipment and construction in progress	(5,492)	(4,540)	(9,666)	(3,369)	(164)	(22,107)
Purchases of available for sale securities	(63,817)	(67,704)	(180,757)	(150,233)	(35,263)	(468,339)
Maturities of available for sale securities	81,592	37,051	94,825	97,497	26,524	335,511
Net cash provided by (used in) investing activities	12,283	(35,193)	(95,598)	(56,105)	(8,903)	(154,935)
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)	(638)	(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	135	859	1,640	9,962	222	11,973
Proceeds from issuance of common stock, net of issuance costs and repurchases	—	86,099	101,086	64,831	20,088	205,619
Net cash provided by financing activities	3,135	87,765	103,489	78,221	19,672	235,479
Net increase (decrease) in cash and cash equivalents	$ 7,119	$ 45,218	$ (7,269)	$ 10,416	$ 1,665	$ 13,211
Cash and cash equivalents, beginning of period	6,092	13,361	13,361	2,945	1,280	—
Cash and cash equivalents, end of period	$ 13,211	$ 58,579	$ 6,092	$ 13,361	$ 2,945	$ 13,211
Supplemental disclosure						
Issuance of preferred stock for cancellation of accounts payable, notes payable and accrued interest	$ —	$ —	$ —	$ —	$ —	$ 499
Issuance of stock options for repayment of certain accrued liabilities	$ —	$ —	$ —	$ —	$ —	$ 137
Issuance of warrants in connection with bridge financing	$ —	$ —	$ —	$ —	$ —	$ 300
Issuance of warrants in connection with 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	$ 204	$ 38	$ 180	$ 129	$ 178	$ 1,150

See accompanying notes.

1. Summary of Significant Accounting Policies

Description of Business and Basis of Presentation

Avigen, Inc. (the "Company") was incorporated on October 22, 1992 in Delaware for the purpose of development and commercialization of gene-based therapeutic products. The Company's activities since inception have consisted principally of acquiring product rights, raising capital, establishing facilities and performing research and development. Accordingly, the Company is considered to be in the development stage. The Company operates in one industry segment.

The Company expects to continue to incur substantial losses over the next several years during its development state. The Company plans to meet its 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. The Company intends to seek additional funding through public or private equity or debt financing, when market conditions allow. There can be no assurance that the Company will be able to enter into financing arrangements on acceptable terms in the future, if at all.

In August 2001, the Company changed its 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 management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Unaudited Financial Information

The accompanying financial information for the six month period ended December 31, 2000, and the financial information for the calendar years ended December 31, 2001 and 2000 presented in Note 13, are unaudited, but have been prepared on the same basis as the financial information for the six month period ended December 31, 2001 and, in the opinion of management, includes all the adjustments (consisting of normal recurring adjustments) that the Company considers necessary for a fair presentation of this information. Operating results for these periods are not necessarily indicative of results that may be expected for any future periods.

Cash, Cash Equivalents, and Available for Sale Securities

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. In accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," the Company has classified its 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. The Company's available-for-sale securities consist principally of corporate debt securities and federal agency obligations with a minimum short-term rating of A1/P1 and a minimum long-term rating of A and with 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.

Concentration of Credit Risk

Cash, cash equivalents and available for sale securities consist of financial instruments that potentially subject the Company to concentrations of credit risk to the extent of the value of the assets recorded on the balance sheet. The Company believes that it has established guidelines for investment of its excess cash that maintain safety and liquidity through its policies on diversification and investment maturity.

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

Revenue consists primarily of grant revenue, which includes amounts earned pursuant to reimbursements under government grants. To date, all reimbursements under government grants have come from the National Institutes of Health. The Company records revenue in the period in which the revenue is earned as defined by the grant agreement.

Stock-Based Compensation

The Company follows Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," ("APB 25") and related interpretations, in accounting for its employee and director stock based compensation. The Company issues employee stock options equal to the market price of the underlying stock on the date of the option grant. As a result, no compensation expense is recognized.

For equity awards to non-employees, including lenders, lessors and consultants, the Company applies 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 expense over the period of services received or the term of the related financing.

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 Costs

Research and development expenses consist of costs incurred for independent and collaborative research and development. These costs include direct costs and research-related overhead expenses and are charged to expense as incurred.

