

**Washington, D.C. 20549**

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

**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: 001-14895**

**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)

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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 ☐ Smaller Reporting Company ☐  
(Do not check if a smaller reporting company)

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 12, 2008) was approximately \$89,141,913 as of March 12, 2008. 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 12, 2008 was 64,782,094.

### Documents Incorporated by Reference

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

The issuer has incorporated into Part III of this annual report on Form 10-K, by reference, portions of its definitive Proxy Statement for its 2008 annual meeting.

---

AVI BioPharma, Inc.

FORM 10-K INDEX

|                        | <b>Page</b>                                                                                    |
|------------------------|------------------------------------------------------------------------------------------------|
| <b><u>PART I</u></b>   |                                                                                                |
| <u>Item 1.</u>         | <u>Description of Business</u> 1                                                               |
| <u>Item 1A.</u>        | <u>Risk Factors</u> 13                                                                         |
| <u>Item 1B.</u>        | <u>Unresolved SEC Comments</u> 19                                                              |
| <u>Item 2.</u>         | <u>Description of Property</u> 19                                                              |
| <u>Item 3.</u>         | <u>Legal Proceedings</u> 19                                                                    |
| <u>Item 4.</u>         | <u>Submission of Matters to a Vote of Security Holders</u> 19                                  |
| <b><u>PART II</u></b>  |                                                                                                |
| <u>Item 5.</u>         | <u>Market for Common Equity and Related Stockholder Matters</u> 20                             |
| <u>Item 6.</u>         | <u>Selected Financial Data</u> 23                                                              |
| <u>Item 7.</u>         | <u>Management's Discussion and Analysis or Plan of Operation</u> 23                            |
| <u>Item 7A.</u>        | <u>Quantitative and Qualitative Disclosures About Market Risk</u> 31                           |
| <u>Item 8.</u>         | <u>Financial Statements</u> 31                                                                 |
| <u>Item 9.</u>         | <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> 31 |
| <u>Item 9A.</u>        | <u>Controls and Procedures</u> 31                                                              |
| <u>Item 9B.</u>        | <u>Other Information</u> 34                                                                    |
| <b><u>PART III</u></b> |                                                                                                |
| <u>Item 10.</u>        | <u>Directors and Executive Officers of the Registrant</u> 35                                   |
| <u>Item 11.</u>        | <u>Executive Compensation</u> 35                                                               |
| <u>Item 12.</u>        | <u>Security Ownership of Certain Beneficial Owners and Management</u> 35                       |
| <u>Item 13.</u>        | <u>Certain Relationships and Related Transactions</u> 35                                       |
| <u>Item 14.</u>        | <u>Principal Accountant Fees and Services</u> 35                                               |
| <u>Item 15.</u>        | <u>Exhibits and Financial Statement Schedules</u> 36                                           |
|                        | <u>Signatures</u> 42                                                                           |

**PART I**

**Item 1. Description of Business**

**General Overview**

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

AVI BioPharma, Inc. is a biopharmaceutical company developing therapeutic products principally based on third-generation NeuGene antisense technology (in this report, we, our, us, AVI, and Company refers to AVI BioPharma, Inc.). Our principal products in development target life-threatening diseases, including cardiovascular, infectious, and genetic 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 186 patents (foreign and domestic) issued or licensed to us and 192 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.

Our net loss in 2007 was \$27.2 million, or \$0.50 per share. Total expenses were \$44.1 million and revenues were \$11.0 million. 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 as well as biologics such as monoclonal antibodies. NeuGene drugs are synthetic polymers that block the function of selected genetic sequences involved in disease processes. Targeting specific genetic sequences could provide for greater selectivity than that available through conventional drugs for the range of disease we are researching. 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. Four NeuGenes have been the subject of nineteen clinical trials; 405 subjects received a NeuGene drug. In each study, the drug was well-tolerated, and no definite drug related serious adverse events were reported.

We believe that our NeuGene chemistry can also be used in a way that is novel from conventional antisense approaches to target splice-joining sites in the pre-RNA. This forces the cellular machinery to skip over targeted exons and creates an altered mRNA template. The process, which we call ESPRIT, for Exon Skipping Pre-RNA Interference Technology, allows the production of altered proteins. We believe that when the skipped exon contains a disease-causing mutation, for example, the resulting altered protein may have its function restored, or partially restored. This approach may be used to overcome the devastating consequences of certain disease-causing mutations.

We have completed pre-clinical and some clinical studies using our NeuGene drugs in the treatment of cardiovascular disease, infectious disease, cancer, polycystic kidney disease (PKD), in regulating drug metabolism via the P450 cytochrome system. 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 with this product. 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 conducting a Phase Ib/II clinical trial for coronary artery bypass grafting in eastern Europe. We are also conducting a proof of concept study in boys with Duchenne Muscular Dystrophy (DMD) in the U.K., in collaboration with the MDEX consortium. In addition, we are in preclinical development for antivirals for Ebola Zaire, Marburg Musoke, Dengue virus, and for influenza A, including H5N1 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 primarily based on NeuGene antisense technology focused on applications in cardiovascular disease, infectious diseases, and genetic diseases. 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>             |              |              |             |                        |           |
| Restenosis: Resten-NG                     | NeuGene Drug | Completed    | Completed   | Completed              |           |
| Restenosis: Resten-MP microparticles      | NeuGene Drug | Completed    | Completed   | Completed (Cook Group) |           |
| CABG: AVI-5126                            | NeuGene Drug | Completed    | In-progress |                        |           |
| <b>Infectious Disease (Viral targets)</b> |              |              |             |                        |           |
| Hepatitis C: AVI-4065                     | NeuGene Drug | Completed    | Completed   |                        |           |
| West Nile: AVI-4020                       | NeuGene Drug | Completed    | Completed   |                        |           |
| Influenza A/Avian: AVI-6001               | NeuGene Drug | In-progress  |             |                        |           |
| SARS: AVI-4179                            | NeuGene Drug | Completed    |             |                        |           |
| Ebola Zaire                               | NeuGene Drug | In-progress  |             |                        |           |
| Marburg Musoke                            | NeuGene Drug | In-progress  |             |                        |           |
| Junin Virus                               | NeuGene Drug | In-progress  |             |                        |           |
| <b>Cancer</b>                             |              |              |             |                        |           |
| Cancer: Oncomyc-NG : AVI-4126             | NeuGene Drug | Completed    | Completed   |                        |           |
| <b>Drug Metabolism</b>                    |              |              |             |                        |           |
| Cytochrome P450: AVI-4557                 | NeuGene Drug | Completed    | Completed   |                        |           |
| <b>Genetic Diseases</b>                   |              |              |             |                        |           |
| PKD: AVI-4126                             | NeuGene Drug | Completed    | Completed   |                        |           |
| DMD: (Intramuscular-local) AVI-4658       | NeuGene Drug | Completed    | In-progress |                        |           |
| DMD: (Intravenous-systemic) AVI-4658      | NeuGene Drug | Completed    |             |                        |           |

\*In this table, In-progress refers to studies or trials that have actively begun recruitment after receipt of all regulatory approvals but are not yet complete in terms of recruitment or analyses; and Completed refers to studies in which all clinical trial or study activities have 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, costs and numbers of subsequent clinical studies or trials for a product, or how a product will proceed toward and through Phase III or pivotal clinical trials prior to regulatory license approval. 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, which occurred in July, 2007. Cook has indicated to us that it is planning additional clinical studies with products based on our Resten-NG platform.

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. We believe that 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, which 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. If this clinical study goes to completion, we believe that it will be considered a pivotal study that would enroll 600 patients who undergo Coronary Artery Bypass Graft (CABG) surgery. The study design is a randomized, double blind, placebo controlled trial incorporating Phase Ib through Phase III components. The Phase Ib stage of the trial is underway and we believe a decision on continuation into the pivotal stages (Phase II/III) of the study will probably be made after evaluation of the first 77 enrolled patients. An additional pivotal study in the United States would need to be initiated for market approval of Resten-CP in this country.

**Infectious Disease Program.** Our infectious disease program is currently focusing on single-stranded RNA viruses using our proprietary NeuGene antisense compounds to target West Nile virus, hepatitis C virus, influenza A virus, dengue virus, the SARS coronavirus, and Ebola Zaire virus, Marburg Musoke virus, and Junin virus, as well as many of the items included on the Department of Homeland Security's list of bioterrorism agents, including 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 development and commercialization in viral diseases will focus on government programs in bioterrorism, like Ebola Zaire and Marburg Musoke, as well as avian influenza, H5N1.

**Genetic Disease Program.** We are conducting an exploratory 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 that is localized to the cell membrane (dystrophin). The absence of dystrophin in muscle cells leads to an abnormally permeable cell ultimately causing its death and replacement by scar tissue. 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, thereby, allowing for production of a new, albeit truncated, dystrophin protein. 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) and entails administration of the drug directly into an affected muscle in DMD boys. We are currently pursuing opportunities to conduct a systemic clinical study with this product with a number of regulatory agencies.

## **Business Strategy**



Our strategy is to:

- focus on near-term opportunities in the cardiovascular disease, infectious diseases and genetic 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 also plan to 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. 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 the 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.

We expect Cook 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 percentage 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. (Ercole) 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.



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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's NeuGene antisense chemistry for the specific targets selected by Ercole. In connection with the December 2006 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.

In May 2007, we entered into a cross-license and collaboration agreement with Ercole to develop drugs that may prove effective in treating the genetic diseases Duchenne muscular dystrophy and beta thalassemia, 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 AVI issued to Ercole shares of AVI's common stock.

On March 13, 2008 AVI announced the execution of a definitive Agreement and Plan of Merger (the "Merger Agreement") pursuant to which Ercole Biotech, Inc. ("Ercole") will become a wholly-owned subsidiary of AVI. Under the terms of the Merger Agreement, subject to adjustment as provided in the Merger Agreement and described below, AVI will issue up to \$7.5 million of AVI common stock, valued at \$1.3161 per share, in exchange for all outstanding shares of Ercole stock not already owned by AVI. In addition, AVI will assume up to \$1.5 million in liabilities of Ercole, to be paid by AVI through a combination of cash and AVI common stock. Liabilities in excess of \$1.5 million will be deducted from the \$7.5 million in common stock. Certain warrants to purchase shares of Ercole's common stock will be exchanged for warrants exercisable for shares of AVI's common stock. Subject to the satisfaction of customary closing conditions, including approval of Ercole's stockholders, the transaction is expected to close by March 21, 2008.

In addition, in anticipation of the closing of the merger, on March 12, 2008, the Company loaned Ercole approximately \$900,000 to be used by Ercole to repay its debt obligation to Isis Pharmaceuticals, Inc. In exchange, Ercole issued a convertible promissory note to the Company. In the event the merger closes, this debt will be forgiven. If the merger does not close, Ercole will either repay the amounts owing or the Company may convert such amounts into shares of Ercole Class A Voting Common Stock.

