

AVI BIOPHARMA INC  
Form 10-K/A  
November 05, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K/A**

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

**For the fiscal year ended December 31, 2006**

**o 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**

(State or other jurisdiction of incorporation  
or organization)

**93-0797222**

(I.R.S. Employer Identification No.)

**One SW Columbia Street, Suite 1105, Portland, Oregon**  
(Address of principal executive offices)

**97258**  
(Zip Code)

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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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. Yes  No .

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934. Yes  No .

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 a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Securities Exchange Act of 1934 (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer .

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). 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 Capital Market on March 14, 2007) was approximately \$135,683,497 as of March 14, 2007. 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, 2007 was 53,282,841.

**Documents Incorporated by Reference**

The issuer has incorporated into Part III of Form 10-K, by reference, portions of its Proxy Statement for its 2007 annual meeting.

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AVI BIOPHARMA, INC.

FORM 10-K/A INDEX

**PART I**

- Item 1.      Description of Business
- Item 1A.    Risk Factors
- Item 1B.    Unresolved SEC Comments
- Item 2.      Description of Property
- Item 3.      Legal Proceedings
- Item 4.      Submission of Matters to a Vote of Security Holders

**PART II**

- Item 5.      Market for Common Equity and Related Stockholder Matters
- Item 6.      Selected Financial Data
- Item 7.      Management's Discussion and Analysis or Plan of Operation
- Item 7A.    Quantitative and Qualitative Disclosures About Market Risk
- Item 8.      Financial Statements
- Item 9.      Changes in and Disagreements with Accountants on Accounting and Financial Disclosure
- Item 9A.    Controls and Procedures

**PART III**

- Item 10.    Directors and Executive Officers of the Registrant
  - Item 11.    Compensation Discussion and Analysis
  - Item 12.    Security Ownership of Certain Beneficial Owners and Management
  - Item 13.    Certain Relationships and Related Transactions
  - Item 14.    Principal Accountant Fees and Services
  - Item 15.    Exhibits and Financial Statement Schedules
  - Signatures
-

**EXPLANATORY NOTE**

We are filing this Amendment to our Form 10-K for the fiscal year ended December 31, 2006, filed on March 16, 2007 (the Original Filing), to amend and restate our balance sheets as of December 31, 2006 and 2005, our statements of operations, shareholders' equity, and cash flows for the years ended December 31, 2006, 2005, 2004, and the period from July 22, 1980 (inception) through December 31, 2006. This will include the restatement of the financial information by quarter for the periods in 2005 and 2006. This Amendment to the Original Filing amends our classification of certain warrants that were previously recorded in equity. These warrants were issued in registered offerings and require settlement in registered shares. As a result, they cannot be classified within equity according to generally accepted accounting principles. Instead, the warrants issued by the Company should be recorded as a liability at fair value at the date of grant, and marked to market at each reporting period. Changes in fair value are recorded in earnings.

For the convenience of the reader, this Amendment sets forth our Original Filing in its entirety, as amended by the changes related to the restatement. No attempt has been made in this Amendment to update other disclosures presented in our Original Filing, except as required to reflect the effects of the restatement. This Amendment does not reflect events occurring after the filing of our Original Filing, or modify or update those disclosures, including the exhibits to the Original Filing effected by subsequent events except as applicable in our financial statement footnotes subsequent event disclosures. The following sections of our Original Filing have been amended:

Part I - Item 1 - Description of Business;

Part I - Item 1A - Risk Factors;

Part II - Item 6 - Selected Financial Data;

Part II - Item 7 - Management's Discussion and Analysis or Plan of Operation; and

Part II - Item 8 - Financial Statements.

This Amendment has been signed as of a current date and all certifications of our Chief Executive Officer and Chief Financial Officer are given as of a current date. Accordingly, this Amendment should be read in conjunction with our filings made with the Securities and Exchange Commission subsequent to the filing of the Original Filing, including any amendments to those filings.

**PART I**

**Item 1. Description of Business**

**General Overview**

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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 and infectious diseases. 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 lead to development of drugs that we believe offer more effective treatment options with fewer side effects than currently approved products. A patent estate including 202 patents (foreign and domestic) issued or licensed to us and 198 pending patent

applications (domestic and foreign) protects our technologies. Our lead product candidate, Resten-NG®, which is targeted at cardiovascular disease, addresses a market we believe may exceed \$3 billion worldwide.

The net loss in 2006 was \$28.7 million, or \$0.54 per share. Total expenses were \$33.1 million and revenues were \$115,291. See Item 7. Management's Discussion and Analysis or Plan of Operation and Item 8. Financial Statements.

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 (short interfering RNA) compounds. In seventeen clinical trials involving 386 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. We believe that 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 chemistry that replaces the modified backbones of competing technologies with a synthetic backbone 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. We filed an IND and conducted an exploratory clinical trial (Phase I/Ib) for Hepatitis C virus (HCV) infection. We are currently evaluating clinical sites for a continuation of our HCV studies. We are currently conducting a Phase Ib/II clinical trial for coronary artery bypass grafting in Eastern Europe. We also will be conducting a proof of concept study in boys with Duchenne Muscular Dystrophy in the U.K., in collaboration with the MDEX consortium. In addition, we are in preclinical development for antivirals for Dengue virus infection and for influenza A, including avian influenza.

This annual report includes our trademarks and registered trademarks, including NEUGENE, AVICINE, Resten-NG, Resten-CP, 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 focused on applications in cardiovascular disease and infectious disease. 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    |
|---|---------|--------------|-------------|--------------|--------------|
| <b>Cardiovascular Disease</b>             |         |              |             |              |              |
|   | NEUGENE |              |             |              | Planned *    |
| Restenosis: Resten-NG                     | Drug    | Completed    | Completed   | Completed    | (Cook Group) |
|   | NEUGENE |              |             | In-progress  |              |
| Restenosis: Resten-MP microparticles      | Drug    | Completed    | Completed   | (Cook Group) |              |
|   | NEUGENE |              |             |              |              |
| CABG: AVI-5126                            | Drug    | Completed    | In-progress | Planned      | Planned      |
| <b>Infectious Disease (Viral targets)</b> |         |              |             |              |              |
|   | NEUGENE |              |             |              |              |
| Hepatitis C: AVI-4065                     | Drug    | Completed    | In-progress |              |              |
|   | NEUGENE |              |             |              |              |
| West Nile: AVI-4020                       | Drug    | Completed    | Completed   |              |              |
|   | NEUGENE |              |             |              |              |
| Influenza A/Avian: AVI-6001               | Drug    | In-progress  |             |              |              |
|   | NEUGENE |              |             |              |              |
| SARS: AVI-4179                            | Drug    | Completed    |             |              |              |
|   | NEUGENE |              |             |              |              |
| Ebola Zaire                               | Drug    | In-progress  |             |              |              |
|   | NEUGENE |              |             |              |              |
| HIV                                       | Drug    | Planned      |             |              |              |
| <b>Cancer</b>                             |         |              |             |              |              |
|   | NEUGENE |              |             |              |              |
| Cancer: Oncomyc-NG : AVI-4126             | Drug    | Completed    | Completed   |              |              |
| <b>Drug Metabolism</b>                    |         |              |             |              |              |
|   | NEUGENE |              |             |              |              |
| Cytochrome P450: AVI-4557                 | Drug    | Completed    | Completed   | Planned      |              |
| <b>Genetic Diseases</b>                   |         |              |             |              |              |
|   | NEUGENE |              |             |              |              |
| PKD: AVI-4126                             | Drug    | Completed    | Completed   |              |              |
|   | NEUGENE |              |             |              |              |
| DMD: AVI-4658                             | Drug    | Completed    | In-progress |              |              |

\*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 \$1,500,000 for a Phase I trial, between \$600,000 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,



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costs and quantities 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. Moreover, we cannot predict whether a product will be successfully commercialized, even if regulatory approval is obtained.

**Cardiovascular Disease Program.** Resten-NG is a NEUGENE antisense drug for treating cardiovascular restenosis, i.e., 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 October 2006 Transcatheter Cardiovascular Therapeutics conference, our licensee and development partner, Cook Group, Incorporated ( Cook ) announced interim Phase II clinical trial data 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 initiated this Phase II clinical trial at three clinical centers in Germany in 2005, and, as part of our license agreement, Cook took responsibility for completion of the study and communication of results. Cook has indicated that it is planning additional clinical studies with products based on our Resten-NG platform, possibly leading to initiating the product approval process in Europe prior to initiating clinical trials in the United States.

Resten-CP is a NEUGENE antisense drug for treating coronary artery bypass grafting, i.e., the narrowing and failure of saphenous vein grafts placed around occluded coronary arteries. The molecular mechanism of vein graft failure is believed to be closely related to the restenosis process and involves the activation of the same regulatory gene. Resten-CP targets that gene in the vessel wall in a thirty minute *ex-vivo* treatment before the vein is engrafted. To enhance delivery of our drug to the target in the vessel wall in the short period of time available prior to bypass surgery, a delivery peptide, called CytoPorter, that enhances drug uptake has been attached to the NEUGENE drug.

Resten-CP has entered a human clinical trial in Eastern Europe with intended expansion into the European Union. This is a pivotal 600 patient randomized, double blind, placebo controlled trial incorporating a Phase Ib through Phase III design. The Phase Ib stage of the trial is underway and a decision on continuation into the pivotal stages (Phase II/III) of the study will be made after evaluation of the first 110 enrolled patients. An additional pivotal study in the United States may also be initiated for market approval.

**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, Influenza A virus, Dengue virus, the SARS coronavirus, and Ebola virus, as well as many of the viruses included on the Department of Homeland Security list of bioterrorism agents, including Marburg, Junin, Anthrax, and Ricin. In June 2003, we filed an IND with the FDA for our West Nile NEUGENE drug candidate, AVI-4020. 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. Due to unpredictable future demand for drugs targeting West Nile virus and the SARS coronavirus, our future efforts toward commercialization in viral diseases will focus on Hepatitis C virus and Influenza A viruses, including avian influenza (H5N1).

We filed an IND for Hepatitis C virus in September 2005 and have ongoing exploratory Phase I/Ib clinical studies. Based on encouraging safety and pharmacokinetic data, we plan to continue HCV clinical studies in 2007. We anticipate filing an IND for Influenza A virus infection if efficacy trials in animals now underway by collaborators support the positive data obtained in 2006 from collaborators in cell culture studies.

**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.

**Genetic 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 conducting a pilot human clinical trial in boys with Duchenne Muscular Dystrophy (DMD) in conjunction with the MDEX consortium in the United Kingdom. Boys with DMD have a mutation in the genetic information that codes for the production of a critical muscle protein (dystrophin). Our NEUGENE antisense drug, AVI-4658, targets the most frequent site of this mutation and forces the genetic machinery to skip over the mutation when processing the genetic instructions. We believe that this could result in the production of the missing dystrophin protein, which might restore or prevent deterioration of muscle function. This is the first clinical application of our Exon Skipping Pre-RNA Interference Technology (ESPRIT).

#### **Business Strategy**



Our strategy is to:

focus on near-term opportunities in the 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 plan to enter into collaborative development agreements with pharmaceutical and biotechnology companies for specific molecular targets for our NEUGENE antisense technology. We will also pursue opportunities to access intellectual property rights through license agreements or other arrangements that complement our portfolio of patents and patent applications.

We anticipate pursuing NEUGENE antisense collaborative research agreements to provide us with funding for internal programs aimed at discovering and developing antisense compounds to inhibit the production of additional molecular targets. Partners in these agreements and collaborative efforts 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, if at all. 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 and/or similar regulatory regimes outside the United States. 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.

#### *Chiron Agreement*

In January 2006, we entered into an agreement with Chiron Corporation that granted us a nonexclusive license to Chiron's patents and patent applications for research, development, and commercialization of antisense therapeutics against hepatitis C virus (HCV). Chiron scientists were the first to clone HCV, and Chiron has been granted more than 100 HCV-related patents.

The license agreement with Chiron further strengthened our patent position on our HCV antisense product candidates, which are already covered by issued U.S. patent claims. AVI's lead NEUGENE antisense compound for HCV, AVI-4065, is currently being evaluated in a dose-ranging study in chronically-infected HCV patients. In conjunction with the license agreement, AVI issued Chiron shares of AVI common stock as an initial license fee payment.

