UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

☒ ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2004

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

For the transition period from to

Commission File Number: 0-22613

AVI BIOPHARMA, INC.

(Name of small business issuer in its charter)

Oregon	**93-0797222**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
One SW Columbia Street, Suite 1105, Portland, Oregon	**97258**
(Address of principal executive offices)	(Zip Code)

Issuer's telephone number, including area code: **503-227-0554**

Securities registered under Section 12(b) of the Exchange Act: **None**

Securities registered under Section 12(g) of the Exchange Act:
Common Stock with $.0001 par value
(Title of Class)

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☒ No ☐

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Stock Market on March 14, 2005) was approximately $110,607,498 as of March 14, 2005. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on March 14, 2005 was 44,144,462.

Documents Incorporated by Reference

The issuer has incorporated into Part III of Form 10-K, by reference, portions of its Proxy Statement for its 2005 annual meeting.

AVI BIOPHARMA, INC.
FORM 10-K INDEX

PART I

Item 1. Description of Business

General Overview

We are a biopharmaceutical company developing therapeutic products principally based on third-generation NEUGENE® antisense technology. Our principal products in development target life-threatening diseases, including cardiovascular disease, infectious disease and cancer. Currently approved drugs or other therapies for these diseases often prove to be ineffective or produce undesirable side effects. Our pre-clinical and clinical studies indicate that our technology may produce drugs that we believe offer more effective treatment options with fewer side effects than currently approved products. A patent estate including 169 patents (foreign and domestic) issued or licensed to us and 148 pending patent applications (domestic and foreign) protects our technologies. Our lead product candidate, Resten-NG®, targets a market we believe may exceed $3 billion worldwide.

We have developed third-generation antisense technology that we believe produces drugs that may be more stable, specific, efficacious, and cost effective than other gene-targeting technologies, including second-generation antisense, ribozyme, and siRNA compounds. In eleven clinical trials involving over 300 subjects, we have not observed any drug-related serious adverse events. NEUGENE drugs are synthetic polymers that block the function of selected genetic sequences involved in disease processes. Targeting specific genetic sequences provides for greater selectivity than that available through conventional drugs. NEUGENE drugs have the potential to provide safe and effective treatment for a wide range of human diseases. NEUGENE drugs are distinguished by a novel backbone chemistry that replaces the modified backbones of competing technologies with a synthetic backbone that has been designed to improve pharmaceutical parameters.

We have completed pre-clinical and some clinical studies using our NEUGENE drugs in the treatment of cardiovascular disease, infectious disease, cancer and polycystic kidney disease (PKD), and in regulating drug metabolism. We filed our first antisense Investigational New Drug application (IND) with the FDA for Resten-NG for cardiovascular restenosis in 1999 and have completed a Phase I and a Phase II clinical trial. We have completed four Phase I trials in our drug metabolism program and two Phase Ib trials in our cancer and polycystic kidney disease programs. We filed an IND and conducted a Phase Ib trial in 2003 for our NEUGENE antisense drug for West Nile virus infection.

This annual report includes our trademarks and registered trademarks, including NEUGENE, AVICINE, Resten-NG and Oncomyc-NG. Each other trademark, trade name or service mark appearing in this annual report belongs to its holder.

Clinical Development Program

Our therapeutic products are based on NEUGENE antisense technology with initial applications in cardiovascular disease, infectious disease, and cancer. We currently have products at various stages of clinical development as summarized below. We will not have marketable products unless and until our drug candidates complete all required clinical trials and receive FDA approval in the United States or approval by regulatory agencies outside of the United States.

Product Candidate	Type	Pre-Clinical	Phase I/Ib	Phase II	Phase III
Cardiovascular Disease					
Restenosis: Resten-NG	NEUGENE Drug	Completed	Completed	Completed	Planned *
Restenosis: Resten-MP microparticles	NEUGENE Drug	Completed	Completed	In-progress	
CABG: AVI-5126	NEUGENE Drug	In-progress	Planned	Planned	
CABG: Resten-MP	NEUGENE Drug	In-progress			
Infectious Disease (Viral targets)					
West Nile: AVI-4020	NEUGENE Drug	Completed	Completed	In-progress	
Hepatitis C: AVI-4065	NEUGENE Drug	In-progress	Planned	Planned	
SARS: AVI-4179	NEUGENE Drug	Completed			
Ebola Zaire	NEUGENE Drug	In-progress	Planned		
Cancer					
Cancer: Oncomyc-NG™	NEUGENE Drug	Completed	Completed	Planned	
Drug Metabolism					
Cytochrome P450: AVI-4557	NEUGENE Drug	Completed	Completed		
Genetic Disorders					
PKD: AVI-4126	NEUGENE Drug	Completed	Completed		

*In this table, “Planned” refers to trials that are being designed although a protocol may not yet be complete; “In-progress” refers to studies or trials that have actively begun but are not yet complete; and “Completed” refers to studies in which the clinical trial or study has ended, the data have substantially been collected and validated, and a full study report is either in progress or complete.

Costs for a clinical trial typically range between $300,000 and $500,000 for a Phase I trial, between $500,000 and $4 million for a Phase II trial and could range between $5 million and $50 million for a Phase III trial. Because the scope, timing and issues encountered in each trial vary, we cannot predict the exact costs associated with a particular trial in advance. For the same reasons, we cannot predict the nature, timing and costs of future studies or trials for a product, how a product will proceed toward and through Phase III clinical trials and, if Phase III clinical trials are successful, when and if FDA approval will be sought and received.

Cardiovascular Disease Program. Resten-NG is a NEUGENE antisense drug for treating cardiovascular restenosis, or the re-narrowing of a coronary artery following angioplasty. Resten-NG targets a key regulatory gene involved in the disease process. We believe that by blocking the action of this gene, vessel wall re-narrowing will be reduced or eliminated. At the September 2003 Transcatheter Cardiovascular Therapeutics conference, we announced interim Phase II clinical trial data showing that Resten-NG delivered via catheter during balloon angioplasty procedures resulted in an approximate 75% reduction in the restenosis rate. At the April 2003 American College of Cardiology meeting, results from two

independent studies were presented that additionally demonstrate the potential of treating cardiovascular restenosis by delivering Resten-NG systemically using our proprietary microparticle delivery technology, possibly lessening the need for, or as an adjunct to, drug eluting stents. We have initiated a Phase II clinical trial with Resten-NG coupled with our microparticle delivery technology at the University of Nebraska Medical Center. We are planning a Phase III trial to be initiated in Europe for Resten-NG delivered on a stent platform to meet the regulatory requirements for a CE Mark, constituting marketing approval for the European Union.

Infectious Disease Program. Our infectious disease program is currently focusing on single-stranded RNA viruses using our proprietary NEUGENE antisense compounds targeting West Nile virus, Hepatitis C virus, Dengue virus, the SARS coronavirus, and Ebola virus, and also targeting many of the viruses included on the Department of Homeland Security list of bioterrorism viruses. In May 2003, we filed an application with the FDA to obtain Orphan Drug designation for our West Nile NEUGENE drug candidate, AVI-4020, and submitted an IND the following month. Our NEUGENE drug candidate AVI-4179, designed to combat the SARS coronavirus, has been evaluated at an independent laboratory and found to be efficacious in pre-clinical studies. Our second clinical trial in West Nile virus is currently underway. We have filed for Orphan Drug designation for our SARS coronavirus drug candidate. Due to unpredictable future demand for drugs targeting West Nile virus and the SARS coronavirus, our efforts toward commercialization in viral diseases will initially focus on Hepatitis C virus.

Cancer Program. We have completed a Phase Ib clinical trial with our NEUGENE drug candidate AVI-4126, which demonstrated the systemic delivery into solid tumor tissues for both breast and prostate cancer patients. AVI-4126 targets the oncogene c-myc. Over-expression of c-myc has been described in many types of cancers. In January 2003, we were awarded a $250,000 grant from the National Cancer Institute to target prostate cancer. We plan to initiate an additional Phase II study in bladder cancer in 2005.

Drug Metabolism Program. We have successfully completed clinical trials demonstrating that our NEUGENE antisense drug improved the pharmacokinetic profile of two different test drugs by down-regulating the liver enzyme that is critical to the body's processing of many drugs. Two clinical studies completed in late 2002 showed that AVI-4557 down-regulated cytochrome P450 3a4, which resulted in an improved pharmacokinetic profile of the test drugs. In 2003, we completed an oral dosing study with this agent to evaluate this route of administration for our antisense compounds. We are pursuing strategic relationships with pharmaceutical co-development partners.

Polycystic Kidney Disease Program. We completed a Phase Ib clinical trial in 2002 to evaluate the safety and pharmacokinetics of three doses of AVI-4126 in adult patients with polycystic kidney disease and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function. We are pursuing public or private sponsorship for any future clinical trials in this area.

Business Strategy

Our strategy is to:

- focus on near-term opportunities in cardiovascular and viral disease areas;
- select gene targets with broad or multiple disease applications;
- manage drug discovery, pre-clinical and early to mid-stage clinical development in-house; and

- initially co-develop or license products with or to strategic partners generally during or after completion of Phase II clinical trials to enhance value and share the costs of late stage clinical trials and commercialization.

Collaborative Agreements

We believe that our NEUGENE technology is broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To exploit this core technology as fully as possible, we expect to enter into collaborative development agreements with pharmaceutical companies for specific molecular targets for our NEUGENE antisense technology. We anticipate that the NEUGENE antisense collaborative research agreements may provide us with some funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from their collaborative research programs. We intend to retain manufacturing rights to our antisense products. There can be no assurance, however, that we will be able to enter into collaborative research agreements with pharmaceutical companies on terms and conditions satisfactory to us. The agreements described in this "Collaborative Agreements" section are generally only cancelable for nonperformance, including failure to make any payments and, in some cases, failure to commercially exploit the technology. There is no assurance the proposed products will be successfully developed under these collaborative arrangements or we will receive any of the potential payments noted herein.

We plan to market the initial products for which we obtain regulatory approval, through co-development and marketing arrangements with strategic partners or other licensing arrangements with larger pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products we develop and our financial resources. We do not expect to establish a direct sales capability for therapeutic compounds for at least the next several years. The timing of our entry into marketing arrangements or other licensing arrangements will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act. Although the implementation of initial aspects of our marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and our marketing strategy therefore may not be implemented for several years.

SuperGen Alliance

In April 2000, we entered into an alliance with SuperGen, Inc. for shared development and marketing rights for AVICINE, our therapeutic cancer vaccine. Under the terms of the agreement, SuperGen and AVI will share equally clinical development and FDA registration costs going forward and share profit equally from product sales in the United States. We will be responsible for the manufacturing of AVICINE and SuperGen will be responsible for marketing and sales. In May 2000, we received a $20 million equity investment from SuperGen and could receive additional payments of up to $80 million based upon achievement of clinical commercialization milestones. Those payments include the following milestone payments, plus certain payments based on product sales (i) $2.5 million in SuperGen stock or cash, upon each completion of a Phase III trial for the pharmaceutical product containing AVICINE or a

derivative thereof as an active ingredient and acceptance by the FDA or the filing of a New Drug Application ("NDA") and (ii) $5 million in SuperGen stock or cash, upon the date the first commercial sale of a pharmaceutical product containing AVICINE or a derivative thereof as an active ingredient occurs within the United States. Commercialization cash milestone payments occur at the following annual sales levels: $100 million, $250 million, $500 million and $1 billion. Payments to AVI occur at the first achievement of these sales levels and increase from $10 million to $25 million in $5 million increments, with a maximum of one milestone payment per year.

We, along with SuperGen, are seeking an additional corporate partner for the further development of AVICINE. We envision that this partner will share the costs of any additional clinical development, including additional Phase II trials, if deemed necessary, and Phase III pivotal trials. The nature, timing, and design of these trials would be dependent upon the prospective partner.

Unless terminated earlier, our agreement with SuperGen expires upon the earlier of (i) the date upon which a generic version of the product is first sold in the U.S. by someone other than SuperGen or (ii) the date which is 15 years after the date of regulatory approval of AVICINE in the United States, subject to certain extension rights.

NEUGENE Alliances

We anticipate that NEUGENE antisense collaborative research agreements may provide us with funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional molecular targets. Partners in antisense may be granted options to obtain licenses to co-develop and to market drug candidates resulting from their collaborative research programs.

Exelixis Agreement

In April 2001, we entered into an alliance with Exelixis Inc. ("Exelixis") for functional genomics and antisense drug development. Under the terms of the agreement, Exelixis will apply its expertise in genetic model systems to discover, validate and screen novel targets suitable for inhibition by antisense therapeutics. We will design and synthesize NEUGENE morpholinos (PMOs) for use as drugs and conduct preclinical and clinical studies on antisense drug candidates arising from the collaboration. The collaborative research project and our obligations to supply PMOs to Exelixis under the agreement expires April 30, 2006. Except as noted, we and Exelixis will jointly own, and Exelixis has an option to co-develop with us, certain antisense products that arise from the alliance.