### *Eleos Agreement*

In January 2007, we announced that we had entered into a cross-license agreement with Eleos Inc. ("Eleos") 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, AVI granted Eleos an exclusive license to AVI's NeuGene® third-generation antisense chemistry to treat cancer with p53-related drugs. In return, Eleos granted an exclusive license to its patents to AVI 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. made an upfront payment of \$500,000 to AVI.

### *Charley's Fund Agreement*

In October 2007, AVI and Charley's Fund, Inc., a nonprofit organization that funds drug development and discovery initiatives specific to Duchenne muscular dystrophy (DMD), announced that AVI had been awarded a \$2.45 million research grant from Charley's Fund. This award will support a new product development program using proprietary exon skipping technologies developed by AVI and its partner, Ercole Biotech, Inc., to overcome the effects of certain genetic errors in the dystrophin gene. The award will allow AVI to accelerate its



development of new therapeutics for DMD.

## **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 site. 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 purchased an additional facility in Corvallis, Oregon. This could provide the Company with future expansion space for the manufacture of potential products and components.

## **Marketing Strategy**

We plan to market initial products, when developed, and for which we obtain regulatory approval, through marketing arrangements or other licensing arrangements with pharmaceutical companies. Implementation of this strategy will depend on many factors, including the market potential of any products we develop, and our financial resources. We do not expect to establish a direct sales capability for therapeutic compounds for at least the next several years, 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**

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

We have developed or acquired a comprehensive body of intellectual property 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 186 patents (domestic and foreign) issued or licensed to us, and 192 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 that 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 licensed certain technology from the United States 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 our patents will be valid or sufficiently broad to protect our technology or provide a significant competitive advantage. Additionally, we cannot provide assurance that 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 to be among 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***



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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 \$34,760,402, \$25,345,588 and \$17,117,750 on research and development activities during the years ended December 31, 2007, 2006 and 2005, 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, 2007, we had 125 employees, 20 of whom hold advanced degrees. One hundred-eight employees are engaged directly in research and development activities, and seventeen 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**



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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>.

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.

*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.

*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 resources 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 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.*

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

We incurred a net loss of \$28.7 million in 2006 and \$27.2 million in 2007. As of December 31, 2007, our accumulated deficit was \$226.4 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 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.*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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.*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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. Patrick Iversen and Dwight Weller. We maintain key man life insurance in the amount of \$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 186 patents (domestic and foreign) issued or licensed to us, and 192 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.

*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.

**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.

*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 64,449,094 shares of common stock as of December 31, 2007 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 6,304,453 shares of common stock of which 4,497,526 shares were exercisable at December 31, 2007. The options outstanding have exercise prices between \$1.76 and \$7.35 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 13,856,411 shares of common stock at December 31, 2007 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 1,834,535 shares of common stock at December 31, 2007 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 208,585 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 purchased an additional facility, totaling 34,000 square feet, in Corvallis, Oregon which could provide the Company with future expansion space for the manufacture of potential products and components. 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, 2007.

**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:

|                             | High    | Low     |
|-----------------------------|---------|---------|
| <u>2006</u>                 |         |         |
| Quarter 1                   | \$ 8.65 | \$ 3.39 |
| Quarter 2                   | 7.55    | 3.71    |
| Quarter 3                   | 4.28    | 2.58    |
| Quarter 4                   | 4.82    | 3.18    |
| <u>2007</u>                 |         |         |
| Quarter 1                   | \$ 3.20 | \$ 2.36 |
| Quarter 2                   | 3.15    | 2.64    |
| Quarter 3                   | 3.06    | 2.49    |
| Quarter 4                   | 3.07    | 1.31    |
| <u>2008</u>                 |         |         |
| Quarter 1 to March 12, 2008 | \$ 1.51 | \$ 1.07 |

The closing price of our common stock on the Nasdaq stock market on March 12, 2008 was \$1.39 per share. The number of shareholders of record and approximate number of beneficial holders on March 10, 2007 was 590 and 11,036 respectively. There were no cash dividends declared or paid in fiscal years 2007 or 2006. We do not anticipate declaring such dividends in the foreseeable future.

During 2007, we issued 39,559 shares of common stock to employees at approximately \$2.27 per share for an aggregate of \$89,740, under our Employee Stock Purchase Plan. During 2006, we issued 41,663 shares of common stock to employees at approximately \$2.95 per share for an aggregate of \$123,005, under our Employee Stock Purchase Plan.

During 2007, we granted 1,263,548 stock options to purchase shares of common stock at approximately \$2.80 per share, under our 2002 Equity Incentive 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.

## Equity Compensation Plan Information

| Plan category                                                 | Number of securities to be<br>issued upon exercise of<br>outstanding options,<br>warrants and rights<br>(a) | Weighted-average exercise price of<br>outstanding options, warrants and<br>rights<br>(b) | Number of securities<br>remaining available for<br>future issuance under<br>equity compensation plans<br>(excluding securities<br>reflected in column (a))<br>(c) |
|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Equity compensation plans<br>approved by security holders     | 4,824,328                                                                                                   | \$ 4.75                                                                                  | 2,043,120                                                                                                                                                         |
| Equity compensation plans not<br>approved by security holders | -0-                                                                                                         |                                                                                          | -0-                                                                                                                                                               |
| <b>Total</b>                                                  | <b>4,824,328</b>                                                                                            | <b>\$ 4.75</b>                                                                           | <b>2,043,120</b>                                                                                                                                                  |

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.

*Comparison of Five-Year Cumulative Total Shareholder Return-December 2002 through December 2007:*

## Performance Graph

The following graph compares the performance of the Company's Common Stock for the periods indicated with the performance of the NASDAQ Composite Index and the Amex Biotech Index. This graph assumes an investment of \$100 on December 31, 2002 in each of the Company's common stock, the NASDAQ Composite Index and the Amex Biotech Index, and assumes reinvestment of dividends, if any. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.

|                    | AVI      | NASDAQ<br>Composite<br>Index | Amex Biotech<br>Index |
|--------------------|----------|------------------------------|-----------------------|
| End of Fiscal 2002 | \$ 100.0 | \$ 100.0                     | \$ 100.0              |
| End of Fiscal 2003 | \$ 81.4  | \$ 150.0                     | \$ 144.9              |
| End of Fiscal 2004 | \$ 47.0  | \$ 162.9                     | \$ 160.9              |
| End of Fiscal 2005 | \$ 69.0  | \$ 165.1                     | \$ 201.3              |
| End of Fiscal 2006 | \$ 63.6  | \$ 180.9                     | \$ 223.0              |
| End of Fiscal 2007 | \$ 28.2  | \$ 198.6                     | \$ 232.5              |



**Item 6. Selected Financial Data**

The following selected financial data is derived from our audited financial statements and should be read in conjunction with, and is qualified in its entirety by, Item 7. Management's Discussion and Analysis or Plan of Operation and Item 8. Financial Statements.

|                                                                   | YEAR ENDED DECEMBER 31, |               |               |               |               |
|-------------------------------------------------------------------|-------------------------|---------------|---------------|---------------|---------------|
|                                                                   | 2007                    | 2006          | 2005          | 2004          | 2003          |
| <b>Operations data:</b>                                           |                         |               |               |               |               |
| Revenues                                                          | \$ 10,985,191           | \$ 115,291    | \$ 4,783,760  | \$ 430,461    | \$ 969,866    |
| Research and development                                          | 34,760,402              | 25,345,588    | 17,117,750    | 20,738,725    | 15,284,396    |
| General and administrative                                        | 9,332,365               | 7,752,752     | 5,182,369     | 4,735,731     | 4,558,948     |
| Interest income, net                                              | 983,976                 | 1,910,037     | 840,495       | 266,301       | 491,098       |
| Gain (loss) on warrant liability                                  | 4,955,875               | 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            |                         |               |               |               |               |
| Net loss                                                          | (27,167,725)            | (28,687,510)  | (18,205,885)  | (21,936,843)  | (13,781,534)  |
| Net loss per share - basic and diluted                            | (0.50)                  | (0.54)        | (0.41)        | (0.61)        | (0.46)        |
| <b>Balance sheet data:</b>                                        |                         |               |               |               |               |
| Cash and investments                                              | \$ 25,074,413           | \$ 33,152,132 | \$ 47,051,082 | \$ 19,515,316 | \$ 37,599,136 |
| Working capital                                                   | 18,959,122              | 25,596,492    | 38,327,343    | 17,948,793    | 34,639,526    |
| Total assets                                                      | 38,637,930              | 40,862,746    | 56,407,982    | 28,518,631    | 47,145,023    |
| Shareholders' equity                                              | 26,381,748              | 32,519,325    | 46,081,931    | 24,456,708    | 39,685,852    |

**Item 7. Management's Discussion and Analysis or Plan of Operation****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,

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

- 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



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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, 2007, our accumulated deficit was \$226,357,555.

## Results of Operations

*Year Ended December 31, 2007 Compared with Year Ended December 31, 2006.*

Revenues, from license fees, grants and research contracts, increased from \$115,291 in 2006 to \$10,985,191 in 2007, due to increases in research contracts revenues of \$10,795,943 and license fees of \$125,000, partially offset by decreases in grants revenues of \$51,043. Revenues for 2007 were primarily due to the recognition of \$10,710,330 in research contract revenue from government funding for work performed on viral disease research projects.

Operating expenses increased from \$33,098,340 in 2006 to \$44,092,767 in 2007 due to increases in research and development, which increased from \$25,345,588 in 2006 to \$34,760,402 in 2007, and increases in general and administrative costs, which increased from \$7,752,752 in 2006 to \$9,332,365 in 2007. This research and development increase for 2007 was due primarily to approximately \$4,500,000 expensed for government research contracts and approximately \$3,900,000 for contracting costs for the production of GMP subunits, which are used by the Company to manufacture compounds for future clinical trials. In addition, professional consultant costs increased approximately \$730,000, government contract related equipment expenses of approximately \$735,000, chemical and lab supply costs increased approximately \$655,000, and patent amortization expenses increased approximately \$100,000. These research and development increases were partially offset by decreases in employee costs of approximately \$1,200,000, of which approximately \$430,000 was related to the acceleration of the vesting of certain stock options in the first quarter of 2006 and decreases in SFAS 123R expenses of approximately \$530,000 and salary and bonuses of approximately \$180,000. The general and administrative increase for 2007 was due primarily to increases in compensation costs of approximately \$850,000, of which approximately \$1,620,000 (including \$562,500 in cash compensation and \$1,057,372 in SFAS 123R expenses) was related to the Separation and Release Agreement with the Company's former Chief Executive Officer and \$100,000 in non-employee compensation, partially offset by decreases in SFAS 123R expenses of approximately \$320,000 and salary and bonuses of approximately \$550,000. General and administrative also includes increases in legal expenses of approximately \$650,000 and accounting expenses of approximately \$185,000, partially offset by decreases in advertising costs of approximately \$80,000.

Net interest income decreased from \$1,910,037 in 2006 to \$983,976 in 2007 due to decreases in average cash, cash equivalents and short-term securities, partially offset by increases in average interest rates of the Company's interest earning investments. Gain on warrant liability increased from \$2,385,502 in 2006 to \$4,955,875 in 2007. 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.