#### *Cook Group Agreement*

In March 2006, we entered into agreements with Cook Group Incorporated (Cook) for the development and commercialization of products for vascular diseases. Cook is the world's largest privately-held manufacturer of medical devices and is a leading designer, manufacturer and global distributor of minimally invasive medical device technology for diagnostic and therapeutic procedures. Pursuant to our agreements, Cook licensed NEUGENE antisense technology for down-regulating c-myc gene expression in the field of cardiovascular disease. Cook has taken over our clinical development of device-related programs for cardiovascular restenosis, including our Resten-NG drug-eluting stent (DES) program, Resten-MP microparticle delivery program, and a program for catheter delivery of Resten-NG.

Cook is expected to fully fund the development, clinical and regulatory costs of licensed programs in the U.S. and Europe leading to commercialization. This funding is expected to result in expenditures by Cook that could reach \$100 million. The license and development agreement provides for payment to AVI of a double-digit royalty on worldwide product sales by Cook and a commercialization milestone. Cook also purchased 692,003 shares of AVI common stock for \$5 million under a stock purchase agreement. Cook has taken over AVI's facilities and personnel in Colorado that were dedicated to the programs now licensed by Cook. Finally, we also entered into a supply agreement to sell Cook c-myc drugs required to support development, clinical studies, and commercialization of the licensed products.



### *Ercole Agreement*

In December 2006, we entered into a cross license and collaboration agreement with Ercole Biotech, Inc. to identify and develop drugs that direct the splicing of messenger RNA (mRNA) to treat a variety of genetic and acquired diseases. Under the terms of the agreement, each company granted the other rights under our respective patents for RNA splice altering technologies.

AVI and Ercole have each selected a set of specific gene targets and are taking the lead in investigating the potential therapeutic effects of shifting splicing of those genes. The license terms also include an exclusive license to Ercole of AVI NEUGENE antisense chemistry for the specific targets selected by Ercole.

In connection with the cross license and collaboration agreement, AVI issued Ercole shares of AVI common stock, and Ercole issued AVI shares of Ercole Series A 2 Preferred Stock.

### **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 offices. We believe that 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 clinical testing phases and into commercialization. See Drug Approval Process and Other Governmental Regulations.

In March 2007, we entered into an agreement to obtain a facility in Corvallis, Oregon, subject to certain conditions. If the acquisition is closed, we intend to conduct certain manufacturing of our products and components there in the future.

### **Marketing Strategy**



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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, if at all. 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 and, to the extent our products are distributed outside of the United States, within the regulatory framework established in other countries. 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 we believe are important to the development of our business and 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 202 patents (domestic and foreign) issued or licensed to us, and 198 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. Based on patented improvements and additional support to such core patents, however, 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 commercialization 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*



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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, limited 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*



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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*





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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*



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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 \$1,500,000 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*



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In Phase II clinical trials, controlled studies are generally 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 \$600,000 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*



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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*





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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 the FDA. The requirements for submitting an NDA are defined by and in conjunction with the FDA. These applications are comprehensive, including all information obtained from each clinical trial as well as all data pertaining to the manufacturing and testing of the product. With the implementation of the Prescription Drug Users Fee Act (PDUFA), review fees are provided at the time of NDA filing. For FY 2006, each NDA with clinical data must be accompanied by a \$767,400 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 FDA reported the estimated median review time for a New Molecular Entity (NME) was estimated to be 13.8 months, however, a priority review of a NME can and has been approved in as little as six months.

### *Marketing Approval*



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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*



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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 gene silencing 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 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 do we.

In 2006, Genta received significant negative press when its antisense drugs 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 Genta, we believe that none of the clinical experiences of Genta 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

We expensed \$25,345,588, \$17,117,750 and \$20,738,725 on research and development activities during the years ended December 31, 2006, 2005 and 2004, 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, 2006, we had 117 employees, 23 of whom hold advanced degrees. One hundred-three employees are engaged directly in research and development activities, and fourteen 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**

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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, our proxy statement 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](http://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 1A. Risk Factors**

**Risks Affecting Future Operating Results**

The following factors should be considered in evaluating our business and prospects for the future. If risks described 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 research and development and may not be determined to be safe or effective.*

We are only in the early stages of research and clinical development with respect to 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 potential products are in the pre-clinical or clinical stages of research and 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. 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 \$18.2 million in 2005 and \$28.7 million in 2006. As of December 31, 2006, our accumulated deficit was \$199.2 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 common stock. 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 stock or debt or other arrangements. We may not be

able to 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 these agencies require new pharmaceutical products to undergo lengthy and detailed clinical testing procedures and other costly and time-consuming compliance procedures. 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.

The financial and technical resources and production and marketing capabilities of many of these entities, some of which are our competitors, exceed our resources and capabilities. 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.*



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We have engaged solely in the research and 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.*





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While we believe that we can produce materials for clinical trials and produce products for human use at our existing and potentially expanded 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 reviewed sites for 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 production 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 202 patents (domestic and foreign) issued or licensed to us, and 198 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 patents from other parties for certain complementary technologies.

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

We cannot assure you that our pending patent applications will result in patents being issued in the United States or foreign countries. In addition, the patents that have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours that 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 are important to our success. The development, improvement and marketing of many of our key therapeutic products are or will be dependent in large part on the efforts of our strategic partners. 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 become 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 may be subject to product liability lawsuits and our insurance may not be adequate to cover damages.*

We believe we carry adequate insurance for our current product development research. 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.*

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In addition to obtaining regulatory approval, the successful commercialization of our products will depend on the ability to obtain reimbursement for the cost of the product and treatment from the consumers of or third-party payors for such products. 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 or our marketing partner's ability to sell our products and may have a material adverse effect on our financial results from 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 these and later pharmaceutical trials and to market our products. 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 partnerships or other relationships, which could impede our ability to bring our products to market. Any such partnerships, if entered into at all, may be on less than 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 these chemicals, such as methylene chloride, isopropyl alcohol, ethyl acetate and acetone, 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 to date. 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.

*If Our stock price is volatile, it will have an impact on our warrant liability and the non-cash gain (loss) recorded to our statement of operations.*

We have warrants that are classified as liabilities and are marked to market based on our common stock price. While these warrants do not have any cash settlement features, increases and decreases in our common stock price will continue to have an impact in our statement of operations. Generally, an increase in our common stock price will result in an increase in our liability and related expense, while a decrease in our common stock price will result in a decrease in our liability and related expense.

### **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, preferential 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 that 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 that 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. 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, strategic partners, 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.

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*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 53,182,841 shares of common stock as of December 31, 2006 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 5,571,470 shares of common stock of which 3,660,483 shares were exercisable at December 31, 2006. The options



outstanding have exercise prices between \$1.76 and \$8.13 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 8,508,103 shares of common stock at December 31, 2006 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 1,710,934 shares of common stock at December 31, 2006 under our stock option plans, which also will be fully saleable when issued except to the extent limited under Rule 144 for resales by our officers and directors;

We are authorized to sell up to 248,144 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate; and

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 1B. Unresolved SEC Comments**

None.

**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 2020. 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. In March 2007, we entered into an agreement to obtain a facility in Corvallis, Oregon, subject to certain conditions. If the acquisition is closed, we intend to conduct certain manufacturing of our products and components there in the future. We believe that our facilities are suitable and adequate for our present operational requirements for the foreseeable future.

**Item 3. Legal Proceedings**

As of March 16, 2007, 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, 2006.

**PART II****Item 5. Market for Common Equity and Related Stockholder Matters**

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

| <b>2005</b>                |    | <b>High</b> |    | <b>Low</b> |
|----------------------------|----|-------------|----|------------|
| Quarter 1                  | \$ | 4.14        | \$ | 2.00       |
| Quarter 2                  |    | 2.95        |    | 2.22       |
| Quarter 3                  |    | 2.64        |    | 2.11       |
| Quarter 4                  |    | 4.03        |    | 2.59       |
| <b>2006</b>                |    |             |    |            |
| Quarter 1                  | \$ | 8.65        | \$ | 3.39       |
| Quarter 2                  |    | 7.55        |    | 3.71       |
| Quarter 3                  |    | 4.28        |    | 2.58       |
| Quarter 4                  |    | 4.82        |    | 3.18       |
| <b>2007</b>                |    |             |    |            |
| Quarter 1 to March 9, 2007 | \$ | 3.20        | \$ | 2.46       |

The number of shareholders of record and approximate number of beneficial holders on March 9, 2007 was 600 and 15,800 respectively. There were no cash dividends declared or paid in fiscal years 2006 or 2005. We do not anticipate declaring such dividends in the foreseeable future.

All securities sold during 2006 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 2006, we issued 41,663 shares of common stock to employees at approximately \$2.95 per share for \$123,005, under our Employee Stock Purchase Plan. During 2005, we issued 60,854 shares of common stock to employees at approximately \$1.82 per share for \$110,730, under our Employee Stock Purchase Plan.

During 2006, we granted 1,172,700 stock options to purchase shares of common stock at approximately \$7.13 per share, under our 2002 Equity Incentive Plan. During 2005, we granted 1,245,937 stock options to purchase shares of common stock at approximately \$2.47 per share, under our 2002 Equity Incentive Plan.



## Equity Compensation Plan Information

| Plan category  | Number of securities to be issued upon exercise of outstanding options, warrants and rights<br>(a) | Weighted-average exercise price of outstanding options, warrants and rights<br>(b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))<br>(c) |
|--|--|--|--|
| Equity compensation plans approved by security holders     | 4,167,981  | \$ 5.36  | 1,959,078  |
| Equity compensation plans not approved by security holders | -0-  |  | -0-  |
| <b>Total</b>   | 4,167,981  | \$ 5.36  | 1,959,078  |

The number of securities remaining available for future issuance under equity compensation plans includes shares from the Company's 2002 Equity Incentive Plan (the "2002 Plan"). The number of shares reserved for issuance is increased by an automatic annual share increase pursuant to which the number of shares available for issuance under the 2002 Plan automatically increases on the first trading day of each fiscal year (the "First Trading Day"), beginning with the 2003 fiscal year and continuing through the fiscal year 2011, by an amount equal to two percent (2%) of the total number of shares outstanding on the last trading day of the immediately preceding fiscal year; such increases being subject to the limitation in the next sentence. The 2002 Plan provides that, following any such adjustment, the number of then outstanding options under the Company's stock option plans and stock purchase plans, together with options in the reserve then available for future grants under the Company's stock option plans, will not exceed twenty percent (20%) of the then outstanding voting shares of capital stock of the Company, and all the actually outstanding stock options under the Company's stock option plans, together with all shares in the reserve then available for future grants under the Company's stock option and stock purchase plans. This automatic share increase feature is designed to assure that a sufficient reserve of Common Stock remains available for the duration of the 2002 Plan to attract and retain the services of key individuals essential to the Company's long-term growth and success. This feature is also designed to eliminate the uncertainty inherent in seeking an individual increase to the reserve each year as to what number of shares will be available in the reserve for option grants. Creating a certain rate of growth under the 2002 Plan assists the Company as it makes strategic personnel decisions in an effort to expand its growth, as the Company will know the approximate number of shares that will become available for issuance under the 2002 Plan. At the same time, the Company has attempted to minimize the dilutive effect that the issuance of Common Stock upon the exercise of options can have on stockholders' percentage of ownership in the Company by adopting

only a 2% growth rate for the 2002 Plan. This rate, while it provides room for growth in the 2002 Plan, is a rate which the Company believes it can reasonably sustain, minimizing the risk to stockholders that the option reserve grows faster than the Company itself. The twenty percent (20%) limitation discussed above further protects shareholders by capping the size of the 2002 Plan in relation to the Company's other securities.