Income Taxes

Income taxes are accounted for in accordance with Statement of Financial Accounting Standards No. 109 "Accounting for Income Taxes" ("SFAS 109"). Under the asset and liability method of SFAS 109, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities, and their respective tax

bases. Deferred tax assets and liabilities are measured 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, the Company has no history of earnings. As such, the Company cannot anticipate taxable income as outlined in SFAS 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:

	Six Months Ended December 31, 2001	Year Ended June 30,		
		2001	2000	1999
Stock options outstanding	4,009,817	3,905,559	2,355,313	1,567,814
Warrants to purchase common stock	1,423,907	1,433,862	1,613,366	2,025,369
	5,433,724	5,339,421	3,968,679	3,593,183

Impairment of Long-Lived Assets

In accordance with Statement of Financial Accounting Standards No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of" ("SFAS 121"), the Company reviews 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. Under SFAS 121, an impairment loss would be recognized when estimated un-discounted future cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. Through December 31, 2001, there have been no such losses.

Reclassifications

The Company has reclassified certain prior year amounts to conform to the current year's presentation. The reclassifications had no impact on the Company's financial position or results of operations.

Recently Issued Accounting Standards

In August 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets", or "SFAS 144". SFAS 144 supercedes SFAS 121, "Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to be Disposed of" and the accounting and reporting provisions of Accounting Principles Board Opinion No. 30, "Reporting the Results of Operations — Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions", for the disposal of a segment of a business. SFAS 144 establishes a single accounting model for assets to be disposed of by sale whether previously held and used or newly acquired. SFAS No. 144 retains the provision of APB No. 30 for the presentation or discontinued operations in the income statement, but broadens the presentation to include a component of an entity. SFAS 144 is effective for fiscal years beginning after December 15, 2001 and the interim periods within. The Company does not believe that the adoption of SFAS 144 will have a material impact on its financial position of results of operations.

2. Available for Sale Securities and Restricted Investments

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

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
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	14,336	174	(22)	14,488
Total	$146,041	$2,303	$(90)	$148,254
Amounts reported as Cash and cash equivalents	13,211	—	—	13,211
Available for sale securities and restricted investments	$132,830	$2,303	$(90)	$135,043

The weighted average maturity of investments held at December 31, 2001 was 450 days, with $43.7 million carrying a weighted average maturity of less than twelve months, and $104.6 million carrying a weighted average maturity between one and three years.

The following is a summary of available for sale securities as of June 30, 2001 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	$ 2,573	$ —	$	$ 2,573
Corporate debt securities	95,748	575	(78)	96,245
Federal agency obligations	50,544	470	(12)	51,002
Asset-backed and other securities	7,832	85	—	7,917
Total	$156,697	$1,130	$(90)	$157,737
Amounts reported as Cash and cash equivalents	6,092	—	—	6,092
Available for sale securities and restricted investments	$150,605	$1,130	$(90)	$151,645

The following is a summary of available for sale securities as of June 30, 2000 (in thousands):

	Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash	$ 1,681	$—	$ —	$ 1,681
Corporate debt securities	66,934	12	(93)	66,853
Federal agency obligations	6,418	4	(1)	6,421
Asset-backed and other securities	3,000	—	(2)	2,998
Total	$78,033	$16	$(96)	$77,953
Amounts reported as Cash and cash equivalents	13,361	—	—	13,361
Available for sale securities and restricted investments	$64,672	$16	$(96)	$64,592

Net realized gains were approximately $650,000 for the six months ended December 31, 2001 and were not material for the years ended June 30, 2001, 2000, and 1999.

3. Property and Equipment

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

	December 31, 2001	June 30, 2001	June 30, 2000
Leasehold improvements	$ 9,428	$ 9,391	$ 1,613
Laboratory equipment	5,675	4,713	1,771
Furniture and fixtures	1,702	1,627	618
	16,805	15,731	4,002
Less accumulated depreciation and amortization	(5,056)	(3,960)	(2,934)
	11,749	11,771	1,068
Construction in progress	5,063	717	2,957
Property and equipment, net	$16,813	$12,488	$ 4,025

As of June 30, 2001, the Company had made all payments due under prior capital lease obligations, and no longer had any outstanding capital lease commitments. As a result, property and equipment at December 31, 2001 and June 30, 2001 did not include any amounts subject to capital leases; however at June 30, 2000, approximately $2,209,000 was under capital lease obligations with related accumulated amortization of $1,973,000.