*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 included with this report on Form 10-K. 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 included with this report on Form 10-K. 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.

## Research and Development Expenses

Historically, the Company has maintained a focus internally upon the development of its core platform antisense technology known as Phosphorodiamidate Morpholino Oligomers (PMOs), also known under the registered trademark of NEUGENES. All internal research and development projects have been performed with the goal of defining the uses, breadth of applicability, limitations, and possible modifications surrounding PMOs. Thus, even specific projects had overarching or common impact upon expanding the Company's knowledge base surrounding this technology. Accordingly, essentially all of the Company's research and development resources have been dedicated to this goal. External research projects may tend to be more focused on given disease areas, but also generate results that have a breadth of applicability across the platform. These external research projects are generally performed at low, or no cost to the Company. Thus, the totals shown for research and development in the Statements of Operations for 2006 and 2005 reflect the amounts of the Company's resources being used toward the above stated goal.

In 2007 the Company began allocating costs on a more program-oriented basis. Our research and development costs allocated by program for the year ended December 31, 2007 were as follows:

|                                        | 2007          |
|----------------------------------------|---------------|
| Program areas:                         |               |
| Infectious diseases                    | \$ 8,871,127  |
| Cardiovascular diseases                | 2,212,434     |
| Genetic diseases                       | 1,854,081     |
| Total programs                         | 12,937,641    |
| Discovery research                     | 21,822,761    |
| Total research and development expense | \$ 34,760,402 |

Direct research and development costs associated with our programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants and other outside services, such as data management and statistical analysis support, and materials and supplies used in support of the clinical programs, as well as other direct research. Indirect costs of our clinical program include wages, payroll taxes and other employee-related expenses including rent, restructuring, stock based compensation, utilities and other facilities-related maintenance. The costs in each category may change in the future and new categories may be added. Costs attributable to our discovery research programs represent our efforts to develop and expand our product pipeline. Due to the number of projects and our ability to utilize resources across several programs, our discovery research costs are not assigned to specific programs.

While we believe our programs are promising, we do not know whether any commercially viable products will result from our research and development efforts. Thus, we believe that the nature, timing, and estimated costs of the efforts necessary to complete the projects and the anticipated completion dates, are not estimable due to many factors, including the following:

- Delivery strategies and potency enhancements of the Company's compounds are still being developed and explored;
- Variability among different disease categories result in successful delivery strategies or potency enhancements not necessarily being applicable across different disease categories;
- Costs of clinical trials, like costs of all forms of medical care, are rapidly changing;
- Variability among different disease categories in terms of dosages, duration of treatment, method of administration, etc. exist;
- Rules surrounding filings and conduct of clinical trials are changing;
- Confidentiality surrounding commercialization is heightening; and
- Clinical endpoints are in a constant state of flux.

### **Liquidity and Capital Resources**

We have financed our operations since inception primarily through sales of common stock and other forms of equity totaling \$215,015,674, from grants and contract research funding of \$20,966,010 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 2008, we expect our expenditures for operations, net of government funding, including our collaborative efforts, and our GMP facilities to be approximately \$19 to \$22 million. This cost could increase if we undertake additional collaborative efforts. However, if need be in 2008, 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 2008.

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 Phase II 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, 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 December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). In February 2008, the contract was extended into the first five months of 2009. The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. During the year ended December 31, 2007, the Company recognized \$8,018,389 in research contract revenue from this contract. Funding of \$24.5 million has been committed through 2008, with the remainder of the contract anticipated in 2009.

In January 2006, the Company announced that the final version of the 2006 Defense Appropriations Act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, we anticipate that we will receive up to \$9.8 million under this allocation. The Company's NEUGENE<sup>®</sup> technology is expected to 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 has received signed contracts for all four of these projects. The Company expects that funding under these signed contracts will be received over the next 12 months. During the year ended December 31, 2007, the Company recognized \$2,691,941 in research contract revenue from these contracts.

Our cash, cash equivalents and short-term securities were \$25,074,413 at December 31, 2007, compared with \$33,152,132 at December 31, 2006. The decrease of \$8,077,719 was due primarily to \$24,677,155 used in operations and \$2,127,094 used for purchases of property and equipment and patent related costs, offset by the receipt of \$18,626,206 in net proceeds from a private equity financing with several institutional investors completed in December 2007 and \$118,742 from the exercise of options and sales under the Company's employee stock purchase plan during the year ended December 31, 2007. In the private equity financing, the Company sold units consisting of one share of common stock, and one-half warrant to purchase a share of common stock for \$1.90 per unit. A total of 10,696,616 shares of common stock and warrants for the purchase of 5,348,308 common shares at \$2.45 per share were sold. These warrants are exercisable starting June 19, 2008 and expire on December 18, 2012.

We do not expect any material revenues in 2008 from our business activities. We expect that our cash requirements for the balance of calendar 2008 will be satisfied by existing cash resources. To fund our operations beyond 2008, 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.

### Off-Balance Sheet Arrangements

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 2007, these expenses totaled \$1,388,000 for operating leases and \$125,000 for royalty payments.

### Contractual Payment Obligations

A summary of our contractual commitments and obligations as of December 31, 2007 is as follows:

| Contractual Obligation | Total         | Payments Due By Period |               |               |                 |
|------------------------|---------------|------------------------|---------------|---------------|-----------------|
|                        |               | 2008                   | 2009 and 2010 | 2011 and 2012 | 2013 and beyond |
| Operating leases       | \$ 18,100,000 | \$ 1,222,000           | \$ 2,387,000  | \$ 2,566,000  | \$ 11,925,000   |
| Royalty payments       | 1,880,000     | 125,000                | 250,000       | 230,000       | 1,275,000       |
|                        | \$ 19,980,000 | \$ 1,347,000           | \$ 2,637,000  | \$ 2,796,000  | \$ 13,200,000   |

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 with this report on Form 10-K included under Part III, Item 15.



**Critical Accounting Policies and Estimates**



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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***

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

Revenue is recorded from research contracts and grants as the services are performed and payment is reasonably assured. In 2007, the Company recognized \$10,710,330 in research contracts revenues from government funding for work performed on viral disease projects. 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*

Long-lived assets held and used by us and intangible assets with determinable lives are reviewed for impairment whenever events or circumstances indicate that the carrying amount of assets may not be recoverable in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. We evaluate recoverability of assets to be held and used by comparing the carrying amount of an asset to future net undiscounted cash flows to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Such reviews assess the fair value of the assets based upon estimates of future cash flows that the assets are expected to generate.

### *Stock-based Compensation Expense*

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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 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.

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**

The information required by this Item 8 begins on page F-1 in Item 15 of Part III of this report on Form 10-K and is incorporated into this item by reference.

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

None.

#### **Item 9A. Controls and Procedures**

##### *Disclosure Controls and Procedures*

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 15d-14 under the Securities Exchange Act of 1934 as of December 31, 2007. Based on that review, the Chief Executive Officer and the

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Securities and Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

The Company does not expect that its disclosure controls and procedures will prevent all error and all fraud. A control procedure, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control procedure are met. Because of the inherent limitations in all control procedures, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any,

within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The Company considered these limitations during the development of its disclosure controls and procedures, and will continually reevaluate them to ensure they provide reasonable assurance that such controls and procedures are effective.

#### *Internal Controls and Procedures*

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

#### *Management's Annual Report on Internal Control over Financial Reporting*

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

- Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

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

The Company's management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2007. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on management's assessment and those criteria, we believe that, as of

December 31, 2007, the Company's internal control over financial reporting is effective.

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

The Board of Directors and Shareholders

AVI BioPharma, Inc.:

We have audited AVI BioPharma, Inc.'s (an Oregon corporation in the development stage) internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management of AVI BioPharma, Inc. is responsible for maintaining effective internal control over financial reporting, included in the accompanying *Management's Annual Report on 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 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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, AVI BioPharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of AVI BioPharma, Inc. as of December 31, 2007 and 2006, and the related statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2007, and 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<sup>nd</sup>, 1980 (inception) through December 31, 2001, is based solely on the report of other auditors. Our report dated March 17, 2008 expressed an unqualified opinion on those consolidated financial statements.

(signed) KPMG LLP

Portland, OR

March 17, 2008

**Item 9B. Other Information**

None.

**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 2008 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

**Item 11. Executive Compensation**

The information required by this item is included in our definitive proxy statement for our 2008 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 2008 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 2008 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 2008 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 and Financial Statement Schedules**

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

(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  | F-1 |
| Report of Arthur Andersen, Independent Auditors                    | F-2 |
| Balance Sheets                                                     | F-3 |
| Statements of Operations                                           | F-4 |
| Statements of Shareholders' Equity and Comprehensive Income (Loss) | F-5 |
| Statements of Cash Flows                                           | F-6 |
| Notes to Financial Statements                                      | F-7 |

**Financial Statement Schedules**

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



**(b) Exhibits**



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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

| Exhibit No. | Description                                                                                                                                                           |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.1         | Underwriting Agreement dated November 14, 2005. (15)                                                                                                                  |
| 1.2         | Placement Agency Agreement between AVI BioPharma, Inc. and Citigroup Global Markets Inc., Oppenheimer & Co. Inc., and Maxim Group, LLC, dated December 12, 2007. (22) |
| 3.1         | Third Restated Articles of Incorporation of AntiVirals Inc. (1)                                                                                                       |
| 3.2         | First Restated Bylaws of AVI BioPharma, Inc. (28)                                                                                                                     |
| 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         | Warrant to purchase 485,290 shares of the Company's common stock dated November 14, 2005. (16)                                                                        |
| 4.3         | Form of Warrant to Purchase Common Stock, issued in connection with the Placement Agency Agreement dated December 12, 2007. (23)                                      |
| 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       | Purchase Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors. (5)                                                            |
| 10.17       | Registration Rights Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors. (5)                                                 |
| 10.18       | Purchase Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors. (5)                                                            |
| 10.19       | Registration Rights Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors. (5)                                                 |
| 10.20       | Subscription Agreement, dated December 1, 1999, by and between SuperGen, Inc. and AVI BioPharma, Inc. (5)                                                             |