## **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, |                    |                    |                    |               |
|---|-------------------------|--------------------|--------------------|--------------------|---------------|
|   | 2006<br>(Restated)      | 2005<br>(Restated) | 2004<br>(Restated) | 2003<br>(Restated) | 2002          |
| <b>Operations data:</b>   |                         |                    |                    |                    |               |
| Revenues  | \$ 115,291              | \$ 4,783,760       | \$ 430,461         | \$ 969,866         | \$ 836,784    |
| Research and development  | 25,345,588              | 17,117,750         | 20,738,725         | 15,284,396         | 22,413,892    |
| General and administrative  | 7,752,752               | 5,182,369          | 4,735,731          | 4,558,948          | 3,763,941     |
| Interest income, net  | 1,910,037               | 840,495            | 266,301            | 491,098            | 460,258       |
| Gain (loss) on warrant liability                                  | 2,385,502               | (1,530,021)        | 2,840,851          | 835,094            |               |
| 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)   |
| Net loss  | (28,687,510)            | (18,205,885)       | (21,936,843)       | (13,781,534)       | (29,359,051)  |
| Net loss per share - basic and diluted                            | (0.54)                  | (0.41)             | (0.61)             | (0.46)             | (1.14)        |
| <b>Balance sheet data:</b>  |                         |                    |                    |                    |               |
| Cash and investments  | \$ 33,152,132           | \$ 47,051,082      | \$ 19,515,316      | \$ 37,599,136      | \$ 19,293,645 |
| Working capital   | 25,596,492              | 38,327,343         | 17,948,793         | 34,639,526         | 15,279,854    |
| Total assets  | 40,862,746              | 56,407,982         | 28,518,631         | 47,145,023         | 28,603,757    |
| Shareholders' equity  | 32,519,325              | 46,081,931         | 24,456,708         | 39,685,852         | 23,481,623    |

## **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,
- results of our research and development efforts, 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 herein and 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 occur. 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, license fees, grants and research contracts, we have had no material revenues from the sale of products or other sources and, other than from government grants and research contracts, 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, 2006, our accumulated deficit was \$199,189,830.

## Results of Operations

*Year Ended December 31, 2006 Compared with Year Ended December 31, 2005.* Revenues, from license fees, grants and research contracts, decreased from \$4,783,760 in 2005 to \$115,291 in 2006, due to decreases in research contract revenues. Revenues for 2005 were primarily due to the recognition of \$4,600,000 in research contract revenue from government funding for work performed on viral disease research projects. Operating expenses increased from \$22,300,119 in 2005 to \$33,098,340 in 2006 due to increases in research and development, which increased from \$17,117,750 in 2005 to \$25,345,588 in 2006, and increases in general and administrative costs, which increased from \$5,182,369 in 2005 to \$7,752,752 in 2006. This research and development increase for 2006 was due primarily to increases in employee costs of approximately \$3,100,000, of which approximately \$2,400,000 was recognized in accordance with SFAS 123R and approximately \$430,000 related to the acceleration of the vesting of certain stock options. See Note 2 to Notes to Financial Statements. Also, approximately \$2,200,000 of this increase in 2006 was due to increases in clinical expenses from the expansion of clinical programs in hepatitis C and coronary artery bypass grafting. Additionally, approximately \$1,700,000 of this increase in 2006 was due to contracting costs for the production of GMP subunits, which are used by the Company to manufacture compounds for future clinical trials. The increase in 2006 for research and development included \$675,000 in AVI common stock issued to Ercole Biotech, Inc. under the terms of a stock purchase agreement and \$500,000 in AVI common stock issued to Chiron Corporation as the first milestone payment due under a license agreement granting AVI a nonexclusive license to Chiron's patents and patent applications for the research, development, and commercialization of antisense therapeutics against hepatitis C virus. See Note 5 to Notes to Financial Statements. The general and administrative increase for 2006 was due primarily to increases in employee costs of approximately \$2,400,000, of which approximately \$1,600,000 was recognized in accordance with SFAS 123R and approximately \$400,000 related to the acceleration of the vesting of certain stock options. Net interest income increased from \$840,495 in 2005 to \$1,910,037 in 2006 due to increases in average cash, cash equivalents and short-term securities balances and increases in average interest rates of the Company's interest earning investments. Gain (loss) on warrant liability was a gain of \$2,385,502 in 2006 compared to a loss of \$1,530,021 in 2005. The gain (loss) on warrant liability is a function of the Company's stock price and fluctuates as the market price of the Company's stock fluctuates.

The Company expects to incur comparable stock-based compensation expense in 2007.

*Year Ended December 31, 2005 Compared with Year Ended December 31, 2004.* Revenues, from license fees, grants and research contracts, increased from \$430,461 in 2004 to \$4,783,760 in 2005, primarily due to increases in research contract revenue, partially offset by decreases in grants revenues. In 2005, the Company recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. Operating expenses decreased from \$25,474,456 in 2004 to \$22,300,119 in 2005 due to decreases in research and development, which decreased from \$20,738,725 in 2004 to \$17,117,750 in 2005, which were partially offset by increases in general and administrative costs, which increased from \$4,735,731 in 2004 to \$5,182,369 in 2005. Approximately \$4.8 million of the research and development decrease was due to lower contracting costs for the production of GMP subunits. These research and development decreases were partially offset by increases in clinical trial expenses, lab supplies, employee costs, and clinical trial insurance. Approximately \$530,000 of this general and administrative increase was due to additional clinical and business development staff hired after the first quarter of 2004. These general and administrative increases were partially offset by decreases in accounting and legal expenses. Net interest income increased from \$266,301



in 2004 to \$840,495 in 2005 due to increases in average cash, cash equivalents and short-term securities balances and increases in average interest rates of the Company's interest earning investments. Gain (loss) on warrant liability decreased to a loss of \$1,530,021 in 2005 from a gain of \$2,840,851 in 2004. The gain (loss) on warrant liability is a function of the Company's stock price and fluctuates as the market price of the Company's stock fluctuates.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through sales of common stock and other forms of equity totaling \$196,270,726, from grants and contract research funding of \$9,980,819 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 2007, we expect our expenditures for operations, including our collaborative efforts, and our GMP facilities to be approximately \$25 to \$28 million. This cost could increase if we undertake additional collaborative efforts. However, if need be in 2007, we believe we can reduce our expenditures because a significant amount of our costs are variable. Those estimated expenditures include amounts necessary to fulfill our obligations under our various collaborative, research and licensing agreements during 2007.

Because of the cost (up to \$1.7 billion) and timeframe (up to 15 years) generally associated with developing a potential drug or pharmaceutical product to the point of FDA approval for human use, our business strategy is to develop our products up to initial Phase III human clinical trials and then look for third parties to fund further development of the product and to market the product through strategic partnerships, license agreements or other relationships. We also look for collaborative and other efforts, such as our relationship with Cook Group, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We believe that this strategy will reduce the potential costs we would otherwise incur in developing a product and bringing it to market. 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 the timing of securing one or more partners to develop and market a potential drug.

Because of the various factors noted above and the expectation that, until we establish revenue sources, we will license or jointly develop our prospective products to or 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.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that we will receive up to \$9.8 million. Under this allocation, our NEUGENE technology will be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company continues to work with the government to define the scope of the work to be performed on these programs. This additional funding has not been received and has not been reflected in the financial statements.

Our cash, cash equivalents and short-term securities were \$33,152,132 at December 31, 2006, compared with \$47,051,082 at December 31, 2005. The decrease of \$13,898,950 was due primarily to \$20,613,369 used in operations and \$1,453,889 used for purchases of property and equipment and patent related costs, offset by the receipt of \$4,955,623 in net proceeds from a stock purchase agreement with Cook Group Inc. ( Cook ) and \$3,207,235 from the exercise of warrants and options and sales under the Company's employee stock purchase plan. The Company sold 692,003 shares of common stock at \$7.23 per share to Cook, as described in Note 4.

We do not expect any material revenues in 2007 from our business activities. We expect that our cash requirements for the balance of calendar 2007 will be satisfied by existing cash resources. To fund our operations beyond 2007, 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. In 2006, these expenses totaled \$1,333,000 for operating leases and \$125,000 for royalty payments.

A summary of our contractual commitments and obligations as of December 31, 2006 is as follows:

| Contractual<br>Obligation | Payments Due By Period |              |                  |                  |                    |
|---------------------------|------------------------|--------------|------------------|------------------|--------------------|
|                           | Total                  | 2007         | 2008 and<br>2009 | 2010 and<br>2011 | 2012 and<br>beyond |
| Operating leases          | \$ 19,245,000          | \$ 1,170,000 | \$ 2,407,000     | \$ 2,441,000     | \$ 13,227,000      |
| Royalty payments          | 2,005,000              | 125,000      | 250,000          | 250,000          | 1,380,000          |
|                           | \$ 21,250,000          | \$ 1,295,000 | \$ 2,657,000     | \$ 2,691,000     | \$ 14,607,000      |

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term. These requirements include the progress of our research and development programs and 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 stock-based compensation, 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 classified as available-for-sale under SFAS 115 and recorded at fair value in 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 evidence indicating that 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. In 2005, we recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. 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. 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 of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet. Based on this analysis, we did not recognize an impairment on long-lived assets during the year ended December 31, 2006. If circumstances related to our long-lived assets change, we may record an impairment charge in the future.

#### ***Stock-based Compensation Expense***

Effective January 1, 2006, the Company adopted SFAS 123R using the modified-prospective application. Under the modified prospective application, stock compensation cost recognized beginning January 1, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted on or subsequent to January 1, 2006, based on the



grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods have not been restated.

Stock-based compensation costs are generally based on the fair value calculated from the Black-Scholes option-pricing model on the date of grant for stock options and on the date of enrollment for the Plan. The fair value of stock grants are amortized as compensation expense on a straight-line basis over the vesting period of the grants. Compensation expense recognized is shown in the operating activities section of the statements of cash flows. Stock options granted to employees are service-based and typically vest over four years.

The fair market values of stock options granted were measured on the date of grant using the Black-Scholes option-pricing model, with weighted average assumptions for the risk-free interest rate, expected dividend yield, expected lives, and expected volatility. As part of the requirements of SFAS 123R, the Company is required to estimate potential forfeiture of stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up in the period of change and will also impact the amount of stock compensation expense to be recognized in future periods.

The assumptions used in calculating the fair value of stock-based compensation expense represent management's best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and the Company uses different assumptions, its stock-based compensation expense could be materially different in the future. In addition, the Company is required to estimate the expected forfeiture rate and recognize expense only for those shares expected to vest. If the Company's actual forfeiture rate is materially different from its estimates, the stock-based compensation expense could be significantly different from what it has recorded in the current period. See Note 2 to Notes to Financial Statements for a further discussion of stock-based compensation.

**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**

*(a) Disclosure Controls and Procedures*

Disclosure controls and procedures are the controls and other procedures that are designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Securities Exchange Act of 1934, as amended (the Exchange Act), is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, among other processes, controls and procedures designed to ensure that information required to be disclosed in the reports that the Company files or submits under the Exchange Act is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

The Company carried out an evaluation, under the supervision and with the participation of management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures as of December 31, 2006 pursuant to Exchange Act Rule 13a-15. As a result of the material weakness described below in Management's Annual Report on Internal Control over Financial Reporting (Restated), the Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were not effective as of December 31, 2006.

*(b) Management's Annual Report on Internal Control over Financial Reporting ( Restated)*

Management is responsible for establishing and maintaining adequate internal control over financial reporting at the Company. The Company's internal control over financial reporting is a process designed under the supervision of the Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting 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.

With the participation of the Chief Executive Officer and the Chief Financial Officer, management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2006, based on

the framework and criteria established in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In the Company's Annual Report on Form 10-K for the year ended December 31, 2006, filed on March 16, 2007, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2006. However, management subsequently determined that the Company needed to restate certain of its previously issued financial statements. As a result of such financial statement restatement, management reassessed the Company's internal control over financial reporting using the COSO criteria and identified the following material weakness in internal control over financial reporting as of December 31, 2006: Management lacked adequate technical expertise to ensure the proper application, at inception, of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* related to certain stock warrants. As a result, the Company failed to identify that certain warrants should be liability classified. This material weakness resulted in a misstatement requiring the restatement of the Company's financial statements for the years ended December 31, 2006, 2005 and 2004 and for each of the interim periods in 2006 and 2005.

As a result of this material weakness, management has revised its earlier assessment and has concluded that the Company's internal control over financial reporting was not effective as of December 31, 2006.

KPMG LLP, the Company's independent auditor, has issued an audit report on management's revised assessment of internal control over financial reporting as of December 31, 2006.

*(c) Changes in Internal Control Over Financial Reporting*

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 of 2006 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

*(d) Remediation of Material Weakness*

Subsequent to December 31, 2006, the Company has adopted additional controls wherein if the issuance of warrants or other derivative financial instruments is contemplated, legal counsel and an independent accountant will be consulted as to the financial statement impact that the issuance of such warrants or other derivative financial instruments may have, prior to issuance.