In the event we and Exelixis co-fund the development of any antisense therapeutic and/or commercialization of any product, the parties will jointly have a worldwide, co-exclusive license and will equally share profits with respect to any such co-funded product in lieu of royalties. Product is defined by our agreement with Exelixis as any human therapeutic or prophylactic product which received regulatory approval that contains or comprises our antisense therapeutic.

Under our agreement with Exelixis, an "Exelixis Product" is defined as, and is deemed to exist when we decide to terminate the development of a co-funded antisense therapeutic and/or commercialization of a particular co-funded product that is being co-funded by Exelixis, and Exelixis assumes the costs and obligations of the continued development of the co-funded antisense therapeutic and/or commercialization of such co-funded product. Similarly, an "AVI Product" is one that is developed by us and not co-funded by Exelixis.

Generally, a 3% or 5% royalty on net sales is payable by the developing party on products covered by the agreement that are not jointly developed. Generally, a party's right to receive royalties expires on a country-by-country basis upon the later of (i) 12 years from the first commercial sale of such product in that country; or (ii) expiration of the last to expire Exelixis patent or AVI patent in such country claiming the antisense therapeutic in such AVI Product or the manufacture, use or sale of such product.

Medtronic Agreement

In May 2001, we entered into a licensing arrangement with Medtronic, Inc. ("Medtronic")

wherein Medtronic received exclusive rights for certain antisense compounds, for use in conjunction with Medtronic devices, to combat vascular disease, including restenosis. We also entered into a supply agreement to provide product to Medtronic. Under an investment agreement, we received a $10 million equity investment from Medtronic International, Ltd. (then Medtronic Asset Management, Inc.)("MIL"). In 2003, we elected to convert Medtronic's license to non-exclusive. In 2004, we terminated this agreement.

Manufacturing

We believe we have developed proprietary manufacturing techniques that will allow large-scale synthesis and purification of NEUGENES. Because our NEUGENE compounds are based upon a well established backbone chemistry, we believe that NEUGENE synthesis will be more cost-effective than competing technologies. We have established a Good Manufacturing Practices, or GMP, manufacturing facility at our Corvallis, Oregon facility. Our GMP facility should provide sufficient manufacturing capacity to continue to meet our early stage clinical trial requirements for the foreseeable future and allow us to produce products incorporating our technology. Our GMP facility is subject to FDA inspection and regulation.

We currently intend to retain manufacturing rights for all products incorporating our patented antisense technology, whether sold directly by us or through collaborative agreements with industry partners.

In March 1993, we moved to our present laboratory facilities and we have expanded our facilities several times. This facility and the laboratory procedures followed by us have not been formally inspected by the FDA and will have to be approved as products move from the research phase through the clinical testing phase and into commercialization. See "Drug Approval Process and Other Governmental Regulations."

Marketing Strategy

We plan to market initial products, when developed, and for which we obtain regulatory approval, through marketing arrangements or other licensing arrangements with pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products we develop, and our financial resources. We do not expect to establish a direct sales capability for therapeutic compounds for at least the next several years. To market products that will serve a large, geographically diverse patient population, we expect to enter into licensing, distribution, or partnering agreements with pharmaceutical companies that have large, established sales organizations. The timing of our entry into marketing arrangements or other licensing arrangements with large pharmaceutical companies will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act, as amended, and regulations promulgated thereunder. Although the implementation of initial aspects of our marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and our marketing strategy therefore may not be implemented for several years. See "Drug Approval Process and Other Governmental Regulation."

Patents and Proprietary Rights

We have developed or acquired a comprehensive body of intellectual rights. The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. We plan to prosecute and aggressively defend our patents and proprietary technology. Our policy is to patent the technology, inventions, and improvements that are

considered important to the development of our business and that are patentable. We also depend upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

A patent estate including 169 patents (domestic and foreign) issued or licensed to us, and 148 pending patent applications (domestic and foreign) protects our technologies. We intend to protect our proprietary technology with additional filings as appropriate. Some of our patents on core technologies expire as early as 2008, including for NEUGENES; however, based on patented improvements and additional support to such core patents, we believe our patent protection for those products and other products will extend beyond 2020.

We have also acquired certain product/technology licenses from The Ohio State University and Dr. Vernon Stevens. These licenses include exclusive royalty-bearing licenses covering the composition, manufacturing and use of AVICINE in all fields of use, including treating and preventing cancer, with the exception of fertility regulation. Our proprietary rights also include the unrestricted use of vaccine technology for non-hormonal cancer applications. We enjoy the right to commercialize any new intellectual property relating to our licensed subject matter, including access to and use of all new experimental data resulting from Dr. Stevens' research. Our licenses have been granted for a period of 30 years or 10 years from the expiration of the last issued patent, whichever comes later. Under these licensing agreements, we have the right to sublicense our products and technology throughout the world. For such rights, we are obligated to pay the licensors minimum annual royalties of $55,000. Subject to such minimums, the royalties are 5% of net sales of products from licensed technology in the United States and Canada; 2% of net sales in countries of the "European Economic Community"; and 25% of any royalties received by us for sublicenses in the United States, the "European Economic Community" or in Korea, subject to certain maximums.

We have licensed certain technology from the Public Health Service (and others) to supplement and support certain of our core technology. We have certain obligations and minimum royalties under those agreements, which costs are not deemed material to our business.

There can be no assurance that any patents we apply for will be granted or that patents held by us will be valid or sufficiently broad to protect our technology or provide a significant competitive advantage. Additionally, we cannot provide assurance that practice of our patents or proprietary technology will not infringe third-party patents.

Drug Approval Process and Other Government Regulation

The system of reviewing and approving drugs in the United States is considered the most rigorous in the world. Costs to bring a single product from research through market approval and launch into commerce range from $800 million (Pharmaceutical Research and Manufacturers Association) to $1.7 billion in 2000 through 2002 (FDA), with the timing to do so typically ranging between 10 and 15 years. The Pharmaceutical Research and Manufacturers Association estimates that of every 5,000 medicines tested, on average, only five are tested in clinical trials, and only 1 of those is approved for human use.

Drug Discovery

In the initial stages of drug discovery before a compound reaches the laboratory, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a screening lead, or starting point for drug development, isolation and structural determination may begin. The development process

results in numerous chemical modifications to the screening lead in an attempt to improve its drug properties. After a compound emerges from the above process, the next steps are to conduct further preliminary studies on the mechanism of action, further in vitro (test tube) screening against particular disease targets and, finally, some in vivo (animal) screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results are positive, the compound emerges from the basic research mode and moves into the pre-clinical phase.

Preclinical Testing

During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests typically take approximately three and one-half years to complete.

Investigational New Drug Application

During the pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. In addition, an Institutional Review Board, comprised of physicians at the hospital or clinic where the proposed studies will be conducted, must review and approve the IND. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA.

Phase I Clinical Trials

After an IND becomes effective, Phase I human clinical trials may begin. These tests, involving usually between 20 and 80 patients or healthy volunteers, typically take approximately one year to complete and cost between $300,000 and $500,000 per trial. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action. Phase I trials are not normally conducted for anticancer product candidates. A Phase Ib study involves patients with the targeted disease and is focused on safety.

Phase II Clinical Trials

In Phase II clinical trials, controlled studies are conducted on approximately 100 to 300 volunteer patients with the targeted disease. The preliminary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately two years and cost between $500,000 and $4 million per trial, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

Phase III Clinical Trials

This phase typically lasts about three years, usually involves 1,000 to 3,000 patients and cost between $5 million and $50 million per trial. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions that may result from long-term use of the drug.

New Drug Application

After the completion of the requisite three phases of clinical trials, if the data indicate that the drug has an acceptable benefit to risk assessment and it is found to be safe and effective, a New Drug Application (NDA) is filed with FDA. The requirements for submitting an NDA are defined by and in conjunction with FDA. These applications are comprehensive, including all information obtained throughout all clinical trials as well as all data pertaining to the manufacturing and testing of the product. In general, these filings can far exceed 100,000 pages. With the implementation of the Prescription Drug Users Fee Act (PDUFA), review fees are provided at the time of NDA filing. In 2005, each NDA with clinical data must be accompanied by a $672,000 review fee. If the NDA is assessed as unacceptable in the initial 30 day review, it is returned to the submitter, with 50% of the fee. The average review time for a New Molecular Entity (NME) has remained static at approximately 16 months, however, new NME can and have been approved in as little as six months.

Marketing Approval

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

Phase IV Clinical Trials and Post Marketing Studies

In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications . The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

Competition

Several companies are pursuing the development of antisense technology, including Eli Lilly, Merck, Genta Incorporated, and ISIS Pharmaceuticals. All of these companies have products in development stages, and, in some cases, are in human trials with antisense compounds generally similar to our NEUGENE compounds.

While we believe that none of these companies is likely to introduce an additional antisense compound into the broad commercial market in the immediate future, many pharmaceutical and biotechnology companies, including most of those listed above, have financial and technical resources greater than those currently available to us and have more established collaborative relationships with industry partners than we do.

In 2004, both Isis and Genta received significant negative press when antisense drugs of each company failed to meet primary endpoints in Phase III clinical trials in certain cancer applications. Because the underlying chemistry of our antisense is fundamentally different and distinct from the antisense chemistries of either Isis of Genta, we believe that none of the clinical experiences of either company are predictive of how an AVI NEUGENE antisense compound may fare in similar, or different, clinical trial settings. We believe that the combination of pharmaceutical properties of our NEUGENE compounds for restenosis, cancer, and drug metabolism affords us competitive advantages when compared with the antisense compounds of competitors.

We can also expect to compete with other companies exploiting alternative technologies that address the same therapeutic needs as do our technologies. The biopharmaceutical market is subject to rapid technological change, and it can be expected that competing technologies will emerge and will present a competitive challenge to us.

Research and Development

The Company expensed $20,738,725, $15,284,396 and $22,413,892 on research and development activities during the years ended December 31, 2004, 2003 and 2002, respectively. Research and development (R&D) expenses include related salaries, contractor fees, materials, utilities and allocations of corporate costs. R&D expenses consist of independent R&D costs and costs associated with collaborative development arrangements. In addition, the Company funded R&D at other companies and research institutions under agreements. Research and development costs are expensed as incurred.

Employees

As of December 31, 2004, we had 112 employees, 22 of whom hold advanced degrees. One hundred-one employees are engaged directly in research and development activities, and eleven are in administration. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

Where You Can Find Additional Information

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. For further information with respect to us, you may read and copy our reports, proxy statements and other information, at the SEC's public reference rooms at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, as well as at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, IL 60661 and at 233 Broadway, New York, NY 10279. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC's web site at "http://www.sec.gov." In addition, you can read and copy our SEC filings at the office of the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as well as our corporate governance guideline, outline of directorship qualifications, code of business conduct and the charter of our audit committee, compensation committee, and nominations committee are all available on our website (www.avibio.com) or by sending a request for a paper copy to: AVI BioPharma, Inc., One S.W. Columbia Ave., Suite 1105, Portland, Oregon 97258, attn. Investor Relations.

Item 2. Description of Property

We occupy 53,000 square feet of leased laboratory and office space at 4575 S.W. Research Way, Suite 200, Corvallis, Oregon 97333. This lease expires in December 2010. We occupy 5,000 square feet of leased laboratory and office space at Unit M, 2150 W. 6th Avenue, Broomfield, Colorado 80020. This lease expires in October 2005. Our executive office is located in 4,400 square feet of leased space at One S.W. Columbia, Suite 1105, Portland, Oregon 97258. This lease expires July 2009. We believe that our facilities are suitable and adequate for our present operational requirements for the foreseeable future. We anticipate being able to renew our lease in Colorado or find adequate space if we are unable to renew.

Item 3. Legal Proceedings

As of March 16, 2005, there were no material, pending legal proceedings to which we are a party. From time to time, we become involved in ordinary, routine or regulatory legal proceedings incidental to our business.

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

No matters were submitted to a vote of our shareholders during the quarter ended December 31, 2004.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters

Our Common Stock is quoted on the Nasdaq National Market System ("Nasdaq NMS") under the symbol "AVII." The following table sets forth the high and low closing sales prices as reported by Nasdaq NMS for each quarterly period in the two most recent fiscal years and quarter-to-date for the next fiscal year:

2003		
Quarter 1	$ 5.83	$ 2.04
Quarter 2	7.05	3.31
Quarter 3	6.15	4.31
Quarter 4	5.50	4.00
2004		
Quarter 1	$ 4.75	$ 2.88
Quarter 2	3.58	2.02
Quarter 3	2.71	1.59
Quarter 4	2.35	2.04
2005		
Quarter 1 to March 14, 2005	$ 4.14	$ 2.00

The number of shareholders of record and approximate number of beneficial holders on March 14, 2005 was 621 and 13,500 respectively. There were no cash dividends declared or paid in fiscal years 2004 or 2003. We do not anticipate declaring such dividends in the foreseeable future.

All securities sold during 2004 by us were either previously reported on our Form 10-Qs filed with the Securities and Exchange Commission or sold pursuant to Registration statements filed under the Securities Act of 1933.