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

|        |                                                                                                                                                  |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| 10.21  | 2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc. (6)                                  |
| 10.22  | United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7) |
| 10.23  | Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)                             |
| 10.24  | Registration Rights Agreement, dated April 14, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)                                          |
| 10.25  | 2000 Employee Share Purchase Plan. (8)                                                                                                           |
| 10.26  | Employment Agreement with Mark M. Webber dated May 11, 2000. (9)                                                                                 |
| 10.27  | Lease Agreement with Spieker Partners, LP dated May 8, 2001. (9)                                                                                 |
| 10.28* | Investment Agreement dated May 22, 2001 between the Company and Medtronic Asset Management, Inc. (9)                                             |
| 10.29  | Warrant dated June 20, 2001 issued to Medtronic Asset Management, Inc. (9)                                                                       |
| 10.30  | Registration Rights Agreement dated June 20, 2001 between the Company and Medtronic Asset Management, Inc. (9)                                   |
| 10.31* | License and Development Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)                                                |
| 10.32* | Supply Agreement dated June 20, 2001 between the Company and Medtronic, Inc. (9)                                                                 |
| 10.33  | Securities Purchase Agreement dated March 25, 2002 between the Company and certain purchasers ( SPA ). (10)                                      |
| 10.34  | Form of Warrant issued by the Company to certain purchasers under the SPA (10)                                                                   |
| 10.35  | Registration Rights Agreement dated March 25, 2002 between the Company and certain purchasers. (10)                                              |
| 10.36  | 2002 Equity Incentive Plan. (11)                                                                                                                 |
| 10.37  | Securities Purchase Agreement dated January 19, 2005 between the Company and certain purchasers ( SPA ). (12)                                    |
| 10.38  | Form of Purchase Warrant issued by the Company to certain purchasers under the SPA. (12)                                                         |
| 10.39  | Amendment to employment agreement of Denis R. Burger, Ph.D. (14)                                                                                 |
| 10.40  | Amendment to employment agreement of Alan P. Timmins. (14)                                                                                       |
| 10.41  | Amendment to employment agreement of Patrick L. Iversen, Ph.D. (14)                                                                              |
| 10.42  | Amendment to employment agreement of Dwight D. Weller, Ph.D. (14)                                                                                |
| 10.43  | Amendment to employment agreement of Peter D. O Hanley, M.D., Ph.D. (14)                                                                         |
| 10.44  | Amendment to employment agreement of Mark M. Webber. (14)                                                                                        |
| 10.45  | Securities Purchase Agreement dated November 14, 2005 between the Company and certain purchasers. (16)                                           |
| 10.46* | Supply Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)                                      |
| 10.47* | License and Development Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)                     |
| 10.48* | Investment Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)                                  |
| 10.49* | License Agreement dated January 26, 2006 by and between with Chiron Corporation and AVI BioPharma, Inc. (18)                                     |
| 10.50  | Stock Purchase Agreement dated January 26, 2006 by and between with Chiron Corporation and A VI BioPharma, Inc. (18)                             |
| 10.51  | Second Lease Extension and Modification Agreement dated January 24, 2006 by and between Research Way Investments and AVI BioPharma, Inc. (19)    |
| 10.52* | Collaboration and License Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (20)                   |

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

- 10.53 Series A-2 Preferred Stock and Common Stock Purchase Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (21)
- 10.54\* Cross License Agreement dated January 8, 2007 by and between Eleos, Inc. and AVI BioPharma, Inc. (24)
- 10.55 Separation and Release Agreement dated March 27, 2007 by and between Denis R. Burger, Ph.D. and AVI BioPharma, Inc. (25)
- 10.56\* Second License and Collaboration Agreement dated May 1, 2007 by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (26)
- 10.57 Real Property Purchase Agreement, dated April 19, 2007, by and between WKL Investments Airport, LLC and AVI BioPharma, Inc. (27)
- 10.58\* Sponsored Research Agreement between AVI BioPharma, Inc. and Charley s Fund, Inc., effective October 12, 2007 (filed herewith).
- 10.59 Shareholder s Trust Agreement between and among AVI BioPharma, Inc., AVI Shareholder Advocacy Trust, The Shareholder Advocate LLC, and Richard Macary, dated October 29, 2007 (filed herewith).
- 10.60 Amended and Restated Employment Agreement between Alan P. Timmins and AVI BioPharma, Inc., dated October 26, 2007 (filed herewith).
- 10.61 Professional Services Agreement between James B. Hicks Ph.D., LLC and AVI BioPharma, Inc., dated October 26, 2007 (filed herewith).
- 10.62 Letter Agreement executed by George Haywood, dated October 29, 2007 (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, Leslie Hudson, Ph.D., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of the Company s Chief Financial Officer, Mark M. Webber, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.0 Certification of CEO and CFO Pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 
- (1) Incorporated by reference to Exhibits to Registrant s Registration Statement on Form SB-2, as amended and filed with the Securities and Exchange Commission on May 29, 1997 (Commission Registration No. 333-20513).
  - (2) Incorporated by reference to Exhibits to Registrant s Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, and filed with the Securities and Exchange Commission on March 30, 1998.
  - (3) Incorporated by reference to Exhibits to Registrant s Registration Statement on Form S-4, as amended, and filed with the Securities and Exchange Commission on August 7, 1998 (Commission Registration No. 333-60849).
  - (4) Incorporated by reference to Exhibits to Registrant s current report on Form 8-K, as filed with the Securities and Exchange Commission on September 30, 1998 (Commission Registration No. 000-22613).
  - (5) Incorporated by reference to Exhibits to Registrant s Registration Statement on Form S-3, as amended, and filed with the Securities and Exchange Commission on December 21, 1999 (Commission Registration No. 333-93135).

- (6) Incorporated by reference to Exhibits to Registrant's Registration Statement on Form S-1 and filed with the Securities and Exchange Commission on June 16, 2000 (Commission Registration No. 333-39542).
- (7) Incorporated by reference to Exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on September 15, 2000 (Commission Registration No. 333-45888).
- (8) Incorporated by reference to Appendix A to Registrant's Definitive Proxy Statement on Form 14-A, as amended, filed with the Securities and Exchange Commission on April 12, 2000.
- (9) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2001, and filed with the Securities and Exchange Commission on August 14, 2001, as amended on April 23, 2002.
- (10) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on April 2, 2002.
- (11) Incorporated by reference to appendixes to Registrant's Definitive Proxy Statement on Schedule 14-A, as filed with the Securities and Exchange Commission on April 11, 2002.
- (12) Incorporated by reference to registrants current report on Form 8-K, as filed with the Securities and Exchange Commission on January 20, 2005.
- (13) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and filed with the Securities and Exchange Commission on March 15, 2004.
- (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.

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

- (20) Incorporated by reference to Exhibit 10.56 to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, filed with the Securities and Exchange Commission on March 16, 2007.
- (21) Incorporated by reference to Exhibit 10.57 to the Registrant's Form 10-K for the fiscal year ended December 31, 2006, filed with the Securities and Exchange Commission on March 16, 2007.
- (22) Incorporated by reference to Exhibit 1.01 to the Registrant's Form 8-K filed with the Securities and Exchange Commission on December 13, 2007.
- (23) Incorporated by reference to Exhibit 4.5 to the Registrant's Form 8-K filed with the Securities and Exchange Commission on December 13, 2007.
- (24) Incorporated by reference to Exhibit 10.58 to the Registrant's Form 10-Q for the quarterly period ended March 31, 2007, filed with the Securities and Exchange Commission on May 10, 2007.
- (25) Incorporated by reference to Exhibit 10.59 to the Registrant's Form 10-Q for the quarterly period ended March 31, 2007, filed with the Securities and Exchange Commission on May 10, 2007.
- (26) Incorporated by reference to Exhibit 10.60 to the Registrant's Form 10-Q for the quarterly period ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007.
- (27) Incorporated by reference to Exhibit 10.61 to the Registrant's Form 10-Q for the quarterly period ended June 30, 2007, filed with the Securities and Exchange Commission on August 9, 2007.
- (28) Incorporated by reference to Exhibit 3.5 to the Registrant's Form 8-K filed with the Securities and Exchange Commission on February 7, 2008.

(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 (\*).

## SIGNATURES

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

Dated: March 17, 2008

AVI BIOPHARMA, INC.

By: /s/ Leslie Hudson, Ph.D.  
Leslie Hudson, Ph.D.  
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 17, 2008:

| Signature                                        | Title                                                                                                 |
|--------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| /s/ LESLIE HUDSON, Ph.D.<br>Leslie Hudson, Ph.D. | Chief Executive Officer and Director<br>(Principal Executive Officer)                                 |
| /s/ ALAN P. TIMMINS<br>Alan P. Timmins           | President and 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/ MICHAEL D. CASEY<br>Michael D. Casey         | Chairman of the Board                                                                                 |
| /s/ JOHN W. FARA, Ph.D.<br>John W. Fara, Ph.D.   | Director                                                                                              |
| /s/ K. MICHAEL FORREST<br>K. Michael Forrest     | Director                                                                                              |
| /s/ WILLIAM A. GOOLSBEE<br>William A. Goolsbee   | Director                                                                                              |
| /s/ JOHN C. HODGMAN<br>John C. Hodgman           | Director                                                                                              |
| /s/ GIL PRICE, M.D.<br>Gil Price, M.D.           | 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, 2007 and 2006, and the related statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2007 and for the period from July 22, 1980 (inception) through December 31, 2007. 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, shareholder 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, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007 and for the period from July 22, 1980 (inception) through December 31, 2007, 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*.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), AVI BioPharma's internal control over financial reporting as of December 31, 2007, 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 17, 2008 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Portland, OR

(signed) KPMG LLP

**March 17, 2008**

F-1

---

***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,  |               |
|------------------------------------------------------------------------------------------------------------------|---------------|---------------|
|                                                                                                                  | 2007          | 2006          |
| <b>Assets</b>                                                                                                    |               |               |
| Current Assets:                                                                                                  |               |               |
| Cash and cash equivalents                                                                                        | \$ 24,802,562 | \$ 20,159,201 |
| Short-term securities available-for-sale                                                                         | 271,851       | 12,992,931    |
| Accounts receivable                                                                                              | 2,869,760     | 51,498        |
| Other current assets                                                                                             | 767,278       | 736,283       |
| Total Current Assets                                                                                             | 28,711,451    | 33,939,913    |
| Property and Equipment, net of accumulated depreciation and amortization of \$11,816,549 and \$10,174,712        | 6,825,145     | 4,329,583     |
| Patent Costs, net of accumulated amortization of \$1,725,074 and \$1,496,699                                     | 3,066,625     | 2,558,541     |
| Other Assets                                                                                                     | 34,709        | 34,709        |
| Total Assets                                                                                                     | \$ 38,637,930 | \$ 40,862,746 |
| <b>Liabilities and Shareholders' Equity</b>                                                                      |               |               |
| Current Liabilities:                                                                                             |               |               |
| Accounts payable                                                                                                 | \$ 3,026,072  | \$ 1,401,584  |
| Accrued employee compensation                                                                                    | 1,171,666     | 1,371,353     |
| Long-term debt, current portion                                                                                  | 71,099        |               |
| Warrant liability                                                                                                | 4,414,657     | 5,192,576     |
| Deferred revenue                                                                                                 | 737,500       |               |
| Other liabilities                                                                                                | 331,335       | 377,908       |
| Total Current Liabilities                                                                                        | 9,752,329     | 8,343,421     |
| Commitments and Contingencies                                                                                    |               |               |
| Long-term debt, non-current portion                                                                              | 2,070,704     |               |
| Other long-term liabilities                                                                                      | 433,149       |               |
| 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; 64,449,094 and 53,182,841 issued and outstanding | 6,445         | 5,318         |
| Additional paid-in capital                                                                                       | 252,732,858   | 231,685,419   |
| Accumulated other comprehensive income                                                                           |               | 18,418        |
| Deficit accumulated during the development stage                                                                 | (226,357,555) | (199,189,830) |
| Total Shareholders' Equity                                                                                       | 26,381,748    | 32,519,325    |
| Total Liabilities and Shareholders' Equity                                                                       | \$ 38,637,930 | \$ 40,862,746 |