Chief Executive Officer

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

Portland, Oregon

November 1, 2007

***Report of Independent Registered Public Accounting Firm***

The Board of Directors and Shareholders

AVI BioPharma, Inc.:

We have audited management's restated assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting (Restated)(Item 9A(b)), that AVI BioPharma, Inc. (an Oregon Corporation in the development stage)(the Company) did not maintain effective internal control over financial reporting as of December 31, 2006, because of the effect of the material weakness identified in management's restated assessment, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management of the Company 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 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.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weakness has been identified and included in management's restated assessment as of December 31, 2006: The Company lacked adequate technical expertise to ensure the proper application, at inception, of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* related to its stock warrants. As a result, the Company failed to identify that the warrants required settlement in registered shares and therefore should be liability classified. This material weakness resulted in a material misstatement requiring the restatement of the Company's financial statements for the years ended

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December 31, 2006, 2005 and 2004 and for each of the interim periods in 2006 and 2005.

As stated in the fourth and fifth paragraphs of Management's Annual Report on Internal Control over Financial Reporting (Restated), management's assessment of the effectiveness of the Company's internal control over financial reporting as of December 31, 2006 has been restated to reflect the impact of the aforementioned material weakness in internal control over financial reporting

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the restated balance sheets of AVI BioPharma, Inc. as of December 31, 2006 and 2005, and the related restated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from July 22, 1980 (inception) through December 31, 2006. 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 comprehensive income (loss), 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. The aforementioned material weakness was considered in determining the nature, timing and extent of audit tests applied in the audit of the 2006 financial statements (restated), and this report does not affect our report dated March 16, 2007, except as to the restatement discussed in Note 3, which is as of November 1, 2007, which expressed an unqualified opinion on those financial statements.

In our opinion, management's restated assessment that the Company did not maintain effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in *Internal Control - Integrated Framework* issued by COSO. Also, in our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, the Company did not maintain effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by COSO.

Portland, Oregon  
March 16, 2007, except as to the fourth  
and fifth paragraphs of Management's  
Annual Report on the Internal Control  
over Financial Reporting (Restated),  
which are as of November 1, 2007



**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 2007 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. Compensation Discussion and Analysis**

The information required by this item is included in our definitive proxy statement for our 2007 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 2007 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 2007 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 2007 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:

Report of KPMG LLP, Independent Registered Public Accounting Firm

Report of Arthur Andersen, Independent Auditors

Balance Sheets

Statements of Operations

Statements of Shareholders' Equity and Comprehensive Income (Loss)

Statements of Cash Flows

Notes to Financial Statements

**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.

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

**(b) Exhibits**

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

| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 1.1                | Underwriting Agreement dated November 14, 2005 (15)   |
| 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)  |
| 4.7                | Warrant to purchase 485,290 shares of the Company's common stock dated November 14, 2005 (16)   |
| 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) |

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- 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 Lease Agreement with Spieker Partners, LP dated May 8, 2001. (9)
- 10.32\* Investment Agreement dated May 22, 2001 between the Company and Medtronic Asset Management, Inc. (9)
- 10.33 Warrant dated June 20, 2001 issued to Medtronic Asset Management, Inc. (9)
- 10.34 Registration Rights Agreement dated June 20, 2001 between the Company and Medtronic Asset Management, Inc. (9)
- 10.35\* License and Development Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
- 10.36\* Supply Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)
- 10.37 Securities Purchase Agreement dated March 25, 2002 between the Company and certain purchasers ( SPA ) (10)
- 10.38 Form of Warrant issued by the Company to certain purchasers under the SPA (10)
- 10.39 Registration Rights Agreement dated March 25, 2002 between the Company and certain purchasers (10)
- 10.40 2002 Equity Incentive Plan (11)
- 10.41 Securities Purchase Agreement dated January 19, 2005 between the Company and certain purchasers ( SPA ). (12)
- 10.42 Form of Purchase Warrant issued by the Company to certain purchasers under the SPA. (12)
- 10.43 Amendment to employment agreement of Denis R. Burger, Ph.D (14)
- 10.44 Amendment to employment agreement of Alan P. Timmins (14)
- 10.45 Amendment to employment agreement of Patrick L. Iversen, Ph.D (14)
- 10.46 Amendment to employment agreement of Dwight D. Weller, Ph.D (14)
- 10.47 Amendment to employment agreement of Peter D. O Hanley, M.D., Ph.D (14)
- 10.48 Amendment to employment agreement of Mark M. Webber (14)
- 10.49 Securities Purchase Agreement dated November 14, 2005 between the Company and certain purchasers (16)
- 10.50\* Supply Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)
- 10.51\* License and Development Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)

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|        |   |
|--------|---|
| 10.52* | Investment Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)   |
| 10.53* | License Agreement dated January 26, 2006 by and between with Chiron Corporation and AVI BioPharma, Inc. (18)  |
| 10.54  | Stock Purchase Agreement dated January 26, 2006 by and between with Chiron Corporation and AVI BioPharma, Inc. (18)   |
| 10.55  | Second Lease Extension and Modification Agreement dated January 24, 2006 by and between Research Way Investments and AVI BioPharma, Inc. (19)                         |
| 10.56* | Collaboration and License Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (filed herewith)                            |
| 10.57  | Series A-2 Preferred Stock and Common Stock Purchase Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (filed herewith) |
| 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.                                 |

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(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.
- (14) Incorporated by reference to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on February 28, 2005.
- (15) Incorporated by reference to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on November 21, 2005.
- (16) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and filed with the Securities and Exchange Commission on March 16, 2006.
- (17) Incorporated by reference to Exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on April 11, 2006 (Commission Registration No. 333-133211).
- (18) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006, and filed with the Securities and Exchange Commission on May 10, 2006.

(19) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2006, and filed with the Securities and Exchange Commission on August 9, 2006.

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

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

\* 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 (\*).

Materials in the exhibit marked with a " " were filed in the originally filed 10-k.



**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: November 2, 2007

AVI BIOPHARMA, INC.

By: /s/ K. Michael Forrest  
K. Michael Forrest  
Interim 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, 2007:

| <b>Signature</b>                               | <b>Title</b>  |
|--|---|
| /s/ K. Michael Forrest<br>K. Michael Forrest   | Interim Chief Executive Officer<br>(Principal Executive Officer)                                      |
| /s/ ALAN P. TIMMINS<br>Alan P. Timmins         | President, Chief Operating Officer  |
| /s/ MARK M. WEBBER<br>Mark M. Webber           | Chief Financial Officer and Chief Information Officer<br>(Principal Financial and Accounting Officer) |
| /s/ JACK L. BOWMAN<br>Jack L. Bowman           | Director  |
| /s/ MICHAEL D. CASEY<br>Michael D. Casey       | Director  |
| /s/ JOHN W. FARA, Ph.D.<br>John W. Fara, Ph.D. | Director  |
| /s/ K. MICHAEL FORREST<br>K. Michael Forrest   | Director  |
| /s/ GIL PRICE, M.D.<br>Gil Price, M.D.         | Director  |
| /s/ JOHN C. HODGMAN<br>John C. Hodgman         | Director  |
| /s/ WILLIAM GOOLSBEE<br>William Goolsbee       | Director  |

**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders

AVI BioPharma, Inc.:

We have audited the accompanying balance sheets of AVI BioPharma, Inc. (an Oregon corporation in the development stage) as of December 31, 2006 and 2005, and the related statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006 and for the period from July 22, 1980 (inception) through December 31, 2006. 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 comprehensive income (loss), 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, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006 and for the period from July 22, 1980 (inception) through December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the financial statements, effective January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*.

As discussed in Note 3 to the financial statements, the Company has restated its balance sheets as of December 31, 2006 and December 31, 2005 and the related statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006.

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, 2006, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 16, 2007, except as to the fourth and fifth paragraphs of Management's Annual Report on Internal Control Over Financial Reporting (Restated), which are as of November 1, 2007, expressed an unqualified opinion on management's restated assessment of, and an adverse opinion on the effective operation of, internal control over financial reporting as of December 31, 2006.

**Portland, Oregon**

**March 16, 2007, except for Note 3,**

**which is as of November 1, 2007**

F-1

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***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,         |                      |
|--|----------------------|----------------------|
|  | 2006<br>(Restated)   | 2005<br>(Restated)   |
| <b>Assets</b>  |                      |                      |
| Current Assets:  |                      |                      |
| Cash and cash equivalents  | \$ 20,159,201        | \$ 34,597,734        |
| Short-term securities available-for-sale   | 12,992,931           | 12,453,348           |
| Accounts receivable  | 51,498               | 1,236,446            |
| Other current assets   | 736,283              | 365,866              |
| <b>Total Current Assets</b>  | <b>33,939,913</b>    | <b>48,653,394</b>    |
| Property and Equipment, net of accumulated depreciation and amortization of \$10,174,712 and \$8,396,923         | 4,329,583            | 5,599,269            |
| Patent Costs, net of accumulated amortization of \$1,496,699 and \$1,270,881                                     | 2,558,541            | 2,117,710            |
| Other Assets   | 34,709               | 37,609               |
| <b>Total Assets</b>  | <b>\$ 40,862,746</b> | <b>\$ 56,407,982</b> |
| <b>Liabilities and Shareholders Equity</b>   |                      |                      |
| Current Liabilities:   |                      |                      |
| Accounts payable   | \$ 1,401,584         | \$ 1,861,604         |
| Accrued employee compensation  | 1,371,353            | 886,369              |
| Warrant liability  | 5,192,576            | 7,578,078            |
| Other liabilities  | 377,908              |                      |
| <b>Total Current Liabilities</b>   | <b>8,343,421</b>     | <b>10,326,051</b>    |
| 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; 53,182,841 and 51,182,751 issued and outstanding | 5,318                | 5,118                |
| Additional paid-in capital   | 231,685,419          | 216,566,165          |
| Accumulated other comprehensive income   | 18,418               | 12,968               |
| Deficit accumulated during the development stage   | (199,189,830)        | (170,502,320)        |
| <b>Total Shareholders Equity</b>   | <b>32,519,325</b>    | <b>46,081,931</b>    |
| <b>Total Liabilities and Shareholders Equity</b>   | <b>\$ 40,862,746</b> | <b>\$ 56,407,982</b> |

See accompanying notes to financial statements.

## AVI BIOPHARMA, INC.

(A Development Stage Company)

## STATEMENTS OF OPERATIONS

|   | 2006<br>(Restated) | Year ended December 31,<br>2005<br>(Restated) | 2004<br>(Restated) | July 22, 1980<br>(Inception) through<br>December 31, 2006<br>(Restated) |
|---|--------------------|---|--------------------|---|
| Revenues from license fees, grants and research contracts   | \$ 115,291         | \$ 4,783,760                                  | \$ 430,461         | \$ 9,980,819  |
| Operating expenses:   |                    |   |                    |   |
| Research and development  | 25,345,588         | 17,117,750                                    | 20,738,725         | 147,647,215   |
| General and administrative  | 7,752,752          | 5,182,369                                     | 4,735,731          | 40,820,528  |
| Acquired in-process research and development  |                    |   |                    | 19,545,028  |
|   | 33,098,340         | 22,300,119                                    | 25,474,456         | 208,012,771   |
| Other income (loss):  |                    |   |                    |   |
| Interest income, net  | 1,910,037          | 840,495                                       | 266,301            | 7,449,542   |
| Gain (loss) on warrant liability  | 2,385,502          | (1,530,021)                                   | 2,840,851          | 4,531,426   |
| Realized gain on sale of short-term securities available-for-sale                                   |                    |   |                    | 3,862,502   |
| Write-down of short-term securities available-for-sale  |                    |   |                    | (17,001,348)  |
|   | 4,295,539          | (689,526)                                     | 3,107,152          | (1,157,878)   |
| Net loss  | \$ (28,687,510)    | \$ (18,205,885)                               | \$ (21,936,843)    | \$ (199,189,830)  |
| Net loss per share - basic and diluted  | \$ (0.54)          | \$ (0.41)                                     | \$ (0.61)          |   |
| Weighted average number of common shares outstanding for computing basic and diluted loss per share | 52,660,711         | 44,655,008                                    | 35,994,976         |   |

See accompanying notes to financial statements.