During 2004, we issued 49,918 shares of common stock to employees at approximately $1.89 per share for $94,558, under our Employee Stock Purchase Plan. During 2003, we issued 30,467 shares of common stock to employees at approximately $4.06 per share for $123,576, under our Employee Stock Purchase Plan.

During 2004, we granted 631,041 stock options to purchase shares of common stock at approximately $3.10 per share, under our 2002 Equity Incentive Plan. During 2003, we granted 212,500 stock options to purchase shares of common stock at approximately $5.07 per share, under our 2002 Equity Incentive Plan. The information required by Item 201(D) of Regulation S-K is incorporated by reference to Note 4 ("Shareholders' Equity") to Notes to Audited Financial Statements for the Year Ended December 31, 2004, page F-13.

Item 6. Selected Financial Data

The following selected financial data should be read in conjunction with Item 7. "Management's Discussion and Analysis or Plan of Operation" and Item 8. "Financial Statements."

	YEAR ENDED DECEMBER 31,				
	2004	2003	2002	2001	2000
Operations data:					
Revenues	$ 430,461	$ 969,866	$ 836,784	$ 706,102	$ 1,297,338
Research and development	20,738,725	15,284,396	22,413,892	12,750,901	9,268,330
General and administrative	4,735,731	4,558,948	3,763,941	3,357,817	2,270,302
Realized gain on sale of short-term securities— available-for-sale	—	3,765,752	—	—	—
Write-down of short-term securities— available-for-sale	—	—	(4,478,260)	(12,523,088)	—
Net loss	(24,777,694)	(14,616,628)	(29,359,051)	(26,925,174)	(9,239,956)
Net loss per share - basic and diluted	(0.69)	(0.49)	(1.14)	(1.20)	(0.49)
Balance sheet data:					
Cash and investments	$ 19,515,316	$ 37,599,136	$ 19,293,645	$ 25,597,121	$ 32,112,099
Working capital	17,948,793	34,639,526	15,279,854	24,230,010	31,408,473
Total assets	28,518,631	47,145,023	28,603,757	33,815,113	35,088,393
Shareholders' equity	26,269,033	43,394,030	23,481,623	30,534,047	33,365,601

Item 7. Management's Discussion and Analysis or Plan of Operations

Forward-Looking Information

This report contains forward-looking statements regarding our plans, expectations, estimates and beliefs. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may," and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. We have based these forward-looking statements largely on our expectations. Forward-looking statements in this report include, but are not necessarily limited to, those relating to:

- our intention to introduce new products,
- receipt of any required FDA or other regulatory approval for our products,
- our expectations about the markets for our products,
- acceptance of our products, when introduced, in the marketplace,
- our future capital needs, and
- success of our patent applications.

Forward-looking statements are subject to risks and uncertainties, certain of which are beyond our control. Actual results could differ materially from those anticipated as a result of

the factors described in the "Risk Factors" and detailed in our other Securities and Exchange Commission filings, including among others:

- the effect of regulation by the FDA and other governmental agencies,
- delays in obtaining, or our inability to obtain, approval by the FDA or other regulatory authorities for our products,
- research and development efforts, including delays in developing, or the failure to develop, our products,
- the development of competing or more effective products by other parties,
- the results of pre-clinical and clinical testing,
- uncertainty of market acceptance of our products,
- problems that we may face in manufacturing, marketing, and distributing our products,
- our inability to raise additional capital when needed,
- delays in the issuance of, or the failure to obtain, patents for certain of our products and technologies, and
- problems with important suppliers and business partners.

Because of these risks and uncertainties, the forward-looking events and circumstances discussed in this report or incorporated by reference might not transpire. Factors that cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the "Risk Factors" section and elsewhere in this report.

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest and grant revenue, we have had no material revenues from the sale of products or from other sources, and we do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue to expand our research and development efforts and enter additional collaborative efforts. As of December 31, 2004, our accumulated deficit was $155,972,380.

Results of Operations

Year Ended December 31, 2004 Compared with Year Ended December 31, 2003. Revenues, from license fees, grants and research contracts, decreased from $969,866 in 2003 to $430,461 in 2004, primarily due to decreases in research contracts revenues, partially offset by increases in grants revenues. Operating expenses increased from $19,843,344 in 2003 to $25,474,456 in 2004 due to increases in research and development. These increases were primarily due to higher manufacturing costs associated with the Company's clinical development efforts, which increased from $15,284,396 in 2003 to $20,738,725 in 2004. Approximately $4,200,000 of this increase was due to the Company contracting for the production of GMP subunits, or precursors, which, in turn, will be converted into finished compounds by ourselves or by others suitable for use in human

clinical trials. The remaining difference is due to increases in outside collaborations and regulatory affairs costs, and additional preclinical and clinical testing of the Company's products. General and administrative costs increased from $4,558,948 in 2003 to $4,735,731 in 2004. Net interest income decreased from $491,098 in 2003 to $266,301 in 2004 due to reductions in market interest rates, which were slightly offset by increases in average cash, cash equivalents and short-term securities.

Year Ended December 31, 2003 Compared with Year Ended December 31, 2002. Revenues, from license fees, grants and research contracts, increased from $836,784 in 2002 to $969,866 in 2003, primarily due to increases in research contracts revenues, partially offset by decreases in grants revenues. Operating expenses decreased from $26,177,833 in 2002 to $19,843,344 in 2003 due to decreases in research and development, primarily due to lower manufacturing costs associated with the Company's clinical development efforts, which decreased from $22,413,892 in 2002 to $15,284,396 in 2003. Approximately $7,000,000 of this decrease was due to the Company satisfying demand for certain NEUGENE components in 2003 by using quantities of the components which had been manufactured and expensed in 2002. Additionally, general and administrative costs increased from $3,763,941 in 2002 to $4,558,948 in 2003 due to increases of $610,000 in legal expenses and $192,000 in director and officer insurance, consistent with industry trends. Net interest income increased from $460,258 in 2002 to $491,098 in 2003 due to earnings on increased cash balances, which were slightly offset by reductions in market interest rates. During the fourth quarter of 2003 the Company sold all of its investment in SuperGen, a related party, for a realized gain on sale of short-term securities—available-for-sale of $3,765,752.

We, along with SuperGen, are seeking an additional corporate partner for the further development of AVICINE. We envision that this partner will share the costs of any additional clinical development, including additional Phase II trials, if deemed necessary, and Phase III pivotal trials. The nature, timing, and design of these trials would be dependent upon the prospective partner.

Liquidity and Capital Resources

We have financed our operations since inception primarily through equity sales totaling $144,580,862, from grants and contract research funding of $5,081,768 from various sources, and $1,480,432 from shared development funding on AVICINE with SuperGen. We expect to continue to incur losses as we continue and expand our research and development activities and related regulatory work and increase our collaborative efforts. For 2005, we expect our expenditures for operations, including our collaborative efforts, and our GMP facilities to be approximately $25 to $27 million. The increase compared to 2004 expenditures is expected to result from the purchase of additional NEUGENE components from an outside GMP manufacturer, coupled with additional clinical trial efforts. That cost could increase if we undertake additional collaborative efforts. However, if need be in 2005, we could reduce our expenditures because the vast majority of our costs are variable. Those estimated expenditures include amounts necessary to fulfill our obligations under our various collaborative, research and licensing agreements during 2005. Our expenditures for 2006 are expected to be greater than or equal to our 2005 estimates.

Because of the cost (up to $1.7 billion) and timeframe (up to 15 years) traditionally associated with developing a potential drug or pharmaceutical product to where FDA approval for human sales is received, our business strategy is to develop our products to initial Phase III human clinical trials and look for third parties to fund completion of development of the product and market the product through strategic partnerships, license agreements or other relationships. We also look for collaborative and other efforts, such as our relationship with Exelixis, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We currently use this strategy to limit the potential cost we would incur in developing a product. Our expected costs under our various contracts and for various drug development products can be estimated for the next year or two, but not much beyond that due to the uncertainty of clinical trial results, research results and when we will find a partner to develop a potential drug.

Because of the various factors noted above and the expectation that, until we establish revenue sources, we will license to, or jointly develop our prospective products with, strategic partners, we review, at least annually, each research program and clinical trial, based on results and progress during the prior year and estimate our needs for that program or trial for the coming year, making adjustments based on the progress of the program during the year. We do not set long-term development budgets or development schedules for bringing our products to market or track our research costs on a product basis, other than against the current budgeted amount.

Our cash, cash equivalents and short-term securities were $19,515,316 at December 31, 2004, compared with $37,599,136 at December 31, 2003. The decrease of $18,083,820 was due primarily to $23,781,953 used in operations and $1,532,929 used for purchases of property and equipment and patent related costs, offset by the receipt of $6,964,356 in net proceeds from the exercise of warrants issued to several institutional investors for the purchase of 1,623,377 shares of the Company's common stock at $4.62 per share. These warrants had been issued pursuant to a direct equity placement of the Company's common stock in December 2003 under the Company's effective shelf registration. These investors also received new five-year warrants to purchase 389,611 common shares for $5.50 per share. These warrants are exercisable commencing on July 28, 2004 and expire on December 8, 2008. In January 2005, the Company announced a private placement of 8,000,000 shares of its common stock at $3.00 per share, together with warrants to acquire an additional 1,600,000 shares of common stock, to a group of institutional investors for a total purchase price of $24 million. The warrants are exercisable starting July 19, 2005 for four years at an exercise price of $5.00 per share. The sale closed January 19, 2005. The securities were sold pursuant to the Company's effective shelf registration statement.

Our short-term securities represent investments in commercial paper. In 2002, short-term securities also included an investment in common stock of SuperGen, a related party, with a fair market value of $1,625,608 at December 31, 2002. During the fourth quarter of 2003 the Company sold all of its investment in SuperGen. The Company reviews the fair market value of its short-term securities in relation to its cost basis of the securities on a quarterly basis. If a decline in fair market value below the cost basis is judged to be other than temporary, the cost basis of the security is written down to fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge.

We do not expect any material revenues in 2005 or 2006 from our business activities. We expect that our cash requirements for the balance of calendar 2005 will be satisfied by existing cash resources. To fund our operations beyond 2006, we will need to raise additional capital. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility, nor do we intend to seek one.

CONTRACTUAL PAYMENT OBLIGATIONS

The Company's off-balance sheet arrangements are limited to operating leases and rents on certain facilities and equipment and license agreements for which it is obligated to pay the licensors a minimum annual royalty. These off-balance sheet arrangements are expensed as incurred. A summary of our contractual commitments and obligations as of December 31, 2004 is as follows:

	Payments Due By Period				
Contractual Obligation	**Total**	**2005**	**2006 and 2007**	**2008 and 2009**	**2010 and beyond**
Operating leases	$ 7,081,000	$ 1,142,000	$ 2,320,000	$ 2,419,000	$ 1,200,000
Royalty payments	2,255,000	125,000	250,000	250,000	1,630,000
	$ 9,336,000	$ 1,267,000	$ 2,570,000	$ 2,669,000	$ 2,830,000

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term, including, without limitation, the progress of our research and development programs, the progress of our pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, our ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of our products. Our cash requirements are expected to continue to increase each year as we expand our activities and operations. There can be no assurance, however, that we will ever be able to generate product revenues or achieve or sustain profitability.

New Accounting Pronouncements

See Note 2 of Notes to Financial Statements included under Part III, Item 15.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to valuation of investments, long-lived assets, and revenue recognition. We base our estimates on historical experience and on various other assumptions. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies and the related judgments and estimates affect the preparation of our financial statements.

Valuation of Investments
Investments in marketable securities are recorded at fair value each period with changes recorded to other comprehensive income. We periodically evaluate our investments for other than temporary impairments and record an impairment unless the positive evidence indicating the carrying amount is recoverable outweighs the negative evidence to the contrary.

Revenue Recognition
Revenue is recorded from research contracts and grants as the services are performed and payment is reasonably assured. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. Fees received from SuperGen pursuant to our Avicine shared development arrangement are netted against research and development expense since the Company and SuperGen share equally in all clinical development and FDA registration costs. Revenue from license and development arrangements has been insignificant to date.

Long-Lived Asset Impairment
We regularly evaluate long-lived assets and certain identified intangible assets for impairment in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," which requires us to review our long-lived assets and certain identifiable intangible assets for impairment

whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable and exceeds its fair value. Recoverability is assessed utilizing an un-discounted cash flow analysis and if less then the carrying value is compared to the fair value for assessing impairment. Based on this analysis, we did not recognize an impairment on long-lived assets during the year ended December 31, 2004. If circumstances related to our long-lived assets change, we may record an impairment charge in the future.

RISK FACTORS

Risks Affecting Future Operating Results

We do not provide forecasts of our future financial performance. While we are optimistic about our long-term prospects, the following factors should be considered in evaluating our outlook. If the possibilities described as risks below actually occur, our operating results and financial condition would likely suffer and the trading price of our common stock may fall, causing a loss of some or all of an investment in our common stock.

Our products are in an early stage of development and may not be determined to be safe or effective.