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

|                                                                                                     | 2007            | Year ended December 31,<br>2006 | 2005            | July 22, 1980<br>(Inception) through<br>December 31, 2007 |
|-----------------------------------------------------------------------------------------------------|-----------------|---------------------------------|-----------------|-----------------------------------------------------------|
| Revenues from license fees, grants and research contracts                                           | \$ 10,985,191   | \$ 115,291                      | \$ 4,783,760    | \$ 20,966,010                                             |
| Operating expenses:                                                                                 |                 |                                 |                 |                                                           |
| Research and development                                                                            | 34,760,402      | 25,345,588                      | 17,117,750      | 182,407,617                                               |
| General and administrative                                                                          | 9,332,365       | 7,752,752                       | 5,182,369       | 50,152,893                                                |
| Acquired in-process research and development                                                        |                 |                                 |                 | 19,545,028                                                |
|                                                                                                     | 44,092,767      | 33,098,340                      | 22,300,119      | 252,105,538                                               |
| Other income (loss):                                                                                |                 |                                 |                 |                                                           |
| Interest income, net                                                                                | 983,976         | 1,910,037                       | 840,495         | 8,433,518                                                 |
| Gain (loss) on warrant liability                                                                    | 4,955,875       | 2,385,502                       | (1,530,021)     | 9,487,301                                                 |
| 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)                                              |
|                                                                                                     | 5,939,851       | 4,295,539                       | (689,526)       | 4,781,973                                                 |
| Net loss                                                                                            | \$ (27,167,725) | \$ (28,687,510)                 | \$ (18,205,885) | \$ (226,357,555)                                          |
| Net loss per share - basic and diluted                                                              | \$ (0.50)       | \$ (0.54)                       | \$ (0.41)       |                                                           |
| Weighted average number of common shares outstanding for computing basic and diluted loss per share | 53,942,015      | 52,660,711                      | 44,655,008      |                                                           |

See accompanying notes to financial statements.

## 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 | Accumulated<br>Other<br>Comprehensive<br>Income<br>(Loss) | Deficit<br>Accumulated<br>During the<br>Development<br>Stage | Total<br>Shareholders<br>Equity |
|---------------------------------------------------------------------------------------------------|----------------------|------------------------|------------------------|----------------------------------|-----------------------------------------------------------|--------------------------------------------------------------|---------------------------------|
| BALANCE AT JULY 22, 1980<br>(Inception)                                                           |                      |                        | \$                     | \$                               | \$                                                        | \$                                                           | \$                              |
| Issuance of partnership units,<br>warrants and common stock                                       | 3,615                | 8,272,916              | 828                    | 33,732,654                       |                                                           |                                                              | 33,733,482                      |
| Compensation expense related to<br>issuance of warrants for common<br>stock and partnership units |                      |                        |                        | 537,353                          |                                                           |                                                              | 537,353                         |
| Exercise of warrants for<br>partnership units and common<br>stock                                 | 42                   | 1,530,858              | 152                    | 1,809,165                        |                                                           |                                                              | 1,809,317                       |
| Exercise of options for common<br>stock                                                           |                      | 734,668                | 73                     | 3,168,373                        |                                                           |                                                              | 3,168,446                       |
| Issuance of common stock for<br>ESPP                                                              |                      | 149,339                | 15                     | 576,037                          |                                                           |                                                              | 576,052                         |
| Issuance of common stock and<br>warrants for cash and securities,<br>net of offering costs        |                      | 21,551,397             | 2,155                  | 118,308,532                      |                                                           |                                                              | 118,310,687                     |
| Issuance of common stock and<br>warrants for the acquisition of<br>ImmunoTherapy Corporation      |                      | 2,132,592              | 213                    | 17,167,199                       |                                                           |                                                              | 17,167,412                      |
| Issuance of common stock and<br>warrants for services                                             |                      | 192,848                | 20                     | 919,243                          |                                                           |                                                              | 919,263                         |
| Compensation expense related to<br>issuance of options for common<br>stock                        |                      |                        |                        | 1,041,349                        |                                                           |                                                              | 1,041,349                       |
| Conversion of debt into common<br>stock and partnership units                                     | 9                    | 9,634                  | 1                      | 87,859                           |                                                           |                                                              | 87,860                          |
| Issuance of common stock in<br>exchange for partnership units                                     | (1,810)              | 1,632,950              | 163                    | (163)                            |                                                           |                                                              |                                 |
| Withdrawal of partnership net<br>assets upon conveyance of<br>technology                          | (1,856)              |                        |                        | (176,642)                        |                                                           |                                                              | (176,642)                       |
| Common stock subject to<br>rescission, net                                                        |                      | (64,049)               | (6)                    | (288,789)                        |                                                           |                                                              | (288,795)                       |
| Comprehensive income (loss):                                                                      |                      |                        |                        |                                  |                                                           |                                                              |                                 |
| Write-down of short-term<br>securities 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<br>securities available-for-sale                                    |                      |                        |                        |                                  | (13,368,237)                                              |                                                              | (13,368,237)                    |
| Net loss                                                                                          |                      |                        |                        |                                  |                                                           | (152,296,435)                                                | (152,296,435)                   |
| Comprehensive loss                                                                                |                      |                        |                        |                                  |                                                           |                                                              | (152,429,076)                   |
| BALANCE AT DECEMBER 31,<br>2004                                                                   |                      | 36,143,153             | \$ 3,614               | \$ 176,882,170                   | \$ (132,641)                                              | \$ (152,296,435)                                             | \$ 24,456,708                   |
| Exercise of options for common<br>stock                                                           |                      | 37,029                 | 4                      | 94,950                           |                                                           |                                                              | 94,954                          |
| Issuance of common stock for<br>ESPP                                                              |                      | 60,854                 | 6                      | 110,724                          |                                                           |                                                              | 110,730                         |
| Compensation expense related to<br>issuance of options for common                                 |                      |                        |                        | 394,225                          |                                                           |                                                              | 394,225                         |

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

|                                                                         |            |          |                |           |                  |               |  |
|-------------------------------------------------------------------------|------------|----------|----------------|-----------|------------------|---------------|--|
| stock                                                                   |            |          |                |           |                  |               |  |
| Issuance of common stock and warrants 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 | \$ 12,968 | \$ (170,502,320) | \$ 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 | \$ 18,418 | \$ (199,189,830) | \$ 32,519,325 |  |
| Exercise of options for common stock                                    | 11,639     | 1        | 29,001         |           |                  | 29,002        |  |
| Issuance of common stock for ESPP                                       | 39,559     | 4        | 89,736         |           |                  | 89,740        |  |
| Issuance of common stock to vendors                                     | 518,439    | 52       | 1,449,948      |           |                  | 1,450,000     |  |
| Compensation expense related to issuance of options for common stock    |            |          | 312,637        |           |                  | 312,637       |  |
| Issuance of common stock for cash and securities, net of offering costs | 10,696,616 | 1,070    | 14,447,180     |           |                  | 14,448,250    |  |
| Stock-based compensation                                                |            |          | 4,718,937      |           |                  | 4,718,937     |  |
| Comprehensive income (loss):                                            |            |          |                |           |                  |               |  |
| Unrealized gain on short-term securities available-for-sale, net        |            |          |                | (18,418)  |                  | (18,418)      |  |
| Net loss                                                                |            |          |                |           | (27,167,725)     | (27,167,725)  |  |
| Comprehensive loss                                                      |            |          |                |           |                  | (27,186,143)  |  |
| BALANCE AT DECEMBER 31, 2007                                            | 64,449,094 | \$ 6,445 | \$ 252,732,858 | \$        | \$ (226,357,555) | \$ 26,381,748 |  |

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

|                                                                                                                                  | 2007            | Year ended December 31,<br>2006 | 2005            | For the Period<br>July 22, 1980<br>(Inception) through<br>December 31, 2007 |
|----------------------------------------------------------------------------------------------------------------------------------|-----------------|---------------------------------|-----------------|-----------------------------------------------------------------------------|
| Cash flows from operating activities:                                                                                            |                 |                                 |                 |                                                                             |
| Net loss                                                                                                                         | \$ (27,167,725) | \$ (28,687,510)                 | \$ (18,205,885) | \$ (226,357,555)                                                            |
| Adjustments to reconcile net loss to net cash flows used in operating activities:                                                |                 |                                 |                 |                                                                             |
| Depreciation and amortization                                                                                                    | 2,013,859       | 2,090,375                       | 1,997,672       | 14,834,098                                                                  |
| Loss on disposal of assets                                                                                                       | 59,381          | 192,369                         | 35,862          | 374,559                                                                     |
| 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                                                                                              | 700,000         | 1,375,000                       |                 | 2,075,000                                                                   |
| 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          | 312,637         | 525,126                         | 394,225         | 2,955,690                                                                   |
| Stock-based compensation                                                                                                         | 4,718,937       | 4,881,470                       |                 | 9,600,407                                                                   |
| Conversion of interest accrued to common stock                                                                                   |                 |                                 |                 | 7,860                                                                       |
| Acquired in-process research and development                                                                                     |                 |                                 |                 | 19,545,028                                                                  |
| (Gain) loss on warrant liability                                                                                                 | (4,955,875)     | (2,385,502)                     | 1,530,021       | (9,487,301)                                                                 |
| (Increase) decrease in:                                                                                                          |                 |                                 |                 |                                                                             |
| Accounts receivable and other current assets                                                                                     | (2,849,257)     | 814,531                         | (919,237)       | (3,637,038)                                                                 |
| Other assets                                                                                                                     |                 | 2,900                           |                 | (34,709)                                                                    |
| Net increase in accounts payable, accrued employee compensation, long-term debt, deferred revenue, and other liabilities         | 2,490,888       | 577,872                         | 498,375         | 5,936,733                                                                   |
| Net cash used in operating activities                                                                                            | (24,677,155)    | (20,613,369)                    | (14,668,967)    | (170,186,727)                                                               |
| Cash flows from investing activities:                                                                                            |                 |                                 |                 |                                                                             |
| Purchase of property and equipment                                                                                               | (1,269,880)     | (767,282)                       | (1,070,801)     | (16,568,391)                                                                |
| Patent costs                                                                                                                     | (857,214)       | (686,607)                       | (397,081)       | (5,332,244)                                                                 |
| Purchase of marketable securities                                                                                                | (110,417)       | (14,969,926)                    | (13,140,581)    | (112,976,213)                                                               |
| Sale of marketable securities                                                                                                    | 12,813,079      | 14,435,793                      | 3,693,329       | 117,613,516                                                                 |
| Acquisition costs                                                                                                                |                 |                                 |                 | (2,377,616)                                                                 |
| Net cash provided by (used in) investing activities                                                                              | 10,575,568      | (1,988,022)                     | (10,915,134)    | (19,640,948)                                                                |
| Cash flows from financing activities:                                                                                            |                 |                                 |                 |                                                                             |
| Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants | 18,744,948      | 8,162,858                       | 43,527,006      | 215,015,674                                                                 |
| 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                                                                                        | 18,744,948      | 8,162,858                       | 43,527,006      | 214,630,237                                                                 |
| Increase (decrease) in cash and cash equivalents                                                                                 | 4,643,361       | (14,438,533)                    | 17,942,905      | 24,802,562                                                                  |
| Cash and cash equivalents:                                                                                                       |                 |                                 |                 |                                                                             |
| Beginning of period                                                                                                              | 20,159,201      | 34,597,734                      | 16,654,829      |                                                                             |
| End of period                                                                                                                    | \$ 24,802,562   | \$ 20,159,201                   | \$ 34,597,734   | \$ 24,802,562                                                               |