In the normal course of business, the Company enters into contracts for the construction and improvement of its research and manufacturing facilities. While these contracts are cancelable, the Company expects the work described in such contracts to be completed and all amounts paid when due. At December 31, 2001, the estimated costs to complete all construction projects in progress was $3.5 million, all of which is expected to be paid within the next twelve months.

4. Loan Payable

The Company has a financing arrangement for construction related activities. Under this arrangement, the Company had the right to borrow up to $10 million through June 1, 2003. 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 3.5% at December 31, 2001. The Company has pledged a portion of its portfolio of available for sale securities equal to the amount of utilized borrowing capacity to secure this long-term obligation, and has identified these pledged assets as restricted investments on its balance sheets. As of December 31, 2001, June 30, 2001 and June 30, 2000, the Company had drawn $8 million, $5 million, and $4 million, respectively, from the line of credit. Payments of interest only are due monthly through June 1, 2003, at which time a balloon payment of outstanding principal is due. In November 2000, the Company reserved the remaining borrowing capacity from the line of credit to secure a $2 million 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, the Company no longer had any remaining borrowing capacity under the line of credit at December 31, 2001.

5. Stockholders' Equity

Common Stock

In August and September 1998, the Company issued an aggregate of 1,306,505 shares of its 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, the Company issued warrants to purchase 261,301 shares of its 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 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 $2,969,000, net proceeds from this transaction approximated $2,735,000.

In December 1998, the Company issued 1,367,280 shares of 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, the Company issued warrants to purchase 273,456 shares of its 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 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 $5,635,000, net proceeds from this transaction approximated $5,197,000.

In February and April 1999, the Company issued an aggregate of 2,198,210 shares of 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, the Company issued warrants to purchase 439,642 shares of its 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, the Company issued an aggregate of 2,033,895 shares of its 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, the Company issued warrants to purchase 406,779 shares of its 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 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 $40,028,000, net proceeds from this transaction approximated $37,222,000.

In March 2000, the Company issued a warrant to purchase 40,000 shares of its common stock as partial consideration for the extension of the Company's 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 the underlying stock at the time of issuance, $56.00, and carries a five-year term.

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

In April and May 2000, the Company issued an aggregate of 1,150,000 shares of its common stock at $26 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, the Company issued an aggregate of 2,291,239 shares of its 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, the Company issued 313,636 shares of common stock at $47.82 per share to Bayer AG, in connection with a collaboration agreement entered into with Bayer Corporation dated November 17, 2000. Net proceeds from this transaction totaled $15,000,000.

At December 31, 2001, the Company had outstanding warrants to purchase shares of common stock as follows:

Number Of Shares	Exercise Price	Issue Date	Expiration Date
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
583,379	$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
50,000	$82.00	2000	2005
1,423,907	$2.47 - $82.00		2003 - 2005

Shares Reserved for Future Issuance

The Company has reserved shares of common stock for future issuance as follows:

	December 31, 2001
Stock options outstanding	4,009,817
Stock options available for grant	3,740,621
Warrants to purchase common stock	1,423,907
Shares available for Employee Stock Purchase Plan	360,000
	9,534,345

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 key employees, directors and consultants of the Company 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, 2001, 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 employees, directors

and consultants of the Company. 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, 2001, there were 2,500,000 shares available 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, 2001, there were options to purchase approximately 1,605,000 shares outstanding under the 1996 Plan and approximately 314,000 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 employees, directors and consultants of the Company 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 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, 2001, there were options to purchase approximately 1,714,000 shares outstanding under the 2000 Plan and approximately 3,286,000 shares available for grant.

Employee Stock Purchase Plan

In September 1997, the Company adopted the 1997 Employee Stock Purchase Plan ("Purchase Plan"). A total of 360,000 shares of common stock have been reserved for issuance under the Purchase Plan. As of December 31, 2001, there have been no employee contributions to the Purchase Plan.

Non-employee Stock Options

In July 1995, the Company granted a member of its Board of Directors an option to purchase 515,248 shares of 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 June 30, 2001, the option was fully vested; however, no part of this option had been exercised. Such grant was made outside of any of the Company's stock option plans.

The 1996 Non-Employee Directors' Stock Option Plan (the "Directors' Plan") provides for automatic grants of options to purchase shares of common stock to non-employee directors of the Company. 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, 2001, nonqualified options to purchase 160,000 shares of common stock between $2.00 - $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 140,000 shares remained outstanding. At December 31, 2001, there were approximately 140,000 shares available for grant under the Directors' Plan.