We are only in the early stages of clinical development with our NEUGENE antisense pharmaceutical products. We have devoted almost all of our time to research and development of our technology and products, protecting our proprietary rights and establishing strategic alliances. Our proposed products are in the pre-clinical or clinical stages of development and will require significant further research, development, clinical testing and regulatory clearances. We have no products available for sale and we do not expect to have any products available for sale for several years. Our proposed products are subject to development risks. These risks include the possibilities that any of the products could be found to be ineffective or toxic, or could fail to receive necessary regulatory clearances. Although we have obtained favorable results in Phase II trials using AVICINE to treat colorectal and pancreatic cancer patients, we may not obtain similar or more favorable results in future clinical trials. We have not received any significant revenues from the sale of products and we may not successfully develop marketable products that will increase sales and, given adequate margins, make us profitable. Third parties may develop superior or equivalent, but less expensive, products.

We have incurred net losses since our inception, and we may not achieve or sustain profitability.

We incurred a net loss of $14.6 million in 2003 and of $24.8 million in 2004. In 2003, we sold all of our investment in SuperGen, Inc., a related party, for a realized gain on sale of short-term securities—available-for-sale of $3,765,752. As of December 31, 2004, our accumulated deficit was $156.0 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from selling, general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

If we fail to attract significant additional capital, we may be unable to continue to successfully develop our products.

Since we began operations, we have obtained operating funds primarily by selling shares of our company. Based on our current plans, we believe that current cash balances will be sufficient to meet our operating needs for the current fiscal year. Furthermore, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include the success of our research and development efforts, the status of our pre-clinical and clinical testing, costs relating to securing regulatory approvals and the costs and timing of obtaining new patent rights, regulatory changes, competition and technological developments in the market. We may need funds sooner than currently anticipated.

If necessary, potential sources of additional funding could include strategic relationships, public or private sales of shares of our common stock or debt or other arrangements. We may not obtain additional funding when we need it on terms that will be acceptable to us or at all. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing shareholders will be diluted. If we are unable to obtain financing when needed, our business and future prospects would be materially adversely affected.

If we fail to receive necessary regulatory approvals, we will be unable to commercialize our products.

All of our products are subject to extensive regulation by the United States Food and Drug Administration, or FDA, and by comparable agencies in other countries. The FDA and comparable agencies require new pharmaceutical products to undergo lengthy and detailed clinical testing procedures and other costly and time-consuming compliance procedures. AVICINE has completed three Phase I and three Phase II studies. Our first NEUGENE antisense drug, Resten-NG, completed Phase I trials in late 2001 and a Phase II trial in 2002. We initiated two additional Phase Ib studies in 2001 for cancer and polycystic kidney disease and completed three Phase I trials on drug metabolism. Except for clinical trials underway or ready to start, we may not initiate additional trials when predicted or at all, or complete our clinical trials that are started or in a timely fashion. We do not know when or if we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies.

We may fail to compete effectively, particularly against larger, more established pharmaceutical companies, causing our business to suffer.

The biotechnology industry is highly competitive. We compete with companies in the United States and abroad that are engaged in the development of pharmaceutical technologies and products. They include: biotechnology, pharmaceutical, chemical and other companies; academic and scientific institutions; governmental agencies; and public and private research organizations.

Many of these companies and many of our other competitors have much greater financial and technical resources and production and marketing capabilities than we do. Our industry is characterized by extensive research and development and rapid technological progress. Competitors may successfully develop and market superior or less expensive products which render our products less valuable or unmarketable.

We have limited operating experience.

We have engaged solely in the development of pharmaceutical technology. Although some members of our management team have experience in biotechnology company operations, we have limited experience in manufacturing or selling pharmaceutical products. We also have only limited experience in negotiating and maintaining strategic relationships, and in conducting clinical trials and other later-stage phases of the regulatory approval process. We may not successfully engage in some or all of these activities.

We have limited manufacturing capability.

While we believe that we can produce materials for clinical trials and produce products for human use at our recently completed GMP manufacturing facility, we may need to expand our commercial manufacturing capabilities for products in the future if we elect not to or cannot contract with others to manufacture our products. This expansion may occur in stages, each of which would require regulatory approval, and product demand could at times exceed supply capacity. We have not selected a site for any expanded facilities and do not know what the construction cost will be for such facilities and whether we will have the financing needed for such construction. We do not know if or when the FDA will determine that such facilities comply with Good Manufacturing Practices. The projected location and construction of any facilities will depend on regulatory approvals, product development, pharmaceutical partners and capital resources, among other factors. We have not obtained regulatory approvals for any productions facilities for our products, nor can we assure investors that we will be able to do so.

If we lose key personnel or are unable to attract and retain additional, highly skilled personnel required for our activities, our business will suffer.

Our success will depend to a large extent on the abilities and continued service of several key employees, including Drs. Denis Burger, Patrick Iversen, and Dwight Weller. We maintain key man life insurance in the amount of $1,000,000 for Dr. Burger and $500,000 for each of Drs. Iversen and Weller. The loss of any of these key employees could significantly delay the achievement of our goals. Competition for qualified personnel in our industry is intense, and our success will depend on our ability to attract and retain highly skilled personnel. To date, we have been successful in attracting and retaining key personnel. We are not aware of any key personnel who plan to retire or otherwise leave the Company in the near future.

Asserting, defending and maintaining our intellectual property rights could be difficult and costly, and our failure to do so will harm our ability to compete and the results of our operations.

Our success will depend on our existing patents and licenses, and our ability to obtain additional patents in the future. A patent estate including 169 patents (domestic and foreign) issued or licensed to us, and 148 pending patent applications (domestic and foreign) protects our technologies. We license the composition, manufacturing and use of AVICINE in all fields, except fertility regulation, from The Ohio State University. We license other patents for certain complementary technologies from others.

Some of our patents on core technologies expire as early as 2008, including for NEUGENES; however, based on patented improvements and additions to such core patents, we believe our patent protection for those products and other products would extend beyond 2020.

We cannot assure investors that our pending patent applications will result in patents being

issued in the United States or foreign countries. In addition, the patents which have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours which do not conflict with our patents. Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of biotechnology firms generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the United States Patent and Trademark Office (USPTO), or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition, there is a substantial backlog of biotechnology patent applications at the USPTO and the approval or rejection of patents may take several years.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others, as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected.

To help protect our proprietary rights in unpatented trade secrets, we require our employees, consultants and advisors to execute confidentiality agreements. However, such agreements may not provide us with adequate protection if confidential information is used or disclosed improperly. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets.

If our strategic relationships are unsuccessful, our business could be harmed.

Our strategic relationships with SuperGen, Exelixis and others are important to our success. The development, improvement and marketing of many of our key therapeutic products are or will be dependent on the efforts of our strategic partners. For example, under the SuperGen relationship, we may fail to achieve clinical and sales milestones; AVICINE may fail to achieve regulatory approval; AVICINE may not be commercially successful; SuperGen may fail to perform its obligations under our agreements, such as failing to devote sufficient resources to marketing AVICINE; and our agreements with SuperGen may be terminated against our will. We may receive additional funding from our strategic partners, including SuperGen, under existing agreements. We may not receive any additional payments from SuperGen and those relationships may not be commercially successful. The transactions contemplated by our agreements with strategic partners, including the equity purchases and cash payments, are subject to numerous risks and conditions. The occurrence of any of these events could severely harm our business.

Our near-term strategy is to co-develop products with strategic partners or to license the marketing rights for our products to pharmaceutical partners after we complete one or more Phase II clinical trials. In this manner, the extensive costs associated with late-stage clinical development and marketing will be shared with, or the responsibility of, our strategic partners.

To fully realize the potential of our products, including development, production and marketing, we may need to establish other strategic relationships.

We have limited sales capability and may not be able to successfully commercialize our products.

We have been engaged solely in the development of pharmaceutical technology. Although some of our management have experience in biotechnology company operations, we have limited experience in manufacturing or selling pharmaceutical products. We also have only limited experience in negotiating and maintaining strategic relationships, and in conducting clinical trials and other later-stage phases of the regulatory approval process. To the extent we rely on strategic partners to fully commercialize our products, we will be dependent on their efforts. We may not successfully engage in any of these activities.

We may be subject to product liability lawsuits and our insurance may not be adequate to cover damages.

We believe we carry adequate insurance for the product development research we currently conduct. In the future, when we have products available for commercial sale and use, the use of our products will expose us to the risk of product liability claims. Although we intend to obtain product liability insurance coverage, product liability insurance may not continue to be available to us on acceptable terms and our coverage may not be sufficient to cover all claims against us. A product liability claim, even one without merit or for which we have substantial coverage, could result in significant legal defense costs, thereby increasing our expenses, lowering our earnings and, depending on revenues, potentially resulting in additional losses.

Continuing efforts of government and third party payers to contain or reduce the costs of health care may adversely affect our revenues and future profitability.

In addition to obtaining regulatory approval, the successful commercialization of our products will depend on our ability to obtain reimbursement for the cost of the product and treatment. Government authorities, private health insurers and other organizations, such as health maintenance organizations are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the growth of healthcare organizations such as HMOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. The cost containment measures that healthcare providers are instituting and any healthcare reform could affect our ability to sell our products and may have a material adverse effect on our operations. Reimbursement in the United States or foreign countries may not be available for any of our products, any reimbursement granted may be reduced or discontinued, and limits on reimbursement available from third-party payors may reduce the demand for, or the price of, our products. The lack or inadequacy of third-party reimbursements for our products would have a material adverse effect on our operations. Additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future that adversely affects our products and our business.

If we fail to establish strategic relationships with larger pharmaceutical partners, our business may suffer.

We do not intend to conduct late-stage (Phase III) human clinical trials ourselves. We anticipate entering into relationships with larger pharmaceutical companies to conduct later pharmaceutical trials and to market our products and we also plan to continue to use

contract manufacturing for late stage clinical and commercial quantities of our products. We may be unable to enter into corporate partnerships which could impede our ability to bring our products to market. Any such corporate partnerships, if entered, may not be on favorable terms and may not result in the successful development or marketing of our products. If we are unsuccessful in establishing advantageous clinical testing, manufacturing and marketing relationships, we are not likely to generate significant revenues and become profitable.

We use hazardous substances in our research activities

We use organic and inorganic solvents and reagents in our clinical development that are customarily used in pharmaceutical development and synthesis. Some of those solvents and reagents we use, such as methylene chloride, isopropyl alcohol, ethyl acetate and acetane, may be classified as hazardous substances, are flammable and, if exposed to human skin can cause anything from irritation to severe burns. We receive, store, use and dispose of such chemicals in compliance with all applicable laws with containment storage facilities and contained handling and disposal safeguards and procedures. We are routinely inspected by federal, state and local governmental and public safety agencies regarding our storage, use and disposal of such chemicals, including the federal Occupational, Safety and Health Agency ("OSHA"), the Oregon Department of Environmental Quality ("DEQ") and local fire departments, without any material noncompliance issues in such inspections. Further, our usage of such chemicals is limited and falls below the reporting thresholds under federal law. Based on our limited use of such chemicals, the nature of such chemicals and the safeguards undertaken by the Company for storage, use and disposal, we believe we do not have any material exposure for toxic tort liability. Further, the cost of such compliance is not a material cost in our operating budget. While we do not have toxic tort liability insurance at this time, we believe our current insurance coverage is adequate to cover most liabilities that may arise from our use of such substances. If we are wrong in any of our beliefs, we could incur a liability in certain circumstances that would be material to our finances and the value of an investment in our securities.

Risks Related to Share Ownership

Our right to issue preferred stock, our classified Board of Directors and Oregon Anti-Takeover laws may delay a takeover attempt and prevent or frustrate any attempt to replace or remove the then current management of the Company by shareholders.

Our authorized capital consists of 200,000,000 shares of common stock and 20,000,000 shares of preferred stock. Our board of directors, without any further vote by the shareholders, has the authority to issue preferred shares and to determine the price, preferences, rights and restrictions, including voting and dividend rights, of these shares. The rights of the holders of shares of common stock may be affected by the rights of holders of any preferred shares that our board of directors may issue in the future. For example, our board of directors may allow the issuance of preferred shares with more voting rights, higher dividend payments or more favorable rights upon dissolution, than the shares of common stock or special rights to elect directors.

In addition, we have a "classified" board of directors, which means that only one-half of our directors are eligible for election each year. Therefore, if shareholders wish to change the composition of our Board of Directors, it could take at least two years to remove a majority of the existing directors or to change all directors. Having a classified board of directors may, in some cases, delay mergers, tender offers or other possible transactions which may be favored by some or a majority of our shareholders and may delay or frustrate action by shareholders to change the then current Board of Directors and management.

The Oregon Control Share Act and Business Combination Act may limit parties who acquire

a significant amount of voting shares from exercising control over us for specific periods of time. These acts may lengthen the period for a proxy contest or for a person to vote their shares to elect the majority of our Board and change management.

Our stock price is volatile and may fluctuate due to factors beyond our control.

Historically, the market price of our stock has been highly volatile as reflected in the table in Part II, Item 5 of this report. The following types of announcements could have a significant impact on the price of our common stock: positive or negative results of testing and clinical trials by ourselves or competitors; delays in entering into corporate partnerships; technological innovations or commercial product introductions by ourselves or competitors; changes in government regulations; developments concerning proprietary rights, including patents and litigation matters; public concern relating to the commercial value or safety of any of our products; financing or other corporate transactions; or general stock market conditions.