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

## 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 (loss) on short-term securities available-for-sale              | \$ | (18,418)  | \$ | 5,450   | \$ | 145,609 | \$ |            |
| Issuance of common stock and warrants in satisfaction of liabilities                      | \$ |           | \$ | 175,000 | \$ |         | \$ | 545,000    |
| Issuance of common stock for building purchase                                            | \$ | 750,000   | \$ |         | \$ |         | \$ | 750,000    |
| Assumption of long-term debt for building purchase                                        | \$ | 2,199,792 | \$ |         | \$ |         | \$ | 2,199,792  |

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 \$24,802,562 and \$20,159,201 as of December 31, 2007 and 2006, 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 \$0 and \$18,418 as of December 31, 2007 and 2006, 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 collectability of individual accounts receivable is known by the company. Amounts included in accounts receivable are as follows:

| As of December 31, | 2007         | 2006      |
|--------------------|--------------|-----------|
| Research contract  | \$ 2,837,615 | \$ 45,846 |
| Grant              | 11,899       | 5,652     |
| Miscellaneous      | 20,246       |           |

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

|                     |    |           |    |        |
|---------------------|----|-----------|----|--------|
| Accounts receivable | \$ | 2,869,760 | \$ | 51,498 |
|---------------------|----|-----------|----|--------|

## *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

---

Amounts included in property and equipment are as follows:

| As of December 31,            | 2007         | 2006         |
|-------------------------------|--------------|--------------|
| Property                      | \$ 3,300,000 | \$ 4,770,021 |
| Lab equipment                 | 5,501,883    | 676,323      |
| Office equipment              | 702,969      | 8,804,831    |
| Leasehold improvements        | 9,136,842    | 253,120      |
| Construction in process       | 18,641,694   | 14,504,295   |
| Less accumulated depreciation | (11,816,549) | (10,174,712) |
| Property and equipment, net   | \$ 6,825,145 | \$ 4,329,583 |

Depreciation expense was \$1,718,227, \$1,844,599 and \$1,749,314 for the years ended December 31, 2007, 2006 and 2005, 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 \$295,632, \$245,776 and \$248,385 for the years ended December 31, 2007, 2006 and 2005, respectively. Estimated aggregate amortization expense over the five succeeding fiscal years is expected to be \$1,500,000.

#### *Revenue Recognition*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

The Company records revenue from research contracts and grants as the services are performed and payment is reasonably assured. In 2007, the Company recognized \$10,710,330 in research contracts revenues from government funding for work performed on viral disease projects. 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***



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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

---

*Other Current Assets*

Amounts included in other current assets are as follows:

| As of December 31,   | 2007       | 2006       |
|----------------------|------------|------------|
| Prepaid expenses     | \$ 388,371 | \$ 480,003 |
| Prepaid rents        | 96,077     | 100,838    |
| Restricted cash      | 282,830    | 155,442    |
| Other current assets | \$ 767,278 | \$ 736,283 |

Starting in April 2006, the Company was required to pledge \$150,000 as collateral for company credit cards issued to certain employees. Starting in April 2007, the Company was required to pledge \$125,000 as collateral for payments on long-term debt. The Company classifies these amounts as restricted cash. As of December 31, 2007, restricted cash including accrued interest was \$282,830. 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.

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. The provisions of FIN 48 are effective for the Company as of January 1, 2007, with cumulative effect, if any, of applying FIN 48 recorded as an adjustment to opening retained earnings in the year of adoption. The Company adopted FIN 48 on January 1, 2007, which did not have a material impact on the consolidated financial statements. See Note 6.

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

## 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,                                                                       | 2007            | 2006            | 2005            |
|-----------------------------------------------------------------------------------------------|-----------------|-----------------|-----------------|
| Net loss                                                                                      | \$ (27,167,725) | \$ (28,687,510) | \$ (18,205,885) |
| 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   | 53,942,015      | 52,660,711      | 44,655,008      |
| 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 | 53,942,015      | 52,660,711      | 44,655,008      |
| Net loss per share - basic and diluted                                                        | \$ (0.50)       | \$ (0.54)       | \$ (0.41)       |

\* Warrants and stock options to purchase 20,160,864, 14,079,573 and 17,025,547 shares of common stock as of December 31, 2007, 2006 and 2005, respectively, were excluded from earnings per share calculation as their effect would have been antidilutive.

## Stock-based Compensation

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 is 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 2007, 2006 and 2005 were measured on the date of grant using the Black-Scholes option-pricing model, with the following weighted average assumptions:

| Year Ended December 31, | 2007      | 2006      | 2005      |
|-------------------------|-----------|-----------|-----------|
| Risk-free interest rate | 4.81%     | 4.14%     | 3.38%     |
| Expected dividend yield | 0%        | 0%        | 0%        |
| Expected lives          | 8.1 Years | 9.3 Years | 9.1 Years |
| Expected volatility     | 89%       | 91%       | 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.



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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 is 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 are recognized through a cumulative catch-up in the period of change and 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, 2007 follows:

| Stock Options                                    | Shares    | Weighted Average<br>Exercisable Price | Weighted<br>Average<br>Remaining<br>Contractual<br>Term | Aggregate Intrinsic<br>Value |
|--------------------------------------------------|-----------|---------------------------------------|---------------------------------------------------------|------------------------------|
| Outstanding at January 1, 2007                   | 5,571,470 | \$ 5.12                               |                                                         |                              |
| Granted                                          | 1,263,548 | \$ 2.80                               |                                                         |                              |
| Exercised                                        | (11,639)  | \$ 2.49                               |                                                         |                              |
| Canceled or expired                              | (518,926) | \$ 5.88                               |                                                         |                              |
| Outstanding at December 31, 2007                 | 6,304,453 | \$ 4.60                               | 5.38                                                    | \$ (11,990,260)              |
| Vested at December 31, 2007 and expected to vest | 6,268,314 | \$ 4.60                               | 5.36                                                    | \$ (11,936,459)              |
| Exercisable at December 31, 2007                 | 4,497,526 | \$ 4.76                               | 4.23                                                    | \$ (9,300,172)               |

The weighted average fair value per share of stock-based payments granted to employees during 2007, 2006 and 2005 was \$2.27, \$6.09 and \$2.12, respectively. During 2007, 2006 and 2005, the total intrinsic value of stock options exercised were \$4,937, \$779,563 and \$36,344, and the total fair value of stock options that vested were \$3,661,565, \$4,047,970 and \$2,219,446, respectively.

As of December 31, 2007, there was \$2,901,838 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 1.7 years.

During the year ended December 31, 2007, \$29,002 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:

|                            | Year Ended<br>December 31, 2007 | Year Ended<br>December 31, 2006 |
|----------------------------|---------------------------------|---------------------------------|
| Research and development   | \$ 1,877,743                    | \$ 2,408,132                    |
| General and administrative | 2,841,194                       | 1,639,838                       |
| Total                      | \$ 4,718,937                    | \$ 4,047,970                    |



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, 2007 the total compensation expense for participants in the ESPP was \$39,359 using the Black-Scholes option-pricing model with a weighted average estimated fair value per share of \$1.02, expected life of six months, risk free interest rate of 4.52%, volatility of 52.79%, and no dividend yield. At December 31, 2007, 208,585 shares remain available for purchase through the plan and there were 110 employees eligible to participate in the plan, of which 30 were participants. 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 27, 2007, in connection with his resignation, the Company entered into a Separation and Release Agreement with AVI's former Chairman and Chief Executive Officer. Pursuant to this agreement, he may exercise his previously granted options until the earlier of the termination date specified in the respective stock option grant agreements or March 28, 2010. This modification of these stock options in the first quarter of 2007 increased compensation costs by \$1,057,372.

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. 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 was \$4,881,470.

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 is 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 2007, 2006 and 2005 was \$312,637, \$525,126 and \$394,225, 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*.

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

The fair market value of these warrants is recorded on the balance sheet at issuance and marked to market at each financial 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:

| Year Ended December 31, | 2007         | 2006          | 2005          |
|-------------------------|--------------|---------------|---------------|
| Risk-free interest rate | 3.1%-3.5%    | 4.6%-4.7%     | 4.3%          |
| Expected dividend yield | 0%           | 0%            | 0%            |
| Expected lives          | .9-5.0 Years | 1.9-3.4 Years | 2.9-4.4 Years |
| Expected volatility     | 58.2%-80.7%  | 76.1%-87.2%   | 83.2%-86.1%   |

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.

For warrants classified as permanent equity in accordance with EITF 00-19, the fair value of the 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 cash equivalents and 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 September 2006, the FASB issued SFAS No. 157, Fair Value Measurements (SFAS No. 157), which defines fair value of certain assets and liabilities, establishes a framework for measuring fair value and expands disclosures about fair value measurements. This statement does not require any new fair value measurements, but may change current practice for certain entities. This statement is effective for financial statements issued for fiscal years beginning after November 15, 2008 and interim periods within those years. The application of SFAS No. 157 is not expected to have a material impact on the Company's financial statements.

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities (SFAS No. 159). SFAS No. 159 permits companies to choose to measure certain financial instruments and certain other items at fair value. The standard requires that unrealized gains and losses on items for which the fair value option has been elected be reported in earnings. SFAS No. 159 is effective for the Company beginning in the first quarter of fiscal year 2008, although earlier adoption is permitted. The application of SFAS No. 159 is not expected to have a material impact on the Company's financial statements.

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

In December 2007, the FASB ratified EITF Issue No. 07-01, Accounting for Collaborative Arrangements ( EITF 07-01 ). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact of adopting EITF 07-01 on our financial statements.

F-14

---

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations (SFAS 141(R)), and SFAS No. 160, Non-Controlling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51 (SFAS 160). These new standards will significantly change the accounting for and reporting for business combination transactions and non-controlling interests in consolidated financial statements. SFAS 141(R) and SFAS 160 are required to be adopted simultaneously and are effective for the first annual reporting period beginning on or after December 15, 2008. We are currently evaluating the impact of adopting SFAS 141(R) and SFAS 160 on our financial statements.

*Commitments and Contingencies.*

In the normal course of business, the Company may be named as a party to various legal claims, actions and complaints, including matters involving employment, intellectual property, effects from the use of drugs utilizing our technology, or others. It is impossible to predict with certainty whether any resulting liability would have a material adverse effect on the Company's financial position, results of operations or cash flows.