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AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF SHAREHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)

|   | Partnership<br>Units | Common Stock<br>Shares | Common Stock<br>Amount | Additional<br>Paid-In<br>Capital<br>(Restated) | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Deficit<br>Accumulated<br>During the<br>Development<br>Stage<br>(Restated) | Total<br>Shareholders<br>Equity<br>(Restated) |
|---|----------------------|------------------------|------------------------|--|---|--|---|
| BALANCE AT JULY 22, 1980<br>(Inception)   |                      |                        | \$                     | \$   | \$  | \$   | \$  |
| Issuance of partnership units, warrants and<br>common stock                                       | 3,615                | 8,272,916              | 828                    | 33,732,654                                     |   |  | 33,733,482                                    |
| Compensation expense related to issuance<br>of warrants for common stock and<br>partnership units |                      |                        |                        | 537,353  |   |  | 537,353                                       |
| Exercise of warrants for partnership units<br>and common stock                                    | 42                   | 1,530,858              | 152                    | 1,809,165                                      |   |  | 1,809,317                                     |
| Exercise of options for common stock  |                      | 730,547                | 73                     | 3,153,387                                      |   |  | 3,153,460                                     |
| Issuance of common stock for ESPP   |                      | 99,421                 | 10                     | 481,484  |   |  | 481,494                                       |
| Issuance of common stock and warrants<br>for cash and securities, net of offering<br>costs        |                      | 19,928,020             | 1,993                  | 112,289,336                                    |   |  | 112,291,329                                   |
| Issuance of common stock and warrants<br>for the acquisition of ImmunoTherapy<br>Corporation      |                      | 2,132,592              | 213                    | 17,167,199                                     |   |  | 17,167,412                                    |
| Issuance of common stock and warrants<br>for services   |                      | 192,848                | 20                     | 919,243  |   |  | 919,263                                       |
| Compensation expense related to issuance<br>of options for common stock                           |                      |                        |                        | 619,714  |   |  | 619,714                                       |
| Conversion of debt into common stock and<br>partnership units                                     | 9                    | 9,634                  | 1                      | 87,859   |   |  | 87,860  |
| Issuance of common stock in exchange for<br>partnership units                                     | (1,810)              | 1,632,950              | 163                    | (163)  |   |  |   |
| Withdrawal of partnership net assets upon<br>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<br>available-for-sale   |                      |                        |                        |  | 17,001,348  |  | 17,001,348                                    |
| Realized gain on sale of short-term<br>securities available-for-sale                              |                      |                        |                        |  | (3,765,752)   |  | (3,765,752)                                   |
| Unrealized loss on short-term securities<br>available-for-sale                                    |                      |                        |                        |  | (13,525,399)  |  | (13,525,399)                                  |
| Net loss  |                      |                        |                        |  |   | (130,359,592)  | (130,359,592)                                 |
| Comprehensive loss  |                      |                        |                        |  |   |  | (130,649,395)                                 |
| BALANCE AT DECEMBER 31, 2003  |                      | 34,465,737             | 3,447                  | 170,331,800                                    | (289,803)   | (130,359,592)  | 39,685,852                                    |
| 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<br>of options for common stock                           |                      |                        |                        | 421,635  |   |  | 421,635                                       |
| Issuance of common stock for cash, net of<br>offering costs                                       |                      | 1,623,377              | 162                    | 6,019,196                                      |   |  | 6,019,358                                     |
| Comprehensive income (loss):  |                      |                        |                        |  |   |  |   |
| Unrealized gain on short-term securities<br>available-for-sale, net                               |                      |                        |                        |  | 157,162   |  | 157,162                                       |
| Net loss  |                      |                        |                        |  |   | (21,936,843)   | (21,936,843)                                  |
| Comprehensive loss  |                      |                        |                        |  |   |  | (21,779,681)                                  |
| BALANCE AT DECEMBER 31, 2004  |                      | 36,143,153             | 3,614                  | 176,882,170                                    | (132,641)   | (152,296,435)  | 24,456,708                                    |

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|   |            |          |                |               |
|---|------------|----------|----------------|---------------|
| Exercise of options for common stock                                    | 37,029     | 4        | 94,950         | 94,954        |
| Issuance of common stock for ESPP                                       | 60,854     | 6        | 110,724        | 110,730       |
| Compensation expense related to issuance of options for common stock    |            |          | 394,225        | 394,225       |
| Issuance of common stock for cash, net of offering costs                | 14,941,715 | 1,494    | 39,084,096     | 39,085,590    |
| Comprehensive income (loss):  |            |          |                |               |
| Unrealized gain on short-term securities available-for-sale, net        |            |          | 145,609        | 145,609       |
| Net loss  |            |          | (18,205,885)   | (18,205,885)  |
| Comprehensive loss  |            |          |                | (18,060,276)  |
| BALANCE AT DECEMBER 31, 2005  | 51,182,751 | \$ 5,118 | \$ 216,566,165 | \$ 46,081,931 |
| Exercise of warrants for common stock                                   | 705,048    | 71       | 2,342,346      | 2,342,417     |
| Exercise of options for common stock                                    | 218,353    | 22       | 741,791        | 741,813       |
| Issuance of common stock for ESPP                                       | 41,663     | 4        | 123,001        | 123,005       |
| Issuance of common stock to vendors                                     | 343,023    | 34       | 1,549,966      | 1,550,000     |
| Compensation expense related to issuance of options for common stock    |            |          | 525,126        | 525,126       |
| Issuance of common stock for cash and securities, net of offering costs | 692,003    | 69       | 4,955,554      | 4,955,623     |
| Stock-based compensation  |            |          | 4,881,470      | 4,881,470     |
| Comprehensive income (loss):  |            |          |                |               |
| Unrealized gain on short-term securities available-for-sale, net        |            |          | 5,450          | 5,450         |
| Net loss  |            |          | (28,687,510)   | (28,687,510)  |
| Comprehensive loss  |            |          |                | (28,682,060)  |
| BALANCE AT DECEMBER 31, 2006  | 53,182,841 | \$ 5,318 | \$ 231,685,419 | \$ 32,519,325 |

See accompanying notes to financial statements.



## AVI BIOPHARMA, INC.

(A Development Stage Company)

## STATEMENTS OF CASH FLOWS

|  | Year ended December 31, |                 |                 | For the Period      |
|--|-------------------------|-----------------|-----------------|---------------------|
|  | 2006                    | 2005            | 2004            | July 22, 1980       |
|  | (Restated)              | (Restated)      | (Restated)      | (Inception) through |
|  |                         |                 |                 | December 31, 2006   |
|  |                         |                 |                 | (Restated)          |
| <b>Cash flows from operating activities:</b>   |                         |                 |                 |                     |
| Net loss   | \$ (28,687,510)         | \$ (18,205,885) | \$ (21,936,843) | \$ (199,189,830)    |
| Adjustments to reconcile net loss to net cash flows used in operating activities:  |                         |                 |                 |                     |
| Depreciation and amortization  | 2,090,375               | 1,997,672       | 1,888,008       | 12,820,239          |
| Loss on disposal of assets   | 192,369                 | 35,862          | 86,947          | 315,178             |
| Realized gain on sale of short-term securities available-for-sale  |                         |                 |                 | (3,862,502)         |
| Write-down of short-term securities available-for-sale   |                         |                 |                 | 17,001,348          |
| Issuance of common stock to vendors  | 1,375,000               |                 |                 | 1,375,000           |
| Compensation expense on issuance of common stock and partnership units   |                         |                 |                 | 861,655             |
| Compensation expense to non-employees on issuance of options and warrants to purchase common stock or partnership units          | 525,126                 | 394,225         | 421,635         | 2,643,053           |
| Stock-based compensation   | 4,881,470               |                 |                 | 4,881,470           |
| Conversion of interest accrued to common stock   |                         |                 |                 | 7,860               |
| Acquired in-process research and development   |                         |                 |                 | 19,545,028          |
| (Gain) loss on warrant liability   | (2,385,502)             | 1,530,021       | (2,840,851)     | (4,531,426)         |
| <b>(Increase) decrease in:</b>   |                         |                 |                 |                     |
| Accounts receivable and other current assets   | 814,531                 | (919,237)       | 108,308         | (787,781)           |
| Other assets   | 2,900                   |                 | (7,762)         | (34,709)            |
| Net increase (decrease) in accounts payable, accrued employee compensation, and other liabilities                                | 577,872                 | 498,375         | (1,501,395)     | 3,445,845           |
| Net cash used in operating activities  | (20,613,369)            | (14,668,967)    | (23,781,953)    | (145,509,572)       |
| <b>Cash flows from investing activities:</b>   |                         |                 |                 |                     |
| Purchase of property and equipment   | (767,282)               | (1,070,801)     | (1,070,338)     | (15,298,511)        |
| Patent costs   | (686,607)               | (397,081)       | (462,591)       | (4,475,030)         |
| Purchase of marketable securities  | (14,969,926)            | (13,140,581)    | (13,123,205)    | (112,865,796)       |
| Sale of marketable securities  | 14,435,793              | 3,693,329       | 35,494,101      | 104,800,437         |
| Acquisition costs  |                         |                 |                 | (2,377,616)         |
| Net cash provided by (used in) investing activities  | (1,988,022)             | (10,915,134)    | 20,837,967      | (30,216,516)        |
| <b>Cash flows from financing activities:</b>   |                         |                 |                 |                     |
| Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants | 8,162,858               | 43,527,006      | 7,073,900       | 196,270,726         |
| 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  | 8,162,858               | 43,527,006      | 7,073,900       | 195,885,289         |

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|  |              |            |           |            |
|--|--------------|------------|-----------|------------|
| Increase (decrease) in cash and cash equivalents | (14,438,533) | 17,942,905 | 4,129,914 | 20,159,201 |
|--|--------------|------------|-----------|------------|

Cash and cash equivalents:

|                     |               |               |               |               |
|---------------------|---------------|---------------|---------------|---------------|
| Beginning of period | 34,597,734    | 16,654,829    | 12,524,915    |               |
| End of period       | \$ 20,159,201 | \$ 34,597,734 | \$ 16,654,829 | \$ 20,159,201 |

SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:

|   |    |         |    |         |                      |
|---|----|---------|----|---------|----------------------|
| Short-term securities available-for-sale received in connection with the private offering | \$ | \$      | \$ | \$      | 17,897,000           |
| Change in unrealized gain on short-term securities available-for-sale                     | \$ | 5,450   | \$ | 145,609 | \$ 157,162 \$ 18,418 |
| Issuance of common stock and warrants in satisfaction of liabilities                      | \$ | 175,000 | \$ | \$      | 545,000              |

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 investments, long-lived asset impairment, and revenue recognition.

*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 and cash equivalents of \$20,159,201 and \$34,597,734 as of December 31, 2006 and 2005, 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). Short-term securities include certificates of deposit, commercial paper and other highly liquid investments with original maturities in excess of 90 days at the time of purchase and less than one year from the balance sheet date. 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 with unrealized gains (losses) recorded as a separate component of shareholders' equity and comprehensive income (loss). The Company's investments in marketable securities had gross unrealized gains of \$18,418 and \$12,968 as of December 31, 2006 and 2005, respectively.

*Accounts Receivable*

Accounts receivable is stated at invoiced amount and do not bear interest. An allowance for doubtful accounts receivable is not necessary since the collect ability of individual accounts receivable is known by the company. Amounts included in accounts receivable are as follows:

| As of December 31, | 2006      | 2005         |
|--------------------|-----------|--------------|
| Research contract  | \$ 45,846 | \$ 1,200,000 |
| Grant              | 5,652     | 36,446       |

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|                     |    |        |    |           |
|---------------------|----|--------|----|-----------|
| Accounts receivable | \$ | 51,498 | \$ | 1,236,446 |
|---------------------|----|--------|----|-----------|

*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, generally five years, using the straight-line method. Expenditures for repairs and maintenance are expensed as incurred. Expenditures that increase the useful life or value are capitalized.

F-8

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Amounts included in property and equipment are as follows:

| As of December 31,            | 2006         | 2005         |
|-------------------------------|--------------|--------------|
| Lab equipment                 | \$ 4,770,021 | \$ 4,634,255 |
| Office equipment              | 676,323      | 700,578      |
| Leasehold improvements        | 8,804,831    | 8,661,359    |
| Construction in process       | 253,120      |              |
|                               | 14,504,295   | 13,996,192   |
| Less accumulated depreciation | (10,174,712) | (8,396,923)  |
| Property and equipment, net   | \$ 4,329,583 | \$ 5,599,269 |

Depreciation expense was \$1,844,599, \$1,749,314 and \$1,678,173 for the years ended December 31, 2006, 2005 and 2004, respectively.

#### *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 \$245,776, \$248,385 and \$209,835 for the years ended December 31, 2006, 2005 and 2004, respectively. Estimated aggregate amortization expense over the five succeeding fiscal years is expected to be \$1,300,000.

#### *Revenue Recognition*





The Company records revenue from research contracts and grants as the services are performed and payment is reasonably assured. In 2005, the Company recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. 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. To date revenue from license and development arrangements has not been significant.

*Research and Development*



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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.