Further, the stock market experiences significant price and volume fluctuations. These fluctuations have particularly affected the market prices of equity securities of many biopharmaceutical companies that are not yet profitable. Often, the effect on the price of such securities is unrelated or disproportionate to the operating performance of such companies. These broad market fluctuations may adversely affect the ability of a shareholder to dispose of his or her shares at a price equal to or above the price at which the shares were purchased.

The significant number of our shares of Common Stock eligible for future sale may cause the price of our common stock to fall.

We have outstanding 36,143,153 shares of common stock as of December 31, 2004 and all are eligible for sale under Rule 144 or are otherwise freely tradeable. In addition:

- Our employees and others hold options to buy a total of 3,803,278 shares of common stock of which 2,912,510 shares were exercisable at December 31, 2004. The options outstanding have exercise prices between $.04 to $10 per share. The shares of common stock to be issued upon exercise of these options, have been registered, and therefore may be freely sold when issued;

- There are outstanding warrants to buy 10,014,330 shares of common stock at December 31, 2004 with exercise prices ranging from $.0003 to $35.63 per share. All of these shares of common stock are registered for resale and may be freely sold when issued.

- We may issue options to purchase up to an additional 2,104,840 shares of common stock at December 31, 2004 under our stock option plans, which also will be fully saleable when issued.

- We are authorized to sell up to 100,661 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate.

- We have also granted certain contractual rights to purchase (i) an additional 352,113 shares of our common stock at a price of $7.10 per share and (ii) the right to purchase up to $7,500,000 of our common stock based on the average closing sales price for the five days preceding the commitment to purchase. If we meet certain technological milestones, the holder of these rights is obligated to purchase shares of common stock from us. The holder of these rights may require us to register the shares issued upon the exercise of such purchase rights.

Sales of substantial amounts of shares into the public market could lower the market price of our common stock.

We do not expect to pay dividends in the foreseeable future.

We have never paid dividends on our shares of common stock and do not intend to pay dividends in the foreseeable future. Therefore, you should only invest in our common stock with the expectation of realizing a return through capital appreciation on your investment. You should not invest in our common stock if you are seeking dividend income.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Due to the short-term nature of our interest bearing assets we believe that our exposure to interest rate market risk is not significant.

Item 8. Financial Statements

All information required by this item begins on page F-1 in item 15 of Part III of this Report and is incorporated into this item by reference.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer, our President, and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934 as of December 31, 2004. Based on that review, the Chief Executive Officer, the President, and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Securities and Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

The Company does not expect that its disclosure controls and procedures will prevent all error and all fraud. A control procedure, no matter how well conceived and operated, can
provide only reasonable, not absolute, assurance that the objectives of the control procedure are met. Because of the inherent limitations in all control procedures, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The Company considered these limitations during the development of it disclosure controls and procedures, and will continually reevaluate them to ensure they provide reasonable assurance that such controls and procedures are effective .

Internal Controls and Procedures

There have not been any changes in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the Company's fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

The management of AVI BioPharma, Inc. (the Company or AVI) is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in "Internal Control-Integrated Framework." Based on management's assessment and those criteria, we believe that, as of December 31, 2004, the Company's internal control over financial reporting is effective.

KPMG LLP, the Company's Independent Registered Public Accounting Firm, has issued an audit report appearing below on our assessment of the Company's internal control over financial reporting.

/s/ Denis R. Burger, Ph.D.
Chief Executive Officer

/s/ Alan P. Timmins
President and Chief Operating Officer

/s/ Mark M. Webber
Chief Financial Officer and Chief Information Officer

Portland, Oregon
March 14, 2005

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
AVI BioPharma, Inc.:

We have audited management's assessment, included in the accompanying *Management's Annual Report on Internal Control over Financial Reporting* appearing under Item 9a, that AVI BioPharma, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management of AVI BioPharma, Inc. is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that AVI BioPharma, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework issued by COSO.* Also, in our opinion, AVI BioPharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework issued by COSO*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of AVI BioPharma, Inc. as of December 31, 2004 and 2003, and the related statements of operations, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and for the period from July 22, 1980 (inception) through December 31, 2004 and our report dated March 15, 2005, expressed an unqualified opinion on those consolidated financial statements. The financial statements of AVI BioPharma, Inc. for the period from July 22, 1980 (inception) through December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 21, 2002. Our opinion on the statements of operations, shareholders' equity and cash flows, insofar as it relates to the amounts included for the period from July 22, 1980 (inception) through December 31, 2001, is based solely on the report of the other auditors

/s/ KPMG LLP

Portland, Oregon
March 15, 2005

PART III

Item 10. Directors and Executive Officers of the Registrant

Information regarding our directors and executive officers required by this item is included in our definitive proxy statement for our 2005 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item is included in our definitive proxy statement for our 2005 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item is included in our definitive proxy statement for our 2005 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions

The information required by this item is included in our definitive proxy statement for our 2005 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this item is included in our definitive proxy statement for our 2005 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

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

(a) The following documents are filed as part of this Report:

Financial Statements

The following financial statements of the Company and the Report of KPMG LLP, Independent Auditors, are included in Part IV of this Report on the pages indicated:

Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or the notes thereto.

(b) Reports on Form 8-K. The following report on Form 8-K were filed during the calendar quarter ended December 31, 2004.

- Form 8-K, Items 2.02, 7.01 and 9.01, November 4, 2004

(c) Exhibits

The following exhibits are filed herewith and this list is intended to constitute the exhibit index:

Exhibit No.	Description
3.1	Third Restated Articles of Incorporation of AntiVirals Inc. (1)
3.2	Bylaws of AntiVirals Inc. (1)
3.3	First Amendment to Third Restated Articles of Incorporation (4)
3.4	Amendment to Article 2 of the Company's Third Restated Articles of Incorporation (11)
4.1	Form of Specimen Certificate for Common Stock. (1)
4.2	Form of Warrant for Purchase of Common Stock. (1)
4.3	Form of Warrant Agreement. (1)
4.4	Form of Representative's Warrant. (1)
4.5	Form of Warrant Agreement between AntiVirals Inc. and ImmunoTherapy Shareholders (3)
4.6	Form of Common Stock Purchase Warrant. (5)
10.1	1992 Stock Incentive Plan (as amended through May 11, 2000). (1)
10.2	Employment Agreement with Denis R. Burger, Ph.D. dated November 4, 1996. (1)
10.3	Employment Agreement with Alan P. Timmins dated November 4, 1996. (1)
10.4	Employment Agreement with Dwight Weller, Ph.D. dated November 4, 1996. (1)
10.5	Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1992. (1)
10.6	Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc. dated January 20, 1996. (1)
10.7	License and Option Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1993. (1)
10.8	Commercial Lease between Research Way Investments, Landlord, and AntiVirals Inc., Tenant, dated June 15, 1992. (1)
10.9	Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated June 17, 1992.(1)
10.10	First Amendment to Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated July 24, 1995. (1)
10.11	Employment Agreement with Patrick L. Iversen, Ph.D. dated July 14, 1997. (2)
10.12	ImmunoTherapy Corporation 1997 Stock Option Plan (3)
10.13	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated March 12, 1996 (3)
10.14	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated December 26, 1996 (3)
10.15	Amendment to License Agreement between ImmunoTherapy Corporation and Ohio State University, dated September 23, 1997 (3)
10.16	Agreement and Plan of Reorganization and Merger dated as of February 2, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.17	First Amendment to Plan of Reorganization and Merger dated as of May 27, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.18	Second Amendment to Plan of Reorganization and Merger dated as of August 4, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.19	Form of Escrow Agreement among AntiVirals Inc., the Escrow Indemnitors and Jeffrey Lillard (3)
10.20	Purchase Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)

10.21	Registration Rights Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.22	Purchase Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.23	Registration Rights Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.24	Subscription Agreement, dated December 1, 1999, by and between SuperGen, Inc. and AVI BioPharma, Inc. (5)
10.25	2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc. (6)
10.26	United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.27	Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.28	Registration Rights Agreement, dated April 14, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.29	2000 Employee Share Purchase Plan (8)
10.30	Employment Agreement with Mark M. Webber dated May 11, 2000. (9)
10.31	Employment Agreement with David H. Mason, Jr. dated November 1, 2000. (9)
10.32	Lease Agreement with Spieker Partners, LP dated May 8, 2001. (9)
10.33*	Investment Agreement dated May 22, 2001 between the Company and Medtronic Asset Management, Inc. (9)
10.34	Warrant dated June 20, 2001 issued to Medtronic Asset Management, Inc. (9)
10.35	Registration Rights Agreement dated June 20, 2001 between the Company and Medtronic Asset Management, Inc. (9)
10.36*	License and Development Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
10.37*	Supply Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
10.38	Securities Purchase Agreement dated March 25, 2002 between the Company and certain purchasers ("SPA") (10)
10.39	Form of Warrant issued by the Company to certain purchasers under the SPA (10)
10.40	Registration Rights Agreement dated March 25, 2002 between the Company and certain purchasers (10)
10.41	2002 Equity Incentive Plan (11)
10.42	Securities Purchase Agreement dated January 19, 2005 between the Company and certain purchasers ("SPA"),(12)
10.43	Form of Purchase Warrant issued by the Company to certain purchasers under the SPA. (12)
14.0	Code of Business Conduct and Ethics (13)
23.0	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Company's Chief Executive Officer, Denis R. Burger, Ph.D., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Company's Chief Financial Officer, Mark M. Webber, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.0	Certification of CEO and CFO Pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form SB-2, as amended and filed with the Securities and Exchange Commission on May 29, 1997 (Commission Registration No. 333-20513).

(2) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, and filed with the Securities and Exchange Commission on March 30, 1998.

(3) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-4, as amended, and filed with the Securities and Exchange Commission on August 7, 1998 (Commission Registration No. 333-60849).

(4) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on September 30, 1998 (Commission Registration No. 000-22613).

(5) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-3, as amended, and filed with the Securities and Exchange Commission on December 21, 1999 (Commission Registration No. 333-93135).

(6) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-1 and filed with the Securities and Exchange Commission on June 16, 2000 (Commission Registration No. 333-39542).

(7) Incorporated by reference to Exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on September 15, 2000 (Commission Registration No. 333-45888).

(8) Incorporated by reference to Appendix A to Registrant's Definitive Proxy Statement on Form 14-A, as amended, filed with the Securities and Exchange Commission on April 12, 2000.

(9) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001, and filed with the Securities and Exchange Commission on August 14, 2001, as amended on April 23, 2002.

(10) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on April 2, 2002.

(11) Incorporated by reference to appendixes to Registrant's Definitive Proxy Statement on Schedule 14-A, as filed with the Securities and Exchange Commission on April 11, 2002.

(12) Incorporated by reference to registrants current report on Form 8-K, as filed with the Securities and Exchange Commission on January 20, 2005.

(13) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and filed with the Securities and Exchange Commission on March 15, 2004.

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

(d) Financial Statement Schedules. See Item 15 (a) above.

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* A Confidential Treatment Request for certain information in this document has been filed with the Securities and Exchange Commission. The information for which treatment has been sought has been deleted from such exhibit and the deleted text replaced by an asterisk (*).

SIGNATURES

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

Dated: March 16, 2005

AVI BIOPHARMA, INC.

By: /s/ Denis R. Burger, Ph.D.
Denis R. Burger, Ph.D.
Chairman of the Board and Chief Executive Officer

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 their capacities indicated on March 16, 2005:

Signature	Title
/s/ DENIS R. BURGER, Ph.D. Denis R. Burger, Ph.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
/s/ ALAN P. TIMMINS Alan P. Timmins	President, Chief Operating Officer, and Director
/s/ MARK M. WEBBER Mark M. Webber	Chief Financial Officer and Chief Information Officer (Principal Financial and Accounting Officer)
/s/ PATRICK L. IVERSEN, Ph.D. Patrick L. Iversen, Ph.D.	Senior Vice President of Research and Development and Director
/s/ DWIGHT D. WELLER, Ph.D. Dwight D. Weller, Ph.D.	Senior Vice President of Chemistry and Manufacturing and Director
/s/ JACK L. BOWMAN Jack L. Bowman	Director
/s/ JOHN W. FARA, Ph.D. John W. Fara, Ph.D.	Director
/s/ K. MICHAEL FORREST K. Michael Forrest	Director
/s/ JAMES B. HICKS, Ph.D. James B. Hicks, Ph.D.	Director
/s/ JOHN C. HODGMAN John C. Hodgman	Director

Report of Independent Registered Public Accounting Firm

The Board of Directors
AVI BioPharma, Inc.:

We have audited the accompanying balance sheets of AVI BioPharma, Inc. (an Oregon corporation in development stage) as of December 31, 2004 and 2003, and the related statements of operations, shareholders' equity and cash flows for the three-year period ended and for the period from July 22, 1980 (inception) through December 31, 2004. 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. The financial statements of AVI BioPharma, Inc. for the period from July 22, 1980 (inception) through December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 21, 2002. Our opinion on the statements of operations, shareholders' equity and cash flows, insofar as it relates to the amounts included for the period from July 22, 1980 (inception) through December 31, 2001, is based solely on the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BioPharma, Inc. as of December 31, 2004 and 2003, and the results of its operations and its cash flows for the years in the three-year period ended December 31, 2004 and for the period from July 22, 1980 (inception) through December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of AVI BioPharma's internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report date March 15, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

KPMG LLP

Portland, OR
March 15, 2005

THIS REPORT IS A CONFORMED COPY OF THE REPORT PREVIOUSLY ISSUED BY ARTHUR ANDERSEN LLP AND HAS NOT BEEN REISSUED BY THAT FIRM.