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

	Outstanding Options	
	Number of Shares	Weighted-Average Exercise Price per Share
Outstanding at July 1, 1998	1,554,413	$ 2.05
Granted	761,751	4.87
Canceled	(278,419)	3.32
Exercised	(181,045)	1.22
Outstanding at June 30, 1999	1,856,700	3.10
Granted	980,344	32.04
Canceled	(42,693)	4.16
Exercised	(439,038)	3.49
Outstanding at June 30, 2000	2,355,313	15.05
Granted	1,774,076	20.27
Canceled	(58,130)	23.54
Exercised	(165,700)	5.25
Outstanding at June 30, 2001	3,905,559	17.71
Granted	175,950	12.00
Canceled	(60,410)	16.71
Exercised	(11,282)	5.32
Outstanding at December 31, 2001	4,009,817	17.51

The following table summarizes information with regard to total stock options outstanding under all stock option plans at December 31, 2001:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Of Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number of Shares	Weighted-Average Exercise Price
$ 0.44 – $ .49	525,406	3.56	$ 0.49	525,406	$ 0.49
0.71 – 3.63	277,745	5.79	2.77	249,583	2.77
4.00 – 6.00	320,637	7.10	5.48	204,690	5.47
6.31 – 10.10	170,495	8.53	8.06	33,006	6.81
10.23 – 14.12	81,057	9.20	12.35	14,164	12.40
14.31 – 17.50	1,303,242	9.17	14.72	115,413	15.00
17.60 – 20.38	84,875	9.16	18.86	13,654	18.94
21.41 – 28.00	97,750	8.48	25.55	42,013	25.22
29.00 – 29.00	257,735	8.38	29.00	79,943	29.00
30.14 – 38.19	714,875	8.54	37.33	232,619	37.04
$38.88 – 56.00	176,000	8.49	43.33	59,298	43.68
	4,009,817	7.80	17.51	1,569,789	12.13

The numbers of options exercisable at June 30, 2001, 2000 and 1999 were 1,217,656, 875,787, and 998,720 respectively, with a weighted average exercise price of $9.25, $2.31, and $1.77 respectively.

Pro forma information regarding net loss and net loss per share is required by SFAS 123 and has been determined as if the Company had accounted for its employee stock options under the fair value method prescribed by SFAS 123. For purposes of pro forma disclosures, the estimated fair value of employee stock options is amortized to expense over the vesting period of the options. The Company uses the Black-Scholes option-pricing model to calculate the fair value of these options with the following assumptions:

	Six Months Ended December 31, 2001	Year Ended June 30, 2001	2000	1999
Expected volatility	2.2492	2.3453	2.5884	2.9242
Risk free interest rate	4.50%	5.50%	6.50%	5.00%
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. The Company's employee stock options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate. In management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options. The pro forma net loss and pro forma basic and diluted net loss per common share using the assumptions noted above are as follows:

	Six Months Ended December 31,		Year Ended June 30,		
	2001	2000 (unaudited)	2001	2000	1999
Net loss — as reported	$(11,319)	$ (6,484)	$(16,014)	$(15,039)	$ (9,611)
Net loss — pro forma	(15,360)	(10,807)	(24,479)	(17,245)	(10,374)
Net loss per share basic and diluted — as reported	(0.57)	(0.37)	(0.85)	(1.03)	(0.99)
Net loss per share basic and diluted — pro forma	(0.77)	(0.61)	(1.31)	(1.18)	(1.07)

7. Employee Profit Sharing/401(k) Plan

In January 1996, the Company adopted a Tax Deferred Savings Plan under Section 401(k) of the Internal Revenue Code (the "Plan") for all full-time employees. Eligible employees can contribute amounts to the Plan via payroll withholding, subject to certain limitations. The Company's contributions to the Plan are discretionary. Effective July 1, 2001, the Company 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. Company matching contributions for all employees for the six months ended December 31, 2001 were approximately $65,000.

8. Collaboration Agreement

In November 2000, the Company entered into a collaboration agreement with Bayer Corporation (Bayer). Under the terms of the agreement, Bayer, in collaboration with the Company, will conduct Phase II/III clinical trials for the Company's product, Coagulin-B™, and receive exclusive worldwide marketing and distribution rights to the product. The Company will file and bear the cost of regulatory approvals and will be the holder of regulatory licenses worldwide. The Company 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 its intellectual property. Bayer will make milestone payments, pay for third-party costs of the clinical trials, and reimburse costs of manufacturing AAV vector used in the clinical trials. As at December 31, 2001 no revenue has been recognized under this agreement.