F-9

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*Other Current Assets*

Amounts included in other current assets are as follows:

| As of December 31,          | 2006              | 2005              |
|-----------------------------|-------------------|-------------------|
| Prepaid expenses            | \$ 480,003        | \$ 272,165        |
| Prepaid rents               | 100,838           | 93,701            |
| Restricted cash             | 155,442           |                   |
| <b>Other current assets</b> | <b>\$ 736,283</b> | <b>\$ 365,866</b> |

Starting in April 2006, the Company was required to pledge \$150,000 as collateral for company credit cards issued to certain employees. The Company classifies this amount as restricted cash. As of December 31, 2006, restricted cash including accrued interest was \$155,442. The remaining components of other current assets include normally occurring prepaid expenses and rents.

*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. A valuation allowance is 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.

*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,   | 2006            | 2005            | 2004            |
|---|-----------------|-----------------|-----------------|
| Net loss (Restated)   | \$ (28,687,510) | \$ (18,205,885) | \$ (21,936,843) |
| 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   | 52,660,711      | 44,655,008      | 35,994,976      |
| 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 | 52,660,711      | 44,655,008      | 35,994,976      |
| Net loss per share - basic and diluted (Restated)   | \$ (0.54)       | \$ (0.41)       | \$ (0.61)       |

\* Warrants and stock options to purchase 14,079,573, 17,025,547 and 13,817,608 shares of common stock as of December 31, 2006, 2005 and 2004, respectively, were excluded from earnings per share calculation as their effect would have been antidilutive.

*Stock-based Compensation*

The Company has two stock-based compensation plans, the 2002 Equity Incentive Plan and the 2000 Employee Stock Purchase Plan, which are described below. Prior to fiscal year 2006, the Company accounted for those plans under the recognition and measurement provisions of Accounting Principles Board (APB) Opinion 25, Accounting for Stock Issued to Employees, and related Interpretations, as permitted by Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standard (SFAS) No. 123, Accounting for Stock-Based Compensation, (SFAS 123). Compensation costs related to stock options granted at fair value under those plans were not recognized in the statements of operations.

In December of 2004, FASB issued SFAS 123 (revised 2004), Share-Based Payment, (SFAS 123R). Under the new standard, companies are no longer to account for share-based compensation transactions using the intrinsic value method in accordance with APB Opinion No. 25. Instead, companies are required to account for such transactions using a fair-value method and recognize the expense in the statements of operations.

Effective January 1, 2006, the Company adopted SFAS 123R using the modified-prospective application. Under the modified prospective application, stock compensation cost recognized beginning January 1, 2006 includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123, and (b) compensation cost for all share-based payments granted on or subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123R. Results for prior periods have not been restated.



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The Company's net loss for the year ended December 31, 2006 was increased by approximately \$4.0 million as a result of the application of SFAS 123R.

Stock-based compensation costs are generally based on the fair value calculated from the Black-Scholes option-pricing model on the date of grant for stock options and on the date of enrollment for the Plan. The fair value of stock grants are amortized as compensation expense on a straight-line basis over the vesting period of the grants. Stock options granted to employees are service-based and typically vest over four years.

The fair market values of stock options granted during 2006, 2005 and 2004 were measured on the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

| Year Ended December 31, | 2006      | 2005      | 2004      |
|-------------------------|-----------|-----------|-----------|
| Risk-free interest rate | 4.14%     | 3.38%     | 3.00%     |
| Expected dividend yield | 0%        | 0%        | 0%        |
| Expected lives          | 9.3 Years | 9.1 Years | 9.2 Years |
| Expected volatility     | 91%       | 93%       | 93%       |

The risk-free interest rate is estimated using an average of treasury bill interest rates. The expected dividend yield is zero as the Company has not paid any dividends to date and does not expect to pay dividends in the future. The expected lives are estimated using expected and historical exercise behavior. The expected volatility is estimated using historical calculated volatility and considers factors such as future events or circumstances that could impact volatility.

As part of the requirements of FSAS 123R, the Company is required to estimate potential forfeiture of stock grants and adjust compensation cost recorded accordingly. The estimate of forfeitures will be adjusted over the requisite service period to the extent that actual forfeitures differ, or are expected to differ, from such estimates. Changes in estimated forfeitures will be recognized through a cumulative catch-up in the period of change and will also impact the amount of stock compensation expense to be recognized in future periods.

A summary of the Company's stock option compensation activity with respect to the year ended December 31, 2006 follows:

| Stock Options                                    | Shares    | Weighted<br>Average<br>Exercisable<br>Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Aggregate<br>Intrinsic<br>Value |
|--|-----------|---|---|---------------------------------|
| Outstanding at January 1, 2006                   | 4,812,396 | \$ 4.55                                     |   |                                 |
| Granted  | 1,172,700 | \$ 7.13                                     |   |                                 |
| Exercised  | (218,353) | \$ 3.40                                     |   |                                 |
| Canceled or expired                              | (195,273) | \$ 5.03                                     |   |                                 |
| Outstanding at December 31, 2006                 | 5,571,470 | \$ 5.12                                     | 5.63  | \$ (1,810,109)                  |
| Vested at December 31, 2006 and expected to vest | 5,533,250 | \$ 5.12                                     | 5.61  | \$ (1,796,164)                  |
| Exercisable at December 31, 2006                 | 3,660,483 | \$ 5.10                                     | 4.19  | \$ (1,112,864)                  |





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The weighted average fair value per share of stock-based payments granted to employees during 2006, 2005 and 2004 was \$6.09, \$2.12 and \$2.70, respectively. During 2006, 2005 and 2004, the total intrinsic value of stock options exercised were \$779,563, \$36,344 and \$3,643, and the total fair value of stock options that vested were \$4,047,970, \$2,219,446 and \$2,011,753, respectively.

As of December 31, 2006, there was \$5,237,126 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan. These costs are expected to be recognized over a weighted-average period of 2.4 years.

During the year ended December 31, 2006, \$741,813 was received for the exercise of stock options. The Company is obligated to issue shares from the 2002 Equity Incentive Plan upon the exercise of stock options. The Company does not currently expect to repurchase shares from any source to satisfy its obligations under the Plan.

The following are the stock-based compensation costs recognized in the Company's statements of operations:

|                            |           | <b>Year Ended<br/>December 31, 2006</b> |
|----------------------------|-----------|---|
| Research and development   | \$        | 2,408,132                               |
| General and administrative |           | 1,639,838                               |
| <b>Total</b>               | <b>\$</b> | <b>4,047,970</b>                        |

Prior to January 1, 2006, the Company accounted for stock options using the intrinsic value method as prescribed by APB 25. The Company provided disclosures of net loss and net loss per share as if the method prescribed by SFAS No. 123, Accounting for Stock-Based Compensation, had been applied in measuring compensation expense as follows:

| <b>For the Year Ended December 31,</b>   | <b>2005</b>            |           | <b>2004</b>         |
|--|------------------------|-----------|---------------------|
| Net loss, as reported (Restated)   | \$ (18,205,885)        | \$        | (21,936,843)        |
| Deduct: Total stock-based employee compensation expense determined under fair value based method, for all awards not previously included in net loss | (2,219,446)            |           | (2,011,753)         |
| <b>Net loss, as adjusted (Restated)</b>  | <b>\$ (20,425,331)</b> | <b>\$</b> | <b>(23,948,596)</b> |
| Basic and diluted net loss per share:  |                        |           |                     |
| As reported (Restated)   | \$ (0.41)              | \$        | (0.61)              |
| As adjusted (Restated)   | \$ (0.46)              | \$        | (0.67)              |

The following table presents the impact of the Company's adoption of SFAS 123R on net loss and loss per share for the year ended December 31, 2006:

| <b>As reported<br/>following<br/>SFAS No.<br/>123R</b> |  | <b>If reported<br/>following<br/>APB 25</b> |
|--|--|---|
|--|--|---|

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|   |    |              |    |              |
|---|----|--------------|----|--------------|
| Net loss (Restated)                             | \$ | (28,687,510) | \$ | (24,639,540) |
| Basic and diluted net loss per share (Restated) | \$ | (0.54)       | \$ | (0.47)       |

F-13

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The 2000 Employee Stock Purchase Plan (ESPP) provides that eligible employees may contribute, through payroll, deductions, up to 10% of their earnings toward the purchase of the Company's Common Stock at 85% of the fair market value at specific dates. On January 1, 2006, the Company adopted SFAS 123R, which requires the measurement and recognition of compensation expense for all share based payment awards made to the Company's employees and directors related to the Employee Stock Purchase Plan, based on estimated fair values. During the year ended December 31, 2006 the total compensation expense for participants in the ESPP was \$56,475 using the Black-Scholes option-pricing model with a weighted average estimated fair value per share of \$1.40, expected life of six months, risk free interest rate of 4.51%, volatility of 84.33%, and no dividend yield. At December 31, 2006, 248,144 shares remain available for purchase through the plan and there were 87 employees eligible to participate in the plan, of which 32 were participants.

On March 15, 2006 unvested stock options for nine employees in the Company's Colorado facility were accelerated. These employees joined Cook Group Inc. in April 2006. See Note 4. The acceleration of these stock options in the first quarter of 2006 increased compensation costs by \$833,500.

During the year ended December 31, 2006, the total compensation expense for stock-based compensation recognized in accordance with SFAS 123R and for acceleration of the vesting of certain stock options was \$4,881,470, 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 performance for services was satisfied on the grant date for stock options granted to non-employees. The total fair value of the options granted to non-employees in 2006, 2005 and 2004 was \$525,126, \$394,225 and \$421,635, respectively, which was expensed to research and development.

#### Warrants

Certain of the Company's warrants issued in connection with financing arrangements are classified as liabilities in accordance with EITF 00-19 *Accounting for derivative financial instruments indexed to, and potentially settled in, a company's own stock*. The fair market values of these warrants is recorded on the balance sheet at issuance and marked to market at each reporting period. The change in the fair value of the warrants is recorded in the statement of operations as a non-cash gain (loss) and is estimated using the Black-Scholes option-pricing model, with the following weighted average assumptions at December 31:

| Year Ended December 31, | 2006          | 2005          | 2004      |
|-------------------------|---------------|---------------|-----------|
| Risk-free interest rate | 4.6%-4.7%     | 4.3%          | 3.20%     |
| Expected dividend yield | 0%            | 0%            | 0%        |
| Expected lives          | 1.9-3.4 Years | 2.9-4.4 Years | 3.9 Years |
| Expected volatility     | 76.1%-87.2%   | 83.2%-86.1%   | 85.2%     |

The risk-free interest rate is estimated using an average of treasury bill interest rates. The expected dividend yield is zero as the Company has not paid any dividends to date and does not expect to pay dividends in the future. The expected lives are based on the remaining contractual lives of the related warrants. The expected volatility is estimated using historical calculated volatility and considers factors such as future events or circumstances that could impact volatility.

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For warrants classified as permanent equity in accordance with EITF 00-19, the fair value of warrants is recorded in shareholders' equity and no further adjustments are made.

### *Comprehensive Income (Loss)*

Comprehensive income (loss) includes charges or credits to equity that did not result from transactions with shareholders. The Company's only component of other comprehensive income (loss) is unrealized gain (loss) on short-term securities available-for-sale. Accordingly, such investment securities are stated on the balance sheet at their fair market value.

### *Recent Accounting Pronouncements*

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and is required to be adopted by the Company in the first quarter of fiscal 2007. The cumulative effects, if any, of applying FIN 48 will be recorded as an adjustment to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the effect that the adoption of FIN 48 will have on its results of operations and financial condition and does not believe that it will have a material impact on the consolidated financial statements.

In September 2006, the SEC issued SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements" (SAB 108). SAB 108 provides guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. SAB 108 establishes an approach that requires quantification of financial statement errors based on the effects of each of the company's balance sheet and statement of operations and the related financial statement disclosures. SAB 108 is effective for fiscal years beginning after November 15, 2006 and is required to be adopted by the Company in the first quarter of fiscal 2007. The Company does not expect the adoption of SAB 108 to have a material impact on its consolidated results of operations and financial condition.

### 3. RESTATEMENT OF PRIOR FINANCIAL INFORMATION:

In December 2003, January 2004, January 2005 and November 2005, the Company issued warrants in connection with various financing transactions in registered offerings. Previously, the Company had classified these warrants in the shareholders' equity section of the Company's balance sheet. In accordance with EITF 00-19, if a financial instrument requires settlement in registered shares, the financial instrument cannot be classified within equity, as the company's ability to maintain an effective registration statement is outside that company's control. The warrants issued by the Company require settlement in registered shares and, accordingly, should be recorded as a liability at fair value at the date of grant, and marked to market at each reporting period.