Report of Independent Public Accountants

To the Board of Directors and Shareholders of
AVI BIOPHARMA, INC.

We have audited the accompanying balance sheet of AVI BIOPHARMA, INC. (an Oregon corporation in the development stage) as of December 31, 2001, and the related statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to 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 AVI BIOPHARMA, INC. as of December 31, 2001, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Portland, Oregon
February 21, 2002

AVI BIOPHARMA, INC.
(A Development Stage Company)
BALANCE SHEETS

	December 31, 2004	December 31, 2003
Assets		
Current Assets:		
Cash and cash equivalents	$ 16,654,829	$ 12,524,915
Short-term securities—available-for-sale	2,860,487	25,074,221
Other current assets	683,075	791,383
Total Current Assets	20,198,391	38,390,519
Property and Equipment, net of accumulated depreciation and amortization of $6,729,046 and $5,198,912	6,313,644	7,008,426
Patent Costs, net of accumulated amortization of $1,061,788 and $877,038	1,968,987	1,716,231
Other Assets	37,609	29,847
Total Assets	$ 28,518,631	$ 47,145,023
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,456,196	$ 3,052,932
Accrued employee compensation	793,402	698,061
Total Current Liabilities	2,249,598	3,750,993
Commitments and Contingencies		
Shareholders' Equity:		
Preferred stock, $.0001 par value, 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, $.0001 par value, 200,000,000 shares authorized; 36,143,153 and 34,465,737 issued and outstanding	3,614	3,447
Additional paid-in capital	182,370,440	174,875,072
Accumulated other comprehensive loss	(132,641)	(289,803)
Deficit accumulated during the development stage	(155,972,380)	(131,194,686)
Total Shareholders' Equity	26,269,033	43,394,030
Total Liabilities and Shareholders' Equity	$ 28,518,631	$ 47,145,023

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF OPERATIONS

	Year ended December 31,			July 22, 1980 (Inception) through
	2004	2003	2002	December 31, 2004
Revenues from license fees, grants and research contracts	$ 430,461	$ 969,866	$ 836,784	$ 5,081,768
Operating expenses:				
Research and development	20,738,725	15,284,396	22,413,892	105,183,877
General and administrative	4,735,731	4,558,948	3,763,941	27,885,407
Acquired in-process research and development	—	—	—	19,545,028
	25,474,456	19,843,344	26,177,833	152,614,312
Other income (loss):				
Interest income, net	266,301	491,098	460,258	4,699,010
Realized gain on sale of short-term securities—available-for-sale	—	3,765,752	—	3,862,502
Write-down of short-term securities—available-for-sale	—	—	(4,478,260)	(17,001,348)
	266,301	4,256,850	(4,018,002)	(8,439,836)
Net loss	$ (24,777,694)	$ (14,616,628)	$ (29,359,051)	$ (155,972,380)
Net loss per share - basic and diluted	$ (0.69)	$ (0.49)	(1.14)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	35,994,976	29,808,539	25,691,549	

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF SHAREHOLDERS' EQUITY

	Partnership Units	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT JULY 22, 1980 (Inception)	—	—	$ —	$ —	$ —	$ —	$ —
Issuance of partnership units, warrants and common stock	3,615	8,272,916	828	33,732,654	—	—	33,733,482
Compensation expense related to issuance of warrants for common stock and partnership units	—	—	—	537,353	—	—	537,353
Exercise of warrants for partnership units and common stock	42	1,513,739	150	1,650,407	—	—	1,650,557
Exercise of options for common stock	—	568,606	57	2,508,824	—	—	2,508,881
Issuance of common stock for ESPP	—	37,188	4	207,356	—	—	207,360
Issuance of common stock and warrants for cash and securities, net of offering costs	—	9,064,385	906	60,856,124	—	—	60,857,030
Issuance of common stock and warrants for the acquisition of ImmunoTherapy Corporation	—	2,132,592	213	17,167,199	—	—	17,167,412
Issuance of common stock and warrants for services	—	54,597	6	429,594	—	—	429,600
Conversion of debt into common stock and partnership units	9	9,634	1	87,859	—	—	87,860
Issuance of common stock in exchange for partnership units	(1,810)	1,632,950	163	(163)	—	—	—
Withdrawal of partnership net assets upon conveyance of technology	(1,856)	—	—	(176,642)	—	—	(176,642)
Common stock subject to rescission, net	—	(64,049)	(6)	(288,789)	—	—	(288,795)
Comprehensive income (loss):							
Write-down of short-term securities—available-for-sale	—	—	—	—	12,523,088	—	12,523,088
Unrealized loss on short-term securities —available-for-sale	—	—	—	—	(11,484,132)	—	(11,484,132)
Net loss	—	—	—	—	—	(87,219,007)	(87,219,007)
Comprehensive loss							(86,180,051)
BALANCE AT DECEMBER 31, 2001	—	23,222,558	2,322	116,711,776	1,038,956	(87,219,007)	30,534,047
Exercise of warrants for common stock	—	17,119	2	158,758	—	—	158,760
Exercise of options for common stock	—	82,301	8	347,324	—	—	347,332
Issuance of common stock for ESPP	—	31,766	3	150,555	—	—	150,558
Issuance of common stock and warrants for services	—	138,251	14	489,649	—	—	489,663
Compensation expense related to issuance of options for common stock	—	—	—	148,254	—	—	148,254
Issuance of common stock and warrants for cash, net of offering costs	—	3,070,671	307	21,320,753	—	—	21,321,060
Comprehensive income (loss):							

Write-down of short-term securities—available-for-sale	—	—	—	—	4,478,260	—	4,478,260
Unrealized loss on short-term securities —available-for-sale	—	—	—	—	(4,787,260)	—	(4,787,260)
Net loss	—	—	—	—	—	(29,359,051)	(29,359,051)
Comprehensive loss							(29,668,051)
BALANCE AT DECEMBER 31, 2002	—	26,562,666	$ 2,656	$ 139,327,069	$ 729,956	$ (116,578,058)	$ 23,481,623
Exercise of options for common stock	—	79,640	8	297,239	—	—	297,247
Issuance of common stock for ESPP	—	30,467	3	123,573	—	—	123,576
Compensation expense related to issuance of options for common stock	—	—	—	471,460	—	—	471,460
Issuance of common stock and warrants for cash, net of offering costs	—	7,792,964	780	34,655,731	—	—	34,656,511
Comprehensive income (loss):							
Realized gain on sale of short-term securities —available-for-sale	—	—	—	—	(3,765,752)	—	(3,765,752)
Unrealized gain on short-term securities —available-for-sale, net	—	—	—	—	2,745,993	—	2,745,993
Net loss	—	—	—	—	—	(14,616,628)	(14,616,628)
Comprehensive loss							(15,636,387)
BALANCE AT DECEMBER 31, 2003	—	34,465,737	$ 3,447	$ 174,875,072	$ (289,803)	$ (131,194,686)	$ 43,394,030
Exercise of options for common stock	—	4,121	—	14,986	—	—	14,986
Issuance of common stock for ESPP	—	49,918	5	94,553	—	—	94,558
Compensation expense related to issuance of options for common stock	—	—	—	421,635	—	—	421,635
Issuance of common stock and warrants for cash, net of offering costs	—	1,623,377	162	6,964,194	—	—	6,964,356
Comprehensive income (loss):							
Unrealized gain on short-term securities —available-for-sale, net	—	—	—	—	157,162	—	157,162
Net loss	—	—	—	—	—	(24,777,694)	(24,777,694)
Comprehensive loss							(24,620,532)
BALANCE AT DECEMBER 31, 2004	—	36,143,153	$ 3,614	$ 182,370,440	$ (132,641)	$ (155,972,380)	$ 26,269,033

See accompanying notes to financial statements

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS

	Year ended December 31,			For the Period July 22, 1980 (Inception) through December 31, 2004
	2004	2003	2002	
Cash flows from operating activities:				
Net loss	$ (24,777,694)	$ (14,616,628)	$ (29,359,051)	$ (155,972,380)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	1,888,008	1,484,349	1,333,335	8,732,192
Loss on disposal of assets	86,947	—	—	86,947
Realized gain on sale of short-term securities —available-for-sale	—	(3,765,752)	—	(3,862,502)
Write-down of short-term securities—available-for-sale	—	—	4,478,260	17,001,348
Compensation expense on issuance of common stock and partnership units	—	—	489,663	861,655
Compensation expense on issuance of options and warrants to purchase common stock or partnership units	421,635	471,460	148,254	1,723,702
Conversion of interest accrued to common stock	—	—	—	7,860
Acquired in-process research and development	—	—	—	19,545,028
(Increase) decrease in:				
Other current assets	108,308	316,960	805,612	(683,075)
Other assets	(7,762)	—	—	(37,609)
Net increase (decrease) in accounts payable and accrued employee compensation	(1,501,395)	(1,371,141)	1,841,068	2,369,598
Net cash used in operating activities	(23,781,953)	(17,480,752)	(20,262,859)	(110,227,236)
Cash flows from investing activities:				
Purchase of property and equipment	(1,070,338)	(1,639,949)	(2,777,663)	(13,460,428)
Patent costs	(462,591)	(397,135)	(453,404)	(3,391,342)
Purchase of marketable securities	(13,123,205)	(44,421,888)	(19,095,394)	(84,755,289)
Sale of marketable securities	35,494,101	31,002,342	19,927,122	86,671,315
Acquisition costs	—	—	—	(2,377,616)
Net cash provided by (used in) investing activities	20,837,967	(15,456,630)	(2,399,339)	(17,313,360)
Cash flows from financing activities:				
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	7,073,900	35,077,334	21,977,710	144,580,862
Buyback of common stock pursuant to rescission offering	—	—	—	(288,795)
Withdrawal of partnership net assets	—	—	—	(176,642)
Issuance of convertible debt	—	—	—	80,000
Net cash provided by financing activities	7,073,900	35,077,334	21,977,710	144,195,425
Increase (decrease) in cash and cash equivalents	4,129,914	2,139,952	(684,488)	16,654,829
Cash and cash equivalents:				
Beginning of period	12,524,915	10,384,963	11,069,451	—
End of period	$ 16,654,829	$ 12,524,915	$ 10,384,963	$ 16,654,829
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:				
Change in unrealized gain (loss) on short-term securities —available-for-sale	$ 157,162	$ (1,019,759)	$ (309,000)	$ (132,641)
Issuance of common stock and warrants for services	$ —	$ —	$ —	370,000

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)

NOTES TO FINANCIAL STATEMENTS

1. ORGANIZATION AND NATURE OF BUSINESS:

AVI BioPharma, Inc. (the Company or AVI) was incorporated in the State of Oregon on July 22, 1980. The mission of the Company is to develop and commercialize improved therapeutic products based upon antisense and cancer immunotherapy technology.

Through May 1993, the financial statements included the combined accounts of the Company and ANTI-GENE DEVELOPMENT GROUP, a limited partnership (AGDG or the Partnership) founded in 1981 and registered in the State of Oregon. Substantially all income generated and proceeds from the Partnership unit sales through that date have been paid to the Company under the terms of research and development contracts entered into by the Partnership and the Company. Significant transactions between the Company and the Partnership through that date have been eliminated.

In March 1993, the Company offered to all partners in the Partnership the opportunity to exchange their partnership units or warrants to purchase partnership units (unit warrants) for common stock or warrants to purchase common stock. Under the terms of the offer, which was completed May 1, 1993, each partner could elect to exchange each unit held or unit warrant held for 1,100 shares of common stock or warrants to purchase 1,100 shares of common stock of the Company, respectively. Total shares and warrants to purchase shares issued in the exchange offer were 1,632,950 and 381,700, respectively.

Effective May 19, 1993, the Company and the Partnership entered into a Technology Transfer Agreement wherein the Partnership conveyed all intellectual property then in its control to the Company. As part of the conveyance, the Company tendered to the Partnership for liquidation all partnership units received pursuant to the exchange offer and received a 49.37 percent undivided interest in the intellectual property. The Company then purchased the remaining undivided interest in the intellectual property for rights to payments of 4.05 percent of gross revenues in excess of $200 million, from sales of products, which would, in the absence of the Technology Transfer Agreement, infringe a valid claim under any patent transferred to the Company. The Company also granted to the Partnership a royalty-bearing license to make, use and sell small quantities of product derived from the intellectual property for research purposes only.