In connection with this collaboration agreement, in February 2001, the Company 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. Related Party Transactions

During the year ended June 30, 1999, the Company paid an entity managed by a Board member $173,000 related to commissions and fund raising services provided by the entity in relation to one of the Company's private placements.

10. Commitments

The Company leases its laboratory, manufacturing, and office facilities under multiple non-cancelable operating lease agreements, which expire at various times through November 2010. Under one of these operating leases, the Company has pledged $2 million of its available for sale securities to secure a letter of credit required under the terms of the lease. This amount is included in restricted investments on the balance sheet at December 31, 2001 and June 30, 2001.

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

	Operating Lease
Year ending June 30:	
2002	$ 2,096
2003	2,343
2004	2,503
2005	2,586
2006	2,654
Thereafter	7,806
Total non-cancelable lease payments	$19,988

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

The Company also enters into commitments to fund collaborative research and clinical work performed by third parties. While these contracts are cancelable, the Company expects 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, 2001, the estimated costs related to these commitments totaled $1.8 million, all of which is expected to be paid within the next twelve to eighteen months.

Legal proceedings

The Company is subject to legal proceedings, claims, and litigation arising in the ordinary course of business. While the outcome of these matters is currently not determinable, management does not expect that the ultimate costs to resolve these matters will have a material adverse effect on the Company's financial position, results of operations, or cashflows.

11. Income Taxes

Significant components of the Company's deferred tax assets are as follows (in thousands):

	December 31, 2001	June 30, 2001	June 30, 2000
Net operating loss carryforward	$ 27,500	$ 23,800	$ 16,552
Research and development credit carryforwards	3,800	3,280	1,743
Capitalized research and development	3,700	2,380	1,887
Capitalized patents	1,700	1,780	1,947
Other	400	860	691
Gross deferred tax assets	37,100	32,100	22,820
Unrealized gain on investment	(800)	(420)	—
Valuation allowance	36,300	(31,680)	(22,820)
Net deferred tax assets	$ —	$ —	$ —

Due to the Company's history of losses, a valuation allowance has been provided against the full amount of deferred tax assets. The valuation allowance increased by $4,620,000, $8,860,000, and $7,379,000 for the six months ended December 31, 2001 and the years ended June 30, 2001 and 2000, respectively.

Deferred tax assets related to carryforwards at December 31, 2001 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, 2001, the Company has net operating loss carryforwards for federal and state income tax purposes of approximately $79,000,000 and $14,000,000, respectively, which expire in fiscal years ended December 31, 2002 through December 31, 2021. At December 31, 2001, the Company has research and development credit carryforwards for federal tax purposes of approximately $2,600,000, which expire in fiscal years ended December 31, 2009 through December 31, 2021.

Because of the "change in ownership" provisions of the Internal Revenue Code of 1986, utilization of the Company's 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.

12. Condensed Quarterly Financial Information (Unaudited)

	Six Months Ended December 31, 2001	
	First Quarter	Second Quarter
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			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
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)

	Year Ended June 30, 2000			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Total revenue	$ —	$ 39	$ 19	$ —
Net loss	(2,367)	(2,482)	(7,178)	(3,012)
Net loss per share, basic and diluted	(0.18)	(0.18)	(0.51)	(0.20)

13. Quarterly Results of Operations (Unaudited)

In August 2001, the Company changed its fiscal year end from June 30 to December 31. The following unaudited quarterly information is presented for informational purposes only:

	12 Months Ended December 31, 2001				Calendar Year 2001
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	
Grant and other revenue	$ —	$ 86	$ —	$ 8	$ 94
Operating expenses:					
Research and development	5,826	5,042	5,385	6,080	22,333
General and administrative	1,653	1,949	1,923	2,034	7,559
	7,479	6,991	7,308	8,114	29,892
Loss from operations	(7,479)	(6,905)	(7,308)	(8,106)	(29,798)
Interest expense	(71)	(72)	(75)	(129)	(347)
Interest income	2,684	2,364	2,000	2,316	9,364
Other (expense) income, net	(30)	(21)	(9)	(8)	(68)
Net loss	$(4,896)	$(4,634)	$(5,392)	$(5,927)	$(20,849)