*Financial Instruments.*

The carrying amounts reported in the balance sheets for cash and cash equivalents, accounts receivable, accounts payable, and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

*License Arrangements.*

License arrangements may consist of non-refundable upfront license fees, data transfer fees, research reimbursement payments, exclusive licensed rights to patented or patent pending compounds, technology access fees, various performance or sales milestones and future product royalty payments. Some of these arrangements are multiple element arrangements.

The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of Company performance under the other elements of the arrangement. In addition, if the Company has continuing involvement through research and development services that are required because its know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

*Long-Lived Asset Impairment*

## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

Long-lived assets held and used by us and intangible assets with determinable lives are reviewed for impairment whenever events or circumstances indicate that the carrying amount of assets may not be recoverable in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. We evaluate recoverability of assets to be held and used by comparing the carrying amount of an asset to future net undiscounted cash flows to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Such reviews assess the fair value of the assets based upon estimates of future cash flows that the assets are expected to generate.

### *Government Research Contract Revenue.*

The Company recognizes revenues from federal research contracts during the period in which the related expenditures are incurred. The Company receives reimbursement of costs incurred, overhead and, in some cases, a fixed fee. The Company presents these revenues and related expenses at gross in the consolidated financial statements in accordance with EITF 99-19 *Reporting Revenue Gross as a Principal versus Net as an Agent*.

### 3. LIQUIDITY:

Since its inception in 1980 through December 31, 2007, the Company has incurred losses of approximately \$226 million, and is still in the development stage. 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. The Company believes it has sufficient cash to fund operations at least through the first quarter of 2009, inclusive of future receipts from billings on existing government contracts, as described below. For 2008, the Company expects expenditures for operations, net of government funding, including collaborative efforts and GMP facilities to be approximately \$19 to \$22 million. Expenditures for 2008 could exceed this level if the Company undertakes additional collaborative efforts. If necessary, however, the Company's management has the ability to curtail certain expenditures because a significant amount of the Company's costs are variable.

In December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. During the year ended December 31, 2007, the Company recognized \$8,018,389 in research contract revenue from this contract. Funding of \$24.5 million has been committed through 2008, with the remainder of the contract anticipated in 2009.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company's NeuGen® technology is expected to 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 has received signed contracts for all four of these projects. The Company expects that funding under these signed contracts will be completed over the next 12 months. During the year ended December 31, 2007, the Company recognized \$2,691,941 in research contract revenue from these contracts.

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 complex regulatory environment in which the Company operates. There can be no assurance that the Company will ever achieve significant revenues or profitable operations.

#### 4. SHAREHOLDERS EQUITY 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.

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.

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.

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.

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 December 2007, the Company closed a private equity financing for net proceeds of \$18,626,206 with several institutional investors. In the private equity financing, the Company sold units consisting of one share of common stock, and one-half warrant to purchase a share of common stock for \$1.90 per unit. A total of 10,696,616 shares of common stock and warrants for the purchase of 5,348,308 common shares at \$2.45 per share were sold. These warrants are exercisable starting June 19, 2008 and expire on December 18, 2012.

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 2007, employees elected to purchase a total of 39,559 shares of the Company's common stock at \$2.27 per share. 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, 2007, 208,585 shares remained available to purchase.

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 8,138,988 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, 2007, 4,824,328 options are outstanding at a weighted-average exercise price of \$4.75 under equity compensations plans approved by security holders. At December 31, 2007, 2,043,120 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,          | 2007      |  |                                       |  | 2006      |  |                                       |  | 2005      |  |                                       |  |
|---------------------------------------------|-----------|--|---------------------------------------|--|-----------|--|---------------------------------------|--|-----------|--|---------------------------------------|--|
|                                             | Shares    |  | Weighted<br>Average Exercise<br>Price |  | Shares    |  | Weighted<br>Average Exercise<br>Price |  | Shares    |  | Weighted<br>Average Exercise<br>Price |  |
| Options outstanding at<br>beginning of year | 5,571,470 |  | \$ 5.12                               |  | 4,812,396 |  | \$ 4.55                               |  | 3,803,278 |  | \$ 5.22                               |  |
| Granted                                     | 1,263,548 |  | 2.80                                  |  | 1,172,700 |  | 7.13                                  |  | 1,245,937 |  | 2.47                                  |  |
| Exercised                                   | (11,639)  |  | 2.49                                  |  | (218,353) |  | 3.40                                  |  | (37,029)  |  | 2.56                                  |  |
| Canceled                                    | (518,926) |  | 5.88                                  |  | (195,273) |  | 5.03                                  |  | (199,790) |  | 4.73                                  |  |
| Options outstanding at end<br>of year       | 6,304,453 |  | 4.60                                  |  | 5,571,470 |  | 5.12                                  |  | 4,812,396 |  | 4.55                                  |  |
|                                             |           |  |                                       |  |           |  |                                       |  |           |  |                                       |  |
| Exercisable at end of year                  | 4,497,526 |  | \$ 4.76                               |  | 3,660,483 |  | \$ 5.10                               |  | 3,308,714 |  | \$ 5.40                               |  |

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

At December 31, 2007, 1,834,535 shares were available for future grant.

The following table summarizes information about stock options outstanding at December 31, 2007:

| Exercise Price | Outstanding Shares at<br>December 31, 2007 | Weighted Average Remaining<br>Contractual Life (Years) | Exercisable Options |
|----------------|--------------------------------------------|--------------------------------------------------------|---------------------|
| \$ 1.76        | 20,000                                     | 1.62                                                   | 20,000              |
| 2.00           | 100,000                                    | 7.03                                                   | 100,000             |
| 2.06           | 20,000                                     | 6.75                                                   | 20,000              |
| 2.20           | 60,000                                     | 5.78                                                   | 53,334              |
| 2.24           | 50,000                                     | 7.38                                                   | 50,000              |
| 2.26           | 2,500                                      | 7.72                                                   | 2,500               |
| 2.29           | 23,333                                     | 7.36                                                   | 13,334              |
| 2.43           | 3,333                                      | 2.36                                                   | 2,001               |
| 2.45           | 450,000                                    | 9.24                                                   | 225,000             |
| 2.53           | 828,921                                    | 6.70                                                   | 623,897             |
| 2.55           | 63,000                                     | 6.48                                                   | 54,750              |
| 2.60           | 5,000                                      | 7.21                                                   | 2,500               |
| 2.64           | 33,000                                     | 7.17                                                   | 16,500              |
| 2.83           | 66,000                                     | 9.83                                                   |                     |
| 2.89           | 100,000                                    | 6.24                                                   | 75,000              |
| 2.92           | 183,334                                    | 6.22                                                   | 137,501             |
| 3.00           | 663,709                                    | 8.14                                                   | 103,626             |
| 3.02           | 33,334                                     | 6.23                                                   | 25,001              |
| 3.03           | 60,000                                     | 9.39                                                   | 34,998              |
| 3.25           | 20,000                                     | 7.88                                                   | 13,334              |
| 3.29           | 10,000                                     | 1.28                                                   | 10,000              |
| 3.31           | 25,000                                     | 1.76                                                   | 25,000              |
| 3.45           | 100,000                                    | 6.25                                                   | 75,000              |
| 3.69           | 28,000                                     | 1.05                                                   | 28,000              |
| 3.81           | 15,000                                     | 0.64                                                   | 15,000              |
| 4.16           | 20,000                                     | 5.28                                                   | 20,000              |
| 4.25           | 20,000                                     | 0.98                                                   | 20,000              |
| 4.34           | 49,031                                     | 3.10                                                   | 49,031              |
| 4.55           | 30,000                                     | 0.62                                                   | 30,000              |
| 4.64           | 83,000                                     | 8.39                                                   | 58,250              |
| 4.87           | 20,000                                     | 5.01                                                   | 20,000              |
| 4.89           | 10,000                                     | 5.01                                                   | 10,000              |
| 5.35           | 745,800                                    | 4.93                                                   | 745,800             |
| 5.53           | 40,000                                     | 2.92                                                   | 40,000              |
| 5.75           | 503,000                                    | 2.00                                                   | 503,000             |
| 5.88           | 45,000                                     | 5.38                                                   | 45,000              |
| 6.63           | 510,000                                    | 0.11                                                   | 510,000             |
| 6.65           | 40,000                                     | 4.37                                                   | 40,000              |
| 6.88           | 132,000                                    | 2.62                                                   | 132,000             |
| 6.98           | 100,000                                    | 8.22                                                   | 33,334              |
| 7.19           | 33,334                                     | 2.58                                                   | 33,334              |
| 7.35           | 959,824                                    | 7.54                                                   | 481,501             |
|                | 6,304,453                                  |                                                        | 4,497,526           |

# Edgar Filing: AVI BIOPHARMA INC - Form 10-K

The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. 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,           | 2007       |                                       | 2006        |                                       | 2005       |                                       |
|----------------------------------------------|------------|---------------------------------------|-------------|---------------------------------------|------------|---------------------------------------|
|                                              | Shares     | Weighted<br>Average Exercise<br>Price | Shares      | Weighted<br>Average Exercise<br>Price | Shares     | Weighted<br>Average Exercise<br>Price |
| Warrants outstanding at<br>beginning of year | 8,508,103  | \$ 11.68                              | 12,213,151  | \$ 10.79                              | 10,014,330 | \$ 12.34                              |
| Granted                                      | 5,348,308  | 2.45                                  |             |                                       | 2,645,921  | 5.00                                  |
| Exercised                                    |            |                                       | (705,048)   | 3.32                                  |            |                                       |
| Expired                                      |            |                                       | (3,000,000) | 10.00                                 | (447,100)  | 9.14                                  |
| Warrants outstanding at end<br>of year       | 13,856,411 | 8.12                                  | 8,508,103   | 11.68                                 | 12,213,151 | 10.79                                 |
| Exercisable at end of year                   | 6,842,225  | \$ 5.85                               | 6,842,225   | \$ 5.85                               | 10,061,353 | \$ 6.95                               |

The following table summarizes information about warrants outstanding at December 31, 2007:

| Exercise Price | Outstanding Warrants at<br>December 31, 2007 | Weighted Average Remaining<br>Contractual Life (Years) | Exercisable Warrants |
|----------------|----------------------------------------------|--------------------------------------------------------|----------------------|
| \$ 0.0003      | 16,667                                       | No expiration date                                     | 16,667               |
| 1.14           | 1,000                                        | No expiration date                                     | 1,000                |
| 2.45           | 5,348,308                                    | 4.96                                                   |                      |
| 5.00           | 2,645,921                                    | 1.70                                                   | 2,645,921            |
| 5.50           | 1,613,637                                    | 0.94                                                   | 1,613,637            |
| 7.00           | 2,565,000                                    | 0.34                                                   | 2,565,000            |
| 35.63          | 1,665,878                                    | 2.25                                                   |                      |
|                | 13,856,411                                   |                                                        | 6,842,225            |

The warrants issued in 2005 and 2007 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 9,607,866, 4,259,558, and 4,350,467 liability classified warrants outstanding at December 31, 2007, 2006, and 2005, respectively.