In March 2000, the Company and AGDG amended the Technology Transfer Agreement to give to AGDG and Gene Tools LLC, related organizations, exclusive, non royalty-bearing rights to in vitro diagnostic applications of the intellectual property. In consideration for this amendment, Gene Tools paid the Company $1 million and reduced the royalty that the Company would pay to AGDG under the Technology Transfer Agreement on future sales of therapeutic products from 4.05% to 3.00%.

The remaining net assets of the Partnership, $176,642 of cash, were no longer combined with those of the Company in May 1993. Under the terms of the Technology Transfer Agreement, the Partnership ceased active sales of partnership units and income generating activities and no longer will enter into research and development contracts with the Company. The Partnership currently exists primarily for the purpose of collecting potential future payments from the Company as called for in the Technology Transfer Agreement.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

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 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. Significant items subject to such estimates and assumptions include the valuation of marketable securities, carrying amount of property, plant and equipment, and valuation allowance for deferred income tax assets.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. The Company held cash equivalents of $16,654,829 and $12,524,915 as of December 31, 2004 and 2003, respectively which consist primarily of money market funds.

Short-Term Securities—Available-For-Sale

The Company accounts for its short-term securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). The Company classifies its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value. At December 31, 2004 and 2003, the Company's investments in marketable securities had gross unrealized losses of $132,641 and $289,803, respectively. The unrealized difference between the cost and the fair market value of these securities has been reflected as a separate component of shareholders' equity. At December 31, 2004 and 2003, these short-term securities represent investments in commercial paper of $2,500,592 and $24,719,804, respectively.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally five years, using the straight-line method. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the asset. Expenditures for repairs and maintenance are expensed as incurred. Expenditures that increase the useful life or value are capitalized.

Amounts included in property and equipment are as follows:

As of December 31,	2004	2003
Lab equipment	$ 4,212,804	$ 3,864,847
Office equipment	669,376	490,352
Leasehold improvements	7,802,300	5,201,139
Construction in process	358,210	2,651,000
	13,042,690	12,207,338
Less accumulated depreciation	(6,729,046)	(5,198,912)
Property and equipment, net	$ 6,313,644	$ 7,008,426

Patent Costs

Patent costs consist primarily of legal and filing fees incurred to file patents on proprietary technology developed by the Company. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the legal lives of the patents, generally 17 years. Patent amortization was $209,835, 268,536 and 242,174 for the years ended December 31, 2004, 2003 and 2002, respectively.

Revenue Recognition

The Company records revenue from research contracts and grants as the services are performed and payment is reasonably assured. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. Fees received from SuperGen, Inc. pursuant to the Company's Avicine shared development arrangement are netted against research and development expense since the Company and SuperGen, Inc. share equally in all clinical development and FDA registration costs. To date revenue from license and development arrangements has not been significant.

Research and Development

Research and development (R&D) expenses include related salaries, contractor fees, materials, utilities and allocations of corporate costs. R&D expenses also consist of independent R&D costs and costs associated with collaborative development arrangements. In addition, the Company funds R&D at other companies and research institutions under agreements. Research and development costs are expensed as incurred.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. 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 and settled.

Net Loss Per Share

Basic EPS is calculated using the weighted average number of common shares outstanding for the period and diluted EPS is computed using the weighted average number of common shares and dilutive common equivalent shares outstanding. Given that the Company is in a loss position, there is no difference between basic EPS and diluted EPS since the common stock equivalents would be antidilutive.

Year Ended December 31,	2004	2003	2002
Net loss	$ (24,777,694)	$ (14,616,628)	$ (29,359,051)
Weighted average number of shares of common stock and common stock equivalents outstanding:			
Weighted average number of common shares outstanding for computing basic earnings per share	35,994,976	29,808,539	25,691,549
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	35,994,976	29,808,539	25,691,549
Net loss per share - basic and diluted	$ (0.69)	$ (0.49)	$ (1.14)

* The following common stock equivalents are excluded from earnings per share calculation as their effect would have been antidilutive:

Year Ended December 31,	2004	2003	2002
Warrants and stock options	13,817,608	14,996,243	14,572,265

Stock-based Compensation

The Financial Accounting Standards Board (FASB) has issued SFAS 123, which defines a fair value based method of accounting for an employee stock option and similar equity instruments and encourages all entities to adopt that method of accounting for all of their employee stock compensation plans. However, it also allows an entity to continue to measure compensation cost for those plans using the method of accounting prescribed by Accounting Principles Board Opinion No. 25 (APB 25). Entities electing to remain with the accounting in APB 25 must make pro forma disclosures of net income (loss) and earnings (loss) per share, as if the fair value based method of accounting defined in SFAS 123 had been adopted. In December 2002, the FASB issued SFAS 148 "Accounting for Stock-Based Compensation – Transition and Disclosure." SFAS 148 amends SFAS 123 for certain transition provisions for companies electing to adopt the fair value method and amends SFAS 123 for certain financial statement disclosures, including interim financial statements. The Company adopted SFAS 148 in December 2002. The Company has elected to account for its stock-based compensation plans (which are described in Note 4) under APB 25. The Company has computed, for pro forma disclosure purposes, the impact on net loss and net loss per share if the Company had accounted for its stock-based compensation plans in accordance with SFAS 123 as follows:

	For the Year Ended December 31,		
	2004	2003	2002
Net loss, as reported	$ (24,777,694)	$ (14,616,628)	$ (29,359,051)
Deduct: Total stock-based employee compensation expense determined under fair value based method, for all awards not previously included in net loss	(2,011,753)	(3,436,587)	(2,177,358)
Pro forma net loss	$ (26,789,447)	$ (18,053,215)	$ (31,536,409)
Basic and diluted net loss per share:			
As reported	$ (0.69)	$ (0.49)	$ (1.14)
Pro forma	$ (0.74)	$ (0.61)	$ (1.23)

No stock-based employee compensation is included in net loss for any of the periods presented since all of the options were granted at the fair market value of the Company's common stock on the date of grant. The effects of applying SFAS 123 in this pro forma disclosure are not indicative of future amounts. Additional awards are anticipated in future years.

The value of all options granted during 2004, 2003 and 2002 using the Black-Scholes options pricing model as prescribed by SFAS 123 used the following weighted average assumptions for grants:

Year Ended December 31,	2004	2003	2002
Risk-free interest rate	3.00%	2.13%	3.61%
Expected dividend yield	0%	0%	0%
Expected lives	9.2 Years	7.5 Years	7.5 Years
Expected volatility	93%	94%	88%

Using the Black-Scholes methodology, the total value of options granted to employees during 2004, 2003 and 2002 was $1,244,461, $397,062 and $4,843,213, respectively, which would be amortized on a pro forma basis over the vesting period of the options (typically four years). The weighted average fair value of options granted to employees during 2004, 2003 and 2002 was $2.70, $4.29 and $4.27, respectively.

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with EITF 96-18 " *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* ." The fair value of the options granted are expensed when the measurement date is known. The total fair value of the options granted to non-employees in 2004 was $421,635.

Comprehensive Income (Loss)

Comprehensive income (loss) includes all changes in the equity of an enterprise that results from transactions and other economic events of the period other than transactions with shareholders. The Company's only component of "other comprehensive income (loss)" is unrealized gain (loss) on short-term securities available-for-sale.

Recent Accounting Pronouncements

In December 2003, the SEC issued Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104), which updates the previously issued revenue recognition guidance in SAB 101, based on the Emerging Issues Task Force Issue 00-21, Revenue Arrangements with Multiple Deliverables. If the deliverables in a sales arrangement constitute separate units of accounting according to the EITF's separation criteria, the revenue-recognition policy must be determined for each identified unit. If the arrangement is a single unit of accounting under the separation criteria, the revenue-recognition policy must be determined for the entire arrangement. The issuance of SAB 104 has not had any impact on the financial results of the Company.

In December 2004, the FASB issued SFAS 123R which requires the measurement of all employee share-based payments to employees, including grants of employee stock options, using a fair-value-based method and the recording of such expense in our consolidated statements of income. The accounting provisions of SFAS 123R are effective for reporting periods beginning after June 15, 2005. We are required to adopt SFAS 123R in the second quarter of fiscal 2005. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See "Stock-based Compensation" above for the pro forma net income (loss) and net income (loss) per share amounts, for fiscal 2002 through fiscal 2004, as if we had used a fair-value-based method similar to the methods required under SFAS 123R to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123R will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123R and expect the adoption to have a significant adverse impact on our consolidated statements of income and net income (loss) per share.

3. LIQUIDITY:

The Company is in the development stage. Since its inception in 1980 through December 31, 2004, the Company has incurred losses of approximately $156 million, substantially all of which resulted from expenditures related to research and development, general and administrative expenses, non-cash write-downs in 2002 of $4,478,260 and in 2001 of $12,523,088 on short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules and a one-time charge of $19,545,028 for acquired in-process research and development reflecting the acquisition of ImmunoTherapy Corporation. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company nevertheless expects to incur operating losses over the next several years.

The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on completing product development of its cancer vaccine and, antisense and/or drug delivery products, obtaining regulatory approvals for such products, and bringing these products to market. During the period required to develop these products, the Company will require substantial financing. There is no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. In January 2005, the Company announced a private placement of 8,000,000 shares of its common stock at $3.00 per share, together with warrants to acquire an additional 1,600,000 shares of common stock, to a group of institutional investors for a total purchase price of $24.0 million, as described in Note 9. The Company believes it has sufficient cash to fund operations through 2005. For 2005, the Company expects expenditures for operations, including collaborative efforts and GMP facilities to be approximately $25 to $27 million. The increase from 2004 expenditures is due to the increased use of an outside GMP manufacturing contractor for production of GMP subunits for later conversion into finished compounds for use in clinical trials. Expenditures for 2005 could increase if the Company undertakes additional collaborative efforts. If necessary, however, the Company's management has the ability to significantly curtail certain expenditures because the vast majority of the Company's costs are variable .

The likelihood of the long-term success of the Company must be considered in light of the expenses, difficulties and delays frequently encountered in the development and commercialization of new pharmaceutical products, competitive factors in the marketplace as well as the burdensome regulatory environment in which the Company operates. There can be no assurance that the Company will ever achieve significant revenues or profitable operations.

4. SHAREHOLDERS' EQUITY:

In May 2001, the Company entered into a license and development agreement with Medtronic, Inc. relating to the Company's antisense compounds which may have application in the treatment of vascular disease. The agreement provides for milestone payments and license royalties upon achievement of certain milestones or product sales. The Company also entered into a separate investment agreement with Medtronic for $10,000,000 in cash in exchange for 1,408,451 shares of AVI common stock and a warrant to purchase 3,000,000 shares of AVI common stock. Closing of the transaction occurred during the second quarter of 2001. Pursuant to the investment agreement, Medtronic agrees to purchase 352,113 shares of common stock at $7.10 per share and an additional $7,500,000 of common stock based on the average trailing 5 days closing price preceding the commitment date. These stock purchases by Medtronic are subject to meeting certain technology milestones and any required regulatory or shareholder approvals.

In March 2002, the Company closed a private equity financing for net proceeds of $21,321,000 with several institutional investors. The Company sold 3,070,671 shares of common stock at $7.50 per share. Investors also received a warrant for the purchase of 614,139 common shares for $10.50 per share. These warrants are immediately exercisable and expire in March 2006.

In May 2003, the Company closed a private equity financing for net proceeds of $20,757,504 with several institutional investors. The Company sold 4,500,000 shares of common stock at $5.00 per share. Investors also received a warrant for the purchase of 2,250,000 common shares for $7.00 per share. These warrants are immediately exercisable and expire in May 2008. In connection with the equity financing, the Company issued 46,211 shares of common stock to the underwriters. The underwriters also received a warrant for the purchase of 315,000 common shares for $7.00 per share. These warrants are immediately exercisable and expire in May 2008.

In December 2003, the Company closed a private equity financing for net proceeds of $13,899,007 with several institutional investors. The Company sold 3,246,753 shares of common stock at $4.62 per share. These investors received a warrant for the purchase of 1,623,377 common shares for $4.62 per share. These warrants were immediately exercisable and were exercised on January 22, 2004. These investors also received a warrant for the purchase of 974,026 common shares for $5.50 per share. These warrants are immediately exercisable and expire in December 2008. In connection with the equity financing, the placement agent received a warrant for the purchase of 340,909 common shares for $5.50 per share. These warrants are immediately exercisable and expire in December 2008.

In January 2004, the institutional investors above exercised warrants for the purchase of 1,623,377 shares of the Company's common stock at $4.62 per share, for net proceeds of $6,964,356. Investors also received new five-year warrants to purchase 389,611 common shares for $5.50 per share. These warrants are exercisable commencing on July 28, 2004 and expire on December 8, 2008.