The Company has evaluated the financial statement impact in each of the previously filed reporting periods effected, and concluded that the changes are quantitatively material to its previously filed financial statements. The amounts previously recorded in each of the three years ended December 31, 2006 will be adjusted to reduce equity and increase liabilities for the issued warrants, and changes in fair value will be recorded on their own line item.

The effect of the correction of this error on the balance sheet as of December 31, 2006 and the statement of operations for the twelve month period ended December 31, 2006 is summarized as follows:

|  | <b>December 31, 2006<br/>As Previously<br/>Reported</b> | <b>Adjustments</b> | <b>December 31, 2006<br/>As Restated</b> |
|--|---|--------------------|--|
| Warrant liability                                |   | 5,192,576          | 5,192,576                                |
| Total Current Liabilities                        | 3,150,845   | 5,192,576          | 8,343,421                                |
| Additional paid-in capital                       | 241,409,421   | (9,724,002)        | 231,685,419                              |
| Deficit accumulated during the development stage | (203,721,256)   | 4,531,426          | (199,189,830)                            |
| Total Shareholders' Equity                       | 37,711,901  | (5,192,576)        | 32,519,325                               |
| Gain on warrant liability                        |   | 2,385,502          | 2,385,502                                |
| Net loss   | (31,073,012)  | 2,385,502          | (28,687,510)                             |
| Net loss per share (basic and diluted)           | (0.59)  | 0.05               | (0.54)                                   |

The effect of the correction of this error on the balance sheet as of December 31, 2005 and the statement of operations for the twelve month period ended December 31, 2005 is summarized as follows:

**Adjustments**

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|  | December 31, 2005<br>As Previously<br>Reported | December 31, 2005<br>As Restated |
|--|--|----------------------------------|
| Warrant liability                                |  | 7,578,078                        |
| Total Current Liabilities                        | 2,747,973                                      | 7,578,078                        |
| Additional paid-in capital                       | 226,290,167                                    | (9,724,002)                      |
| Deficit accumulated during the development stage | (172,648,244)                                  | 2,145,924                        |
| Total Shareholders' Equity                       | 53,660,009                                     | (7,578,078)                      |
| Loss on warrant liability                        |  | (1,530,021)                      |
| Net loss   | (16,675,864)                                   | (1,530,021)                      |
| Net loss per share (basic and diluted)           | (0.37)   | (0.04)                           |

The effect of the correction of this error on the statement of shareholders' equity and the statement of operations for the twelve month period ended December 31, 2004 is summarized as follows:

|  | December 31, 2004<br>As Previously<br>Reported | Adjustments | December 31, 2004<br>As Restated |
|--|--|-------------|----------------------------------|
| Additional paid-in capital                       | 182,370,440                                    | (5,488,270) | 176,882,170                      |
| Deficit accumulated during the development stage | (155,972,380)                                  | 3,675,945   | (152,296,435)                    |
| Total Shareholders' Equity                       | 26,269,033                                     | (1,812,325) | 24,456,708                       |
| Gain on warrant liability                        |  | 2,840,851   | 2,840,851                        |
| Net loss   | (24,777,694)                                   | 2,840,851   | (21,936,843)                     |
| Net loss per share (basic and diluted)           | (0.69)   | 0.08        | (0.61)                           |

The effect of the correction of this error on the statement of shareholders' equity for the period ended December 31, 2003 is summarized as follows:

|  | December 31, 2003<br>As Previously<br>Reported | Adjustments | December 31, 2003<br>As Restated |
|--|--|-------------|----------------------------------|
| Additional paid-in capital                       | 174,875,072                                    | (4,543,272) | 170,331,800                      |
| Deficit accumulated during the development stage | (131,194,686)                                  | 835,094     | (130,359,592)                    |
| Total Shareholders' Equity                       | 43,394,030                                     | (3,708,178) | 39,685,852                       |

The effect of the correction of this error on the statement of operations from July 22, 1980 (Inception) through December 31, 2006 is summarized as follows:

|                           | July 22, 1980<br>(Inception) through<br>December 31, 2006<br>As Previously<br>Reported | Adjustments | July 22, 1980<br>(Inception) through<br>December 31, 2006<br>As Restated |
|---------------------------|--|-------------|--|
| Gain on warrant liability |  | 4,531,426   | 4,531,426  |
| Net loss                  | (203,721,256)  | 4,531,426   | (199,189,830)  |





The Company has also restated the quarterly information for the periods 2006 and 2005 (see note 10). The correction of this error did not impact cash used in operating activities, cash provided by (used in) investing activities, or cash provided by financing activities.

#### 4. LIQUIDITY:

The Company is in the development stage. Since its inception in 1980 through December 31, 2006, the Company has incurred losses of approximately \$199 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 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 antisense 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 additional financing. There is no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. On March 13, 2006, the Company announced that it had entered into agreements with Cook Group Inc. (Cook) for Cook's development and commercialization of products for vascular and cardiovascular diseases. Under a stock purchase agreement with Cook, the Company received net proceeds of \$4,955,623. The Company sold 692,003 shares of common stock at \$7.23 per share to Cook, as described in Note 4. The Company believes it has sufficient cash to fund operations through 2007. For 2007, the Company expects expenditures for operations, including collaborative efforts and GMP facilities to be approximately \$25 to \$28 million. Expenditures for 2007 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 a significant amount of the Company's costs are variable.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that we will receive up to \$9.8 million. Under this allocation, our NEUGENE technology will be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company continues to work with the government to define the scope of the work to be performed on these programs. This additional funding has not been received and has not been reflected in the financial statements.

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.

## 5. SHAREHOLDERS EQUITY AND WARRANT LIABILITY:

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. The fair value of these warrants has been recorded as a liability and is marked to market each period, with the resulting gain (loss) recorded in the Statement of Operations.

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 starting July 28, 2004 and expire on December 8, 2008. The fair value of these warrants has been recorded as a liability and is marked to market each period, with the resulting gain (loss) recorded in the Statement of Operations.

In January 2005, the Company closed a private equity financing for net proceeds of \$22,300,338 with several institutional investors. The Company sold 8,000,000 shares of common stock at \$3.00 per share. These investors also received warrants for the purchase of 1,600,001 common shares at \$5.00 per share. These warrants are exercisable starting July 19, 2005 and expire on July 19, 2009. In connection with the equity financing, the placement agent received a warrant for the purchase of an additional 560,000 common shares at \$5.00 per share. These warrants also are exercisable starting July 19, 2005 and expire on July 19, 2009. The fair value of these warrants has been recorded as a liability and is marked to market each period, with the resulting gain (loss) recorded in the Statement of Operations.

In November 2005, the Company closed a private equity financing for net proceeds of \$21,020,984 with several institutional investors. The Company sold 6,941,715 shares of common stock at \$3.26 per share. In connection with the equity financing, the placement agent received a warrant for the purchase of 485,920 common shares at \$5.00 per share. These warrants are exercisable commencing on May 14, 2006 and expire on May 14, 2010. The fair value of these warrants has been recorded as a liability and is marked to market each period, with the resulting gain (loss) recorded in the Statement of Operations.

In March 2006, the Company announced that it had entered into agreements with Cook Group Inc. (Cook) for Cook's development and commercialization of products for vascular and cardiovascular diseases. There may be future royalty and milestone payments from Cook based on the License and Development Agreement. Under a stock purchase agreement with Cook, the Company received net proceeds of \$4,955,623. The Company sold 692,003 shares of common stock at \$7.23 per share to Cook.

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 2006, employees elected to purchase a total of 41,663 shares of the Company's common stock at \$2.95 per share. During 2005, employees elected to purchase a total of 60,854 shares of the Company's common stock at \$1.82 per share. During 2004, employees elected to purchase a total of 49,918 shares of the Company's common stock at \$1.89 per share. At December 31, 2006, 248,144 shares remained available to purchase.



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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 7,282,404 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. At December 31, 2006, 4,167,981 options are outstanding at a weighted-average exercise price of \$5.36 under equity compensations plans approved by security holders. At December 31, 2006, 1,959,078 shares were available to issue under equity compensation plans approved by security holders.

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

| For the Year Ended<br>December 31,       | 2006      |  | 2005      |  | 2004      |  |
|--|-----------|--|-----------|--|-----------|--|
|  | Shares    | Weighted<br>Average<br>Exercise<br>Price | Shares    | Weighted<br>Average<br>Exercise<br>Price | Shares    | Weighted<br>Average<br>Exercise<br>Price |
| Options outstanding at beginning of year | 4,812,396 | \$ 4.55                                  | 3,803,278 | \$ 5.22                                  | 3,333,861 | \$ 5.60                                  |
| Granted                                  | 1,172,700 | 7.13                                     | 1,245,937 | 2.47                                     | 631,041   | 3.10                                     |
| Exercised                                | (218,353) | 3.40                                     | (37,029)  | 2.56                                     | (4,121)   | 3.64                                     |
| Canceled                                 | (195,273) | 5.03                                     | (199,790) | 4.73                                     | (157,503) | 4.75                                     |
| Options outstanding at end of year       | 5,571,470 | 5.12                                     | 4,812,396 | 4.55                                     | 3,803,278 | 5.22                                     |
| Exercisable at end of year               | 3,660,483 | \$ 5.10                                  | 3,308,714 | \$ 5.40                                  | 2,912,510 | \$ 5.63                                  |

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At December 31, 2006, 1,710,934 shares were available for future grant.

The following table summarizes information about stock options outstanding at December 31, 2006:

| Exercise Price | Outstanding Shares at December 31, 2006 | Weighted Average Remaining Contractual Life (Years) | Exercisable Options |
|----------------|---|---|---------------------|
| \$ 1.76        | 20,000                                  | 2.62  | 20,000              |
| 2.00           | 100,000                                 | 8.03  | 100,000             |
| 2.06           | 20,000                                  | 7.75  | 20,000              |
| 2.20           | 60,000                                  | 6.78  | 40,001              |
| 2.24           | 50,000                                  | 8.38  | 50,000              |
| 2.26           | 2,500                                   | 8.72  | 2,500               |
| 2.29           | 26,666                                  | 8.36  | 6,667               |
| 2.43           | 7,333                                   | 3.36  | 2,001               |
| 2.53           | 844,824                                 | 7.61  | 311,833             |
| 2.55           | 63,000                                  | 7.48  | 46,500              |
| 2.60           | 5,000                                   | 8.21  | 1,250               |
| 2.64           | 33,000                                  | 8.17  | 8,250               |
| 2.89           | 100,000                                 | 7.24  | 50,000              |
| 2.92           | 183,334                                 | 7.22  | 91,668              |
| 3.02           | 33,334                                  | 7.23  | 16,668              |
| 3.25           | 20,000                                  | 8.88  | 6,667               |
| 3.29           | 10,000                                  | 2.28  | 10,000              |
| 3.31           | 25,000                                  | 2.76  | 25,000              |
| 3.45           | 100,000                                 | 7.25  | 50,000              |
| 3.50           | 53,159                                  | 0.61  | 53,159              |
| 3.69           | 28,000                                  | 2.05  | 28,000              |
| 3.81           | 15,000                                  | 1.64  | 15,000              |
| 3.97           | 21,360                                  | 1.00  | 21,360              |
| 4.16           | 20,000                                  | 6.28  | 20,000              |
| 4.25           | 20,000                                  | 1.98  | 20,000              |
| 4.34           | 51,596                                  | 4.00  | 44,930              |
| 4.55           | 30,000                                  | 1.62  | 30,000              |
| 4.64           | 83,000                                  | 9.39  | 29,165              |
| 4.87           | 20,000                                  | 6.01  | 15,000              |
| 4.89           | 10,000                                  | 6.01  | 7,500               |
| 5.35           | 745,800                                 | 5.93  | 745,800             |
| 5.53           | 40,000                                  | 3.92  | 40,000              |
| 5.75           | 503,000                                 | 3.00  | 503,000             |
| 5.88           | 45,000                                  | 6.38  | 45,000              |
| 6.00           | 33,334                                  | 0.16  | 33,334              |
| 6.38           | 235,000                                 | 0.44  | 235,000             |
| 6.63           | 510,000                                 | 1.11  | 510,000             |
| 6.65           | 40,000                                  | 5.37  | 40,000              |
| 6.69           | 100,000                                 | 0.69  | 100,000             |
| 6.88           | 132,000                                 | 3.62  | 132,000             |
| 6.98           | 100,000                                 | 9.22  |                     |
| 7.19           | 33,334                                  | 3.58  | 33,334              |
| 7.35           | 972,896                                 | 8.48  | 74,896              |
| 8.13           | 25,000                                  | 0.84  | 25,000              |
|                | <b>5,571,470</b>                        |   | <b>3,660,483</b>    |