## 5. 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 Incorporated ( 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, paid cash and sold fixed assets 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.

On January 8, 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 granted Eleos Inc. an exclusive license to the Company's NeuGen® third-generation antisense chemistry to treat cancer with p53-related drugs. In return, Eleos Inc. granted an exclusive license to its patents to the Company 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. made an upfront payment of \$500,000 to the Company. The Company recognized \$125,000 in license fees in the year ended December 31, 2007; the remaining \$375,000 has been classified as deferred revenue.

In February 2007, the Company issued 100,000 shares of the Company's common stock with a market value of \$300,000 for consulting services, which was expensed as a component of research and development.



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

On March 27, 2007, the Board of Directors appointed K.Michael Forrest as interim Chief Executive Officer and set his compensation as follows: (a) annual salary - \$385,000 and (b) options to acquire 300,000 shares of the Company's common stock. The stock options granted to Mr. Forrest become exercisable starting one month after the grant date, with one-twelfth of the options becoming exercisable at that time and an additional one-twelfth of the options becoming exercisable each month thereafter. The exercise price is \$2.45 per share.

On March 27, 2007, in connection with the resignation of AVI's Chairman and Chief Executive Officer, the Company entered into a Separation and Release Agreement, pursuant to which the former Chairman and CEO is entitled to receive his base compensation for 18 months (\$562,500 in the aggregate) and medical insurance for the same 18 month period and may exercise his previously granted options until the earlier of the termination date of the respective stock option grant agreements or March 28, 2010. The Company recognized \$1,619,872 in total compensation expense to general and administrative in the first quarter of 2007, including \$562,500 in cash compensation and \$1,057,372 in SFAS 123R expenses.

On April 19, 2007, the Company entered into a real property purchase agreement with WKL Investments Airport, LLC ( WKL ) to purchase a parcel of real property, including improvements situated on the land and intangibles related to the land, for \$3,300,000. The Company paid the purchase price as follows: \$350,208 in cash, assumption of two loans secured by the property in the amount of \$2,199,792, and issuance of 270,758 shares of AVI common stock (at \$2.77 per share or \$750,000 in the aggregate).

On May 2, 2007, the Company entered into a cross-license and collaboration agreement with Ercole Biotech, Inc. ( Ercole ) to develop drugs that may prove effective in treating the genetic diseases Duchenne muscular dystrophy and beta thalassemia 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 73,607 shares of the Company's common stock with a market value of \$200,000 and which was expensed to research and development.

In August 2007, the Company issued 74,074 shares of the Company's common stock with a market value of \$200,000 for consulting services, which was expensed as a component of research and development.

On October 15, 2007, the Company and Charley's Fund, Inc. announced that the Company has been awarded a \$2.45 million research grant from Charley's Fund, a nonprofit organization that funds drug development and discovery initiatives specific to Duchenne muscular dystrophy (DMD). This award will support a new product development program using proprietary exon skipping technologies developed by the Company and its partner, Ercole Biotech, Inc., to overcome the effects of certain genetic errors in the dystrophin gene. The award will allow the Company to accelerate its development of new therapeutics for DMD. In the fourth quarter of 2007 the Company received \$400,000 from Charley's Fund. The Company recognized \$37,500 in research contract revenue in the year ended December 31, 2007; the remaining \$362,500 has been classified as deferred revenue.

On October 30, 2007, the Company obtained a loan for \$4,500,000 from a lending institution with a \$7,500 loan fee at a fixed interest rate of 7.2%. This loan was paid when due on December 7, 2007.

**6. INCOME TAXES:**

As of December 31, 2007 the Company has net operating loss carryforwards of approximately \$170,938,000, available to reduce future taxable income, which expire 2008 through 2027. Of this \$170,938,000, 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 \$168,338,000 in losses based on ownership changes and the value of the Company's stock. Approximately \$3,927,000 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 \$94,631,000 and \$79,398,000 at December 31, 2007 and 2006, 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 \$15,233,000, \$11,769,000 and \$9,056,000 for the years ended December 31, 2007, 2006 and 2005, 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,                                | 2007          | 2006          |
|---------------------------------------------|---------------|---------------|
| Net operating loss carryforwards            | \$ 66,666,000 | \$ 58,688,000 |
| Difference in depreciation and amortization | 1,786,000     | 1,413,000     |
| Capital loss carryforward                   | 5,007,000     | 5,007,000     |
| Research and development tax credits        | 17,850,000    | 12,575,000    |
| FAS 123R stock compensation                 | 2,268,000     | 946,000       |
| Stock options for consulting services       | 887,000       | 765,000       |
| Deferred Rent                               | 147,000       | 0             |
| Other                                       | 20,000        | 4,000         |
|                                             | 94,631,000    | 79,398,000    |
| Valuation allowance                         | (94,631,000)  | (79,398,000)  |
|                                             | \$            | \$            |

The Company adopted the provisions of FIN 48 on January 1, 2007, which did not materially impact its consolidated financial statements. No unrecognized tax benefits were recorded as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on its balance sheet at December 31, 2007 and at December 31, 2006, and has not recognized interest and/or penalties in the statement of operations for the year ended December 31, 2007.

At December 31, 2007, the Company had net deferred tax assets of \$94,631,000. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules under Section 382 could limit the future use of its net operating loss and R&D credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

## **7. COMMITMENTS:**

### ***Lease Obligations***



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2020. Rent expense under these leases was \$1,388,000, \$1,333,000 and \$1,160,000 for the years ended December 31, 2007, 2006 and 2005, respectively, and \$9,931,000 for the period from July 22, 1980 through December 31, 2007.

At December 31, 2007, the aggregate noncancelable future minimum payments under these leases are as follows:

| Year ending December 31,     |    |            |
|------------------------------|----|------------|
| 2008                         | \$ | 1,222,000  |
| 2009                         |    | 1,210,000  |
| 2010                         |    | 1,177,000  |
| 2011                         |    | 1,264,000  |
| 2012                         |    | 1,302,000  |
| Thereafter                   |    | 11,925,000 |
| Total minimum lease payments | \$ | 18,100,000 |

*Royalty Obligations*



## Edgar Filing: AVI BIOPHARMA INC - Form 10-K

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, 2007, 2006 and 2005, respectively, and \$1,108,750 for the period from July 22, 1980 through December 31, 2007.

At December 31, 2007, the aggregate future minimum royalty payments under these agreements are as follows:

| Year ending December 31,       |    |           |
|--------------------------------|----|-----------|
| 2008                           | \$ | 125,000   |
| 2009                           |    | 125,000   |
| 2010                           |    | 125,000   |
| 2011                           |    | 125,000   |
| 2012                           |    | 105,000   |
| Thereafter                     |    | 1,275,000 |
| Total minimum royalty payments | \$ | 1,880,000 |

F-24

---

**8. FINANCIAL INFORMATION BY QUARTER (UNAUDITED):**

| <b>2007 for quarter ended</b>                             | <b>December 31</b> | <b>September 30</b> | <b>June 30</b> | <b>March 31</b> |
|-----------------------------------------------------------|--------------------|---------------------|----------------|-----------------|
| Revenues from license fees, grants and research contracts | \$ 5,186,319       | \$ 2,911,406        | \$ 2,351,424   | \$ 536,042      |
| Operating expenses:                                       |                    |                     |                |                 |
| Research and development                                  | 9,401,465          | 9,880,480           | 9,160,816      | 6,317,641       |
| General and administrative                                | 1,453,172          | 1,544,512           | 2,030,796      | 4,303,885       |
|                                                           | 10,854,637         | 11,424,992          | 11,191,612     | 10,621,526      |
| Other income (loss):                                      |                    |                     |                |                 |
| Interest income, net                                      | 135,579            | 182,320             | 303,568        | 362,509         |
| Gain (loss) on warrant liability                          | 1,405,545          | 1,296,322           | 755,317        | 1,498,691       |
| Net income (loss)                                         | \$ (4,127,194)     | \$ (7,034,944)      | \$ (7,781,303) | \$ (8,224,284)  |
| Net income (loss) per share basic                         | \$ (0.07)          | \$ (0.13)           | \$ (0.15)      | \$ (0.15)       |
| Net income (loss) per share diluted                       | \$ (0.07)          | \$ (0.13)           | \$ (0.15)      | \$ (0.15)       |
| Shares used in per share calculations basic               | 55,252,905         | 53,693,693          | 53,560,360     | 53,241,730      |
| Shares used in per share calculations diluted             | 55,252,905         | 53,693,693          | 53,560,360     | 53,241,730      |

| <b>2006 for quarter ended</b>                             | <b>December 31</b> | <b>September 30</b> | <b>June 30</b> | <b>March 31</b> |
|-----------------------------------------------------------|--------------------|---------------------|----------------|-----------------|
| 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      |

**9. SUBSEQUENT EVENTS:**

**On February 11, 2008, AVI BioPharma, Inc. (the "Company") announced that its Board of Directors had appointed Leslie Hudson, Ph.D. as the Company's Chief Executive Officer, effective as of February 8, 2008. As of that date, Dr. Hudson assumed the responsibilities of the Company's Chief Executive Officer from K. Michael Forrest, who had served as the Company's interim Chief Executive Officer since March 2007, pending the appointment of a new chief executive officer for the Company. Effective with Dr. Hudson's appointment as the Company's Chief Executive Officer, Mr. Forrest ceased to serve as an officer of the Company. Mr. Forrest will continue as a member of the Board of Directors. Also effective February 8, 2008, Dr. Hudson was appointed as a member of the Company's Board of Directors.**

On March 13, 2008, the Company announced the execution of a definitive Agreement and Plan of Merger (the "Merger Agreement") pursuant to which Ercole Biotech, Inc. ("Ercole") will become a wholly-owned subsidiary of the Company. Under the terms of the Merger Agreement, subject to adjustment as provided in the Merger Agreement and described below, the Company will issue up to \$7.5 million of the Company's common stock, valued at \$1.3161 per share, in exchange for all outstanding shares of Ercole stock not already owned by the Company. In addition, the Company will assume up to \$1.5 million in liabilities of Ercole, to be paid by the Company through a combination of cash and the Company's common stock. Liabilities in excess of \$1.5 million will be deducted from the \$7.5 million in common stock. Certain warrants to purchase shares of Ercole's common stock will be exchanged for warrants exercisable for shares of the Company's common stock. Subject to the satisfaction of customary closing conditions, including approval of Ercole's stockholders, the transaction is expected to close by March 21, 2008.

In addition, in anticipation of the closing of the merger, on March 12, 2008, the Company loaned Ercole approximately \$900,000 to be used by Ercole to repay its debt obligation to Isis Pharmaceuticals, Inc. In exchange, Ercole issued a convertible promissory note to the Company. In the event the merger closes, this debt will be forgiven. If the merger does not close, Ercole will either repay the amounts owing or the Company may convert such amounts into shares of Ercole Class A Voting Common Stock.