In 2000, the Board of Directors and the Company's shareholders approved the Employee Stock Purchase Plan under which the Company is authorized to sell up to 250,000 shares of common stock to its full-time employees, nearly all of whom are eligible to participate. Under the terms of the Plan, employees may elect every six months to have up to 10% of their compensation withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the beginning-of-plan period or end-of-plan period market price of the Company's common stock. During 2004, employees elected to purchase a total of 49,918 shares of the Company's common stock at $1.89 per share. During 2003, employees elected to purchase a total of 30,467 shares of the Company's common stock at $4.06 per share. During 2002, employees elected to purchase a total of 31,766 shares of the Company's common stock at $4.74 per share. During 2001, employees elected to purchase 29,419 shares of the Company's common stock at $5.61 per share.

The Company has two stock option plans, the 2002 Equity Incentive Plan and the 1997 Stock Option Plan (the Plans). The 2002 Plan provides for the issuance of incentive stock options to employees and nonqualified stock options, stock appreciation rights and bonus rights to employees, directors of the Company and consultants. The 1997 Plan provides for the assumption of the ImmunoTherapy Options under the Merger Agreement. The Company has reserved 5,908,118 shares of common stock for issuance under the Plans. Options issued under the Plans generally vest ratably over four years and expire five to ten years from the date of grant.

A summary of the status of the Company's stock option plans and changes are presented in the following table:

	2004		2003		2002	
For the Year Ended December 31,	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**	**Shares**	**Weighted Average Exercise Price**
Options outstanding at beginning of year	3,333,861	$ 5.60	3,668,581	$ 5.68	2,857,049	$ 5.82
Granted	631,041	3.10	212,500	5.07	1,195,338	4.99
Exercised	(4,121)	3.64	(79,640)	3.73	(82,301)	4.22
Canceled	(157,503)	4.75	(467,580)	6.34	(301,505)	4.69
Options outstanding at end of year	3,803,278	5.22	3,333,861	5.60	3,668,581	5.68
Exercisable at end of year	2,912,510	$ 5.63	2,556,828	$ 5.65	2,220,518	$ 5.85

At December 31, 2004, 2,104,840 shares were available for future grant.

The following table summarizes information about stock options outstanding at December 31, 2004:

Exercise Price	Outstanding Shares at December 31, 2004	Weighted Average Remaining Contractual Life (Years)	Exercisable Options
$ 0.04	11,500	0.92	11,500
1.76	20,000	4.62	—
2.06	20,000	9.75	—
2.20	20,000	9.91	—
2.55	53,000	9.34	11,666
2.89	100,000	9.24	—
2.92	183,334	9.22	—
3.02	33,334	9.23	—
3.29	10,000	4.28	—
3.31	25,000	4.76	25,000
3.45	100,000	9.23	—
3.50	207,589	2.61	207,589
3.69	28,000	4.05	28,000
3.81	15,000	3.64	15,000
3.97	132,768	2.12	132,768
4.16	25,000	8.28	12,500
4.25	20,000	3.98	20,000
4.28	5,000	3.10	2,500
4.34	81,344	5.29	61,344
4.55	30,000	3.62	30,000
4.75	31,773	0.99	31,773
4.87	20,000	8.01	5,000
4.89	10,000	8.01	2,500
4.95	99,158	0.23	99,158
5.35	745,800	7.93	497,200
5.53	40,000	5.92	13,334
5.75	503,000	5.00	503,000
5.88	45,000	8.38	15,000
6.00	66,668	1.70	66,668
6.38	235,000	2.44	235,000
6.63	510,000	3.11	510,000
6.65	48,334	7.37	48,334
6.69	100,000	2.69	100,000
6.88	132,000	5.62	132,000
7.19	33,334	5.58	33,334
8.10	27,342	1.88	27,342
8.13	25,000	2.84	25,000
10.00	10,000	0.41	10,000
	3,803,278		2,912,510

The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. The 389,611, 5,503,312, and 614,139 warrants granted in 2004, 2003 and 2002, respectively, have not been considered in the fair value based method of accounting defined in SFAS 123 as such warrant grants related to the raising of additional equity. A summary of the status of the Company's warrants and changes are presented in the following table:

	2004		2003		2002	
For the Year Ended December 31,	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Warrants outstanding at beginning of year	11,662,382	$ 11.20	10,903,684	$ 15.16	10,307,745	$ 15.42
Granted	389,611	5.50	5,503,312	5.94	614,139	10.50
Exercised	(1,623,377)	4.62	—	—	(17,119)	9.62
Expired	(414,286)	4.03	(4,744,614)	13.43	(1,081)	8.70
Warrants outstanding at end of year	10,014,330	12.34	11,662,382	11.20	10,903,684	15.16
Exercisable at end of year	8,348,452	$ 7.70	9,996,504	$ 7.13	9,187,806	$ 11.47

The following table summarizes information about warrants outstanding at December 31, 2004:

Exercise Price	Outstanding Warrants at December 31, 2004	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
$ 0.0003	16,667	No expiration date	16,667
1.14	1,000	No expiration date	1,000
4.62	614,139	1.23	614,139
5.50	1,704,546	3.94	1,704,546
7.00	2,565,000	3.34	2,565,000
8.70	297,100	0.58	297,100
10.00	3,150,000	1.42	3,150,000
35.63	1,665,878	5.25	—
	10,014,330		8,348,452

5. INCOME TAXES:

As of December 31, 2004 the Company has net operating loss carryforwards of approximately $114,687,000, available to reduce future taxable income, which expire 2005 through 2023. Of this $114,687,000, approximately $2,600,000 relates to net operating losses assumed as part of the ImmunoTherapy Corporation acquisition. Utilization of these ImmunoTherapy Corporation net operating losses is limited to approximately $1,200,000 per year. In addition, the Internal Revenue Code rules under Section 382 could limit the future use of the remaining $112,087,000 in losses based on ownership changes and the value of the Company's stock. Approximately $3,360,000 of the Company's carryforwards were generated as a result of deductions related to exercises of stock options. When utilized, this portion of the Company's carryforwards, as tax effected, will be accounted for as a direct increase to contributed capital rather than as a reduction of that year's provision for income taxes. The principal differences between net operating loss carryforwards for tax purposes and the accumulated deficit result from depreciation, amortization, investment write-downs, and treatment of research and development costs and deductions related to the exercise of stock options for income tax purposes.

The Company had net deferred tax assets of $58,573,000 and $46,480,000 at December 31, 2004 and 2003, primarily from net operating loss carryforwards. A valuation allowance was recorded to reduce the net deferred tax asset to zero because it is more likely than not the deferred tax asset will not be realized. The net change in the valuation allowance for deferred tax assets was an increase of approximately $12,093,000, $5,136,000 and $13,228,000 for the years ended December 31, 2004, 2003 and 2002, respectively, mainly due to the increase in the net operating loss carryforwards, research and development tax credits and write-down of short-term securities.

An analysis of the deferred tax assets(liabilities) are as follows:

December 31,	2004	2003
Net operating loss carryforwards	$ 44,728,000	$ 40,747,000
Difference in depreciation and amortization	520,000	(727,000)
Capital loss carryforward	5,007,000	—
Research and development tax credits	7,892,000	6,460,000
Stock options for consulting services	406,000	—
Other	20,000	—
	58,573,000	46,480,000
Valuation allowance	(58,573,000)	(46,480,000)
	$ —	$ —

6. RELATED PARTY TRANSACTIONS:

In April 2000, the Company entered into an alliance with SuperGen, Inc. for shared development and marketing rights for Avicine. Under the terms of the agreement, AVI and SuperGen, Inc. will equally share in future clinical development and FDA registration costs as well as in profits from product sales in the United States. Additionally, AVI may receive up to $80 million from SuperGen, Inc. upon meeting commercialization benchmarks.

During the year ended December 31, 2004, 2003 and 2002, the Company paid Boston Healthcare Associates, Inc., of which former director Andrew J. Ferrara is President, $986, $67,900 and $73,563, respectively, for business development consulting services. The Company expects to pay Mr. Ferrara, or his firm, for additional consulting services that may be performed for the Company during 2005.

In June 2002, the Company loaned the chief executive officer of AVI $500,000 under a one year term loan. The loan was secured by the chief executive officer's stock in AVI. Interest on the loan accrues at the rate of 4.75% per annum. This loan was made prior to the Sarbanes-Oxley Act, which prohibits loans to executives, and therefore is grandfathered in. On June 13, 2003, the loan to the Company's chief executive officer was repaid in full with accrued interest.

7. COMMITMENTS:

Lease Obligations

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2010. Rent expense under these leases was $1,485,000, $912,000 and $946,000 for the years ended December 31, 2004, 2003 and 2002, respectively, and $6,050,000 for the period from July 22, 1980 through December 31, 2004.

At December 31, 2004, the aggregate noncancelable future minimum payments under these leases are as follows:

Year ending December 31,		
2005	$	1,142,000
2006		1,144,000
2007		1,176,000
2008		1,209,000
2009		1,210,000
Thereafter		1,200,000
Total minimum lease payments	$	7,081,000

Royalty Obligations

The Company has license agreements for which it is obligated to pay the licensors a minimum annual royalty. Royalty payments under these agreements was $125,000, $175,000 and $175,000 for the years ended December 31, 2004, 2003 and 2002, respectively, and $733,750 for the period from July 22, 1980 through December 31, 2004.

At December 31, 2004, the aggregate future minimum royalty payments under these agreements are as follows:

Year ending December 31,		
2005	$	125,000
2006		125,000
2007		125,000
2008		125,000
2009		125,000
Thereafter		1,630,000
Total minimum royalty payments	$	2,255,000

8. FINANCIAL INFORMATION BY QUARTER (UNAUDITED):

2004 for quarter ended	December 31	September 30	June 30	March 31
Revenues from license fees, grants and research contracts	$ 285,588	$ 9,151	$ 36,271	$ 99,451
Operating expenses:				
Research and development	3,805,658	4,167,209	6,151,870	6,613,988
General and administrative	1,416,803	964,700	1,116,027	1,238,201
	5,222,461	5,131,909	7,267,897	7,852,189
Other income (loss):				
Interest income (loss), net	(53,381)	15,792	83,664	220,226
Net loss	$ (4,990,254)	$ (5,106,966)	$ (7,147,962)	$ (7,532,512)
Net loss per share, basic and diluted	$ (0.14)	$ (0.14)	$ (0.20)	$ (0.21)
Shares used in per share calculations	36,133,472	36,123,790	36,109,016	35,610,687

2003 for quarter ended	December 31	September 30	June 30	March 31
Revenues from license fees, grants and research contracts	$ 135,181	$ 414,352	$ 162,410	$ 257,923
Operating expenses:				
Research and development	6,405,351	3,533,868	2,539,282	2,805,895
General and administrative	888,440	1,560,026	1,177,081	933,401
	7,293,791	5,093,894	3,716,363	3,739,296
Other income (loss):				
Interest income, net	296,630	75,887	56,025	62,556
Realized gain on sale of short-term securities—available-for-sale	3,765,752	—	—	—
Net loss	$ (3,096,228)	$ (4,603,655)	$ (3,497,928)	$ (3,418,817)
Net loss per share, basic and diluted	$ (0.10)	$ (0.15)	$ (0.12)	$ (0.13)
Shares used in per share calculations	32,024,069	31,186,464	29,380,554	26,567,968

9. SUBSEQUENT EVENTS:

On January 19, 2005, the Company announced a private placement of 8,000,000 shares of its common stock at $3.00 per share, together with warrants to acquire an additional 1,600,000 shares of common stock, to a group of institutional investors for a total purchase price of $24.0 million. The warrants are exercisable starting July 19, 2005 for four years at an exercise price of $5.00 per share. The sale closed January 19, 2005. The securities are being sold pursuant to the company's effective shelf registration statement.

EXHIBIT 23.0

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
AVI BioPharma, Inc.

We consent to the incorporation by reference in the registration statement Nos. 333-86778, 333-105412, 333-10915, 333-68502, 333-45888, 333-93135 and 333-86039 on Forms S-3 and Nos. 333-101826, 333-49996, 333-49994 and 333-34047 on Forms S-8 of AVI BioPharma, Inc. of our reported dated March 15, 2005, with respect to the balance sheets of AVI BioPharma, Inc. as of December 31, 2004 and 2003 and the related statements of operations, shareholders' equity and cash flows for the years in the three-year period ended December 31, 2004, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting as of December 31, 2004, which reports appear in the December 31, 2004 annual report on Form 10-K of AVI BioPharma, Inc.

/s/ KPMG LLP

Portland, Oregon,
March 15, 2005

EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Denis R. Burger, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15 (f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

By: /s/ Denis R. Burger
Denis R. Burger,
Chief Executive Officer and Chairman
of the Board
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark M. Webber, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15 (f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2005

By: /s/ Mark M. Webber
Mark M. Webber,
Chief Financial Officer and Chief Information Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.0

CERTIFICATION OF CEO AND CFO PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of AVI BioPharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2004 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Denis R. Burger, as Chief Executive Officer of the Company, and Mark M. Webber, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge,:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Denis R. Burger

Denis R. Burger
Chairman and Chief Executive Officer
AVI BioPharma, Inc.
March 16, 2005

/s/ Mark M. Webber

Mark M. Webber
Chief Financial Officer and Chief Information Officer
AVI BioPharma, Inc.
March 16, 2005

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

See also the certification pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002, which is also attached to this Report.