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The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. The 2,645,921, and 389,611 warrants granted in 2005 and 2004, 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:

| For the Year Ended<br>December 31,           | 2006        |                                       | 2005       |                                       | 2004        |                                       |
|--|-------------|---------------------------------------|------------|---------------------------------------|-------------|---------------------------------------|
|  | Shares      | Weighted<br>Average<br>Exercise Price | Shares     | Weighted<br>Average<br>Exercise Price | Shares      | Weighted<br>Average Exercise<br>Price |
| Warrants outstanding at<br>beginning of year | 12,213,151  | \$ 10.79                              | 10,014,330 | \$ 12.34                              | 11,662,382  | \$ 11.20                              |
| Granted                                      |             |                                       | 2,645,921  | 5.00                                  | 389,611     | 5.50                                  |
| Exercised                                    | (705,048)   | 3.32                                  |            |                                       | (1,623,377) | 4.62                                  |
| Expired                                      | (3,000,000) | 10.00                                 | (447,100)  | 9.14                                  | (414,286)   | 4.03                                  |
| Warrants outstanding at<br>end of year       | 8,508,103   | 11.68                                 | 12,213,151 | 10.79                                 | 10,014,330  | 12.34                                 |
| Exercisable at end of year                   | 6,842,225   | \$ 5.85                               | 10,061,353 | \$ 6.95                               | 8,348,452   | \$ 7.70                               |

The following table summarizes information about warrants outstanding at December 31, 2006:

| Exercise<br>Price | Outstanding<br>Warrants at<br>December 31,<br>2006 | Weighted Average<br>Remaining<br>Contractual Life<br>(Years) | Exercisable<br>Warrants |
|-------------------|--|--|-------------------------|
| \$ 0.0003         | 16,667   | No expiration date   | 16,667                  |
| 1.14              | 1,000  | No expiration date   | 1,000                   |
| 5.00              | 2,645,921  | 2.70   | 2,645,921               |
| 5.50              | 1,613,637  | 1.94   | 1,613,637               |
| 7.00              | 2,565,000  | 1.34   | 2,565,000               |
| 35.63             | 1,665,878  | 3.25   |                         |
|                   | 8,508,103  |  | 6,842,225               |

The warrants issued in 2004 and 2005 do not require net cash settlement, however, as the warrants require settlement in registered shares, the Company has recorded the warrants as liabilities on the accompanying balance sheet. There is no effect on cash flows from these warrants as the mark to market adjustment is reflected as a non-cash charge within the Company's Statements of Operations. There were 4,350,467 liability classified warrants outstanding at December 31, 2006 and 2005, and 1,704,546 liability classified warrants outstanding at December 31, 2004.

**6. SIGNIFICANT AGREEMENTS:**

On January 27, 2006, the Company announced that it had entered into a definitive License Agreement with Chiron Corporation ( Chiron ) granting the Company a nonexclusive license to Chiron's patents and patent applications for the research, development, and commercialization of antisense therapeutics against hepatitis C virus, in exchange for the payment of certain milestone and royalty payments to Chiron. In lieu of the first milestone payment due under the License Agreement, the Company and Chiron also entered into a separate agreement under which the Company issued to Chiron 89,012 shares of the Company's common stock with a market value of \$500,000 and which was expensed to research and development. There may be future payments made to Chiron by the Company based on milestones in the License Agreement.

On March 13, 2006, the Company announced that it had entered into agreements with Cook Group Inc. ( Cook ) for Cook's development and commercialization of products for vascular and cardiovascular diseases. See Note 4.

Effective January 1, 2006, the Company extended the lease on its facility located at 4575 SW Research Way, Suite 200, Corvallis, OR 97333. This lease now expires on December 31, 2020. As of December 31, 2005, the Company had an accrued rent payable of \$615,163 related to back rent payments. During the first half of 2006 the Company issued 31,154 shares of the Company's common stock with a market value of \$175,000, and paid cash to Research Way Investments to pay off the accrued rent payable related to back rent payments.

In January 2006, the Company issued 30,000 shares of the Company's common stock with a market value of \$200,000 to the Oregon State University Foundation to secure access to certain university research facilities, which was expensed to research and development.

In December 2006, the Company entered into a cross-license and collaboration agreement with Ercole Biotech, Inc. ( Ercole ) to identify and develop drugs that direct the splicing of messenger RNA (mRNA) to treat a variety of genetic and acquired diseases and a stock purchase agreement in connection therewith. Under the terms of the stock purchase agreement, Ercole issued AVI shares of Ercole Series A 2 Preferred Stock, and the Company issued to Ercole 192,857 shares of the Company's common stock with a market value of \$675,000 and which was expensed to research and development.



**7. INCOME TAXES:**

As of December 31, 2006 the Company has net operating loss carryforwards of approximately \$150,482,000, available to reduce future taxable income, which expire 2007 through 2026. Of this \$150,482,000, 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 \$147,882,000 in losses based on ownership changes and the value of the Company's stock. Approximately \$3,923,000 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, treatment of research and development costs, limitations on the length of time that net operating losses may be carried forward, and differences in the recognition of stock-based compensation.

The Company had net deferred tax assets of \$79,398,000 and \$67,629,000 at December 31, 2006 and 2005, 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 \$11,769,000, \$9,056,000 and \$12,093,000 for the years ended December 31, 2006, 2005 and 2004, 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,                                | 2006          | 2005          |
|---|---------------|---------------|
| Net operating loss carryforwards            | \$ 58,688,000 | \$ 50,079,000 |
| Difference in depreciation and amortization | 1,413,000     | 1,031,000     |
| Capital loss carryforward                   | 5,007,000     | 5,007,000     |
| Research and development tax credits        | 12,575,000    | 10,935,000    |
| FAS 123R stock compensation                 | 946,000       | 0             |
| Stock options for consulting services       | 765,000       | 560,000       |
| Other                                       | 4,000         | 17,000        |
|   | 79,398,000    | 67,629,000    |
| Valuation allowance                         | (79,398,000)  | (67,629,000)  |
|   | \$            | \$            |

**8. RELATED PARTY TRANSACTIONS:**

During the year ended December 31, 2004, the Company paid Boston Healthcare Associates, Inc., of which former director Andrew J. Ferrara is President, \$986 for business development consulting services.



**9. COMMITMENTS:**

*Lease Obligations*

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The Company leases office and laboratory facilities under various noncancelable operating leases through December 2020. Rent expense under these leases was \$1,333,000, \$1,160,000 and \$1,485,000 for the years ended December 31, 2006, 2005 and 2004, respectively, and \$8,543,000 for the period from July 22, 1980 through December 31, 2006.

At December 31, 2006, the aggregate noncancelable future minimum payments under these leases are as follows:

| <b>Year ending December 31,</b>     |           |                   |
|-------------------------------------|-----------|-------------------|
| 2007                                | \$        | 1,170,000         |
| 2008                                |           | 1,206,000         |
| 2009                                |           | 1,201,000         |
| 2010                                |           | 1,177,000         |
| 2011                                |           | 1,264,000         |
| Thereafter                          |           | 13,227,000        |
| <b>Total minimum lease payments</b> | <b>\$</b> | <b>19,245,000</b> |

### ***Royalty Obligations***

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The Company has license agreements for which it is obligated to pay the licensors a minimum annual royalty. Royalty payments under these agreements were \$125,000, \$125,000 and \$125,000 for the years ended December 31, 2006, 2005 and 2004, respectively, and \$983,750 for the period from July 22, 1980 through December 31, 2006.

At December 31, 2006, the aggregate future minimum royalty payments under these agreements are as follows:

| <b>Year ending December 31,</b>       |           |                  |
|---------------------------------------|-----------|------------------|
| 2007                                  | \$        | 125,000          |
| 2008                                  |           | 125,000          |
| 2009                                  |           | 125,000          |
| 2010                                  |           | 125,000          |
| 2011                                  |           | 125,000          |
| Thereafter                            |           | 1,380,000        |
| <b>Total minimum royalty payments</b> | <b>\$</b> | <b>2,005,000</b> |

F-23

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**10. FINANCIAL INFORMATION BY QUARTER (UNAUDITED) (SEE FOOTNOTE 3):**

| 2006 for quarter ended                                    | December 31<br>(Restated) | September 30<br>(Restated) | June 30<br>(Restated) | March 31<br>(Restated) |
|---|---------------------------|----------------------------|-----------------------|------------------------|
| Revenues from license fees, grants and research contracts | \$ 17,519                 | \$ 13,252                  | \$ 18,558             | \$ 65,962              |
| Operating expenses:                                       |                           |                            |                       |                        |
| Research and development                                  | 6,721,547                 | 5,938,867                  | 5,921,929             | 6,763,245              |
| General and administrative                                | 2,068,201                 | 1,347,114                  | 1,515,711             | 2,821,726              |
|   | 8,789,748                 | 7,285,981                  | 7,437,640             | 9,584,971              |
| Other income (loss):                                      |                           |                            |                       |                        |
| Interest income, net                                      | 443,042                   | 492,083                    | 517,053               | 457,859                |
| Gain (loss) on warrant liability                          | 2,250,049                 | 529,136                    | 13,801,693            | (14,195,376)           |
| Net income (loss)   | \$ (6,079,138)            | \$ (6,251,510)             | \$ 6,899,664          | \$ (23,256,526)        |
| Net income (loss) per share - basic                       | \$ (0.11)                 | \$ (0.12)                  | \$ 0.13               | \$ (0.45)              |
| Net income (loss) per share - diluted                     | \$ (0.11)                 | \$ (0.12)                  | \$ 0.13               | \$ (0.45)              |
| Shares used in per share calculations - basic             | 53,000,236                | 52,964,049                 | 52,946,054            | 51,715,050             |
| Shares used in per share calculations - diluted           | 53,000,236                | 52,964,049                 | 54,060,830            | 51,715,050             |

| 2005 for quarter ended                                    | December 31<br>(Restated) | September 30<br>(Restated) | June 30<br>(Restated) | March 31<br>(Restated) |
|---|---------------------------|----------------------------|-----------------------|------------------------|
| Revenues from license fees, grants and research contracts | \$ 1,417,446              | \$ 3,281,805               | \$ 39,317             | \$ 45,192              |
| Operating expenses:                                       |                           |                            |                       |                        |
| Research and development                                  | 4,913,490                 | 4,147,201                  | 3,915,155             | 4,141,904              |
| General and administrative                                | 1,409,066                 | 1,052,244                  | 1,272,529             | 1,448,530              |
|   | 6,322,556                 | 5,199,445                  | 5,187,684             | 5,590,434              |
| Other income (loss):                                      |                           |                            |                       |                        |
| Interest income, net                                      | 353,538                   | 225,169                    | 215,725               | 46,063                 |
| Gain (loss) on warrant liability                          | (1,990,461)               | (533,842)                  | 833,797               | 160,485                |
| Net loss  | \$ (6,542,033)            | \$ (2,226,313)             | \$ (4,098,845)        | \$ (5,338,694)         |
| Net loss per share, basic and diluted                     | \$ (0.14)                 | \$ (0.05)                  | \$ (0.09)             | \$ (0.13)              |
| Shares used in per share calculations                     | 47,838,357                | 44,184,293                 | 44,167,565            | 42,455,512             |

**11. SUBSEQUENT EVENTS:**

On January 9, 2007, the Company announced that it had entered into a cross-license agreement with Eleos Inc. for the development of antisense drugs targeting p53, a well-studied human protein that controls cellular response to genetic damage. Under the terms of the agreement, the Company is granting Eleos Inc. an exclusive license to the Company's NeuGen<sup>®</sup> third-generation antisense chemistry to treat cancer with p53-related drugs. In return, Eleos Inc. is granting the Company an exclusive license to its patents for treatment of most viral diseases with drugs that target p53. The companies are sharing rights in other medical fields where targeting p53 may be therapeutically useful. Each company will make milestone payments and royalty payments to the other on development and sales of products that utilize technology licensed under the agreement. In addition, Eleos Inc. is making an upfront payment of \$500,000 to the Company.