	12 Months Ended December 31, 2000				Calendar Year 2000
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	
Grant and other revenue	$ 19	$ —	$ 30	$ —	$ 49
Operating expenses:					
Research and development	1,900	2,695	2,825	3,345	10,765
General and administrative	1,113	1,376	1,468	1,693	5,650
In-license fees	5,034	—	—	—	5,034
	8,047	4,071	4,293	5,038	21,449
Loss from operations	(8,028)	(4,071)	(4,263)	(5,038)	(21,400)
Interest expense	(15)	(59)	(35)	(3)	(112)
Interest income	870	1,121	1,249	1,611	4,851
Other (expense) income, net	(4)	(3)	(3)	(2)	(12)
Net loss	$(7,177)	$(3,012)	$(3,052)	$(3,432)	$(16,673)

This page left intentionally blank

AVIGEN | CORPORATE INFORMATION

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, and Former Vice President, Business Development and Planning, Bristol-Myers Squibb Co.

Yuichi Iwaki, M.D., Ph.D.
Professor of Urology and Pathology, and Director, Metic Transplantation and Immunogenetics Institute, 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

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

Janice Castillo
Vice President, Regulatory Affairs and Quality Assurance

Kenneth G. Chahine, Ph.D., J.D.
Vice President, Business Development and Intellectual Property

Fred Johnson, Ph.D.
Vice President, Operations

Alan McClelland, Ph.D.
Vice President, Research and Development

SCIENTIFIC ADVISORY BOARD

Alan McClelland, Ph.D.
Chairman of the Advisory Board
Vice President, Research and Development, Avigen, Inc.

Jef D. Boeke, Ph.D., D.Sc.
Professor of Molecular Biology and Genetics, Johns Hopkins University School of Medicine

Katherine A. High, M.D.
William H. Bennett Associate Professor of Pediatrics, University of Pennsylvania, and Director of Research, Hematology Division, The Children's Hospital of Philadelphia

Mark Israel, M.D.
Professor of Pediatrics and Genetics, Dartmouth Medical School

Yuichi Iwaki, M.D., Ph.D.
Professor, Departments of Urology and Pathology, Transplantation Immunology and Immunogenetic Laboratory, University of Southern California, and Director, Avigen, Inc.

Y.W. Kan, M.D., D.Sc.
Louis K. Diamond Professor of Hematology, University of California at San Francisco

Randall J. Kaufman, Ph.D.
Professor of Biological Chemistry and Investigator, Howard Hughes Medical Institute, University of Michigan Medical School

Mark Kay, M.D., Ph.D.
Director of the Program in Human Gene Therapy and Professor, Department of Pediatrics and Genetics, Stanford University School of Medicine

Haig H. Kazazian, Jr., M.D.
Seymour Gray Professor and Chairman, Department of Genetics, University of Pennsylvania School of Medicine

Keiya Ozawa, M.D., Ph.D.
Professor and Chairman, Department of Hematology, Center for Molecular Medicine, Jichi Medical School, Japan

Jeffrey M. Rosen, Ph.D.
C.C. Bell Professor of Molecular and Cellular Biology, Baylor College of Medicine

David W. Russell, M.D., Ph.D.
Associate Professor, Department of Medicine, University of Washington

CORPORATE HEADQUARTERS

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

LEGAL COUNSEL

Cooley Godward LLP
Palo Alto, California

INDEPENDENT AUDITORS

Ernst & Young LLP
Palo Alto, California

TRANSFER AGENT & REGISTRAR

Stockholders with questions regarding stock transfer requirements, lost certificates, and changes of address should contact our Transfer Agent:
American Stock Transfer & Trust Co.
59 Maiden Lane
New York, New York 10038
1-800-937-5449

COMMON STOCK INFORMATION

Avigen's common stock is traded on the Nasdaq National Market under the symbol AVGN. As of March 8, 2002 there were approximately 188 stockholders of record of Avigen's common stock and 20,068,139 shares of common stock outstanding. Avigen has not paid dividends on its common stock since its inception and does not anticipate paying any dividends in the foreseeable future.

INVESTOR RELATIONS

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

ANNUAL MEETING

The annual meeting of stockholders will be held on Monday, May 20, 2002, at 9:00 a.m. PST at Avigen's corporate headquarters,
1301 Harbor Bay Parkway
Alameda, California 94502

TRADEMARKS

Coagulin-B is a trademark of Avigen, Inc.

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