

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**Form 10-K**

**ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2006

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-22613

**AVI BIOPHARMA, INC.**

(Name of small business issuer in its charter)

**Oregon**

(State or other jurisdiction of incorporation  
or organization)

**93-0797222**

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

**One SW Columbia Street, Suite 1105, Portland, Oregon**

(Address of principal executive offices)

**97258**

(Zip Code)

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 .

No .

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Securities Exchange Act of 1934 (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer .

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes  No .

The aggregate market value of the voting stock held by non-affiliates of the Registrant (based on the closing sale price of the Common Stock as reported on the Nasdaq Capital Market on March 14, 2007) was approximately \$135,683,497 as of March 14, 2007. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The number of outstanding shares of the Registrant's Common Stock as of the close of business on March 14, 2007 was 53,282,841.

**Documents Incorporated by Reference**

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

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## **PART I**

### **Item 1. Description of Business**

#### **General Overview**

We are a biopharmaceutical company developing therapeutic products principally based on third-generation NEUGENE antisense technology. Our principal products in development target life-threatening diseases, including cardiovascular and infectious diseases. Currently approved drugs or other therapies for these diseases often prove to be ineffective or produce undesirable side effects. Our pre-clinical and clinical studies indicate that our technology may lead to development of drugs that we believe offer more effective treatment options with fewer side effects than currently approved products. A patent estate including 202 patents (foreign and domestic) issued or licensed to us and 198 pending patent applications (domestic and foreign) protects our technologies. Our lead product candidate, Resten-NG®, which is targeted at cardiovascular disease, addresses a market we believe may exceed \$3 billion worldwide.

The net loss in 2006 was \$31.1 million, or \$0.59 per share. Total expenses were \$33.1 million and revenues were \$115,291. See Item 7. "Management's Discussion and Analysis or Plan of Operation" and Item 8. "Financial Statements."

We have developed third-generation antisense technology that we believe produces drugs that may be more stable, specific, efficacious, and cost effective than other gene-targeting technologies, including second-generation antisense, ribozyme, and siRNA (short interfering RNA) compounds. In seventeen clinical trials involving 386 subjects, we have not observed any drug-related serious adverse events. NEUGENE drugs are synthetic polymers that block the function of selected genetic sequences involved in disease processes. Targeting specific genetic sequences provides for greater selectivity than that available through conventional drugs. We believe that NEUGENE drugs have the potential to provide safe and effective treatment for a wide range of human diseases. NEUGENE drugs are distinguished by a novel chemistry that replaces the modified backbones of competing technologies with a synthetic backbone designed to improve pharmaceutical parameters.

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

our drug metabolism program and two Phase Ib trials in our cancer and polycystic kidney disease programs. We filed an IND and conducted a Phase Ib trial in 2003 for our NEUGENE antisense drug for West Nile virus infection. We filed an IND and conducted an exploratory clinical trial (Phase I/Ib) for Hepatitis C virus (HCV) infection. We are currently evaluating clinical sites for a continuation of our HCV studies. We are currently conducting a Phase Ib/II clinical trial for coronary artery bypass grafting in Eastern Europe. We also will be conducting a proof of concept study in boys with Duchenne Muscular Dystrophy in the U.K., in collaboration with the MDEX consortium. In addition, we are in preclinical development for antivirals for Dengue virus infection and for influenza A, including avian influenza.

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

## Clinical Development Program

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

Product Candidate	Type	Pre-Clinical	Phase I/Ib	Phase II	Phase III
<b>Cardiovascular Disease</b>					
Restenosis: Resten-NG	NEUGENE Drug	Completed	Completed	Completed	Planned * (Cook Group)
Restenosis: Resten-MP microparticles	NEUGENE Drug	Completed	Completed	In-progress (Cook Group)	
CABG: AVI-5126	NEUGENE Drug	Completed	In-progress	Planned	Planned
<b>Infectious Disease (Viral targets)</b>					
Hepatitis C: AVI-4065	NEUGENE Drug	Completed	In-progress		
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			
HIV	NEUGENE Drug	Planned			
<b>Cancer</b>					
Cancer: Oncomyc-NG™: AVI-4126	NEUGENE Drug	Completed	Completed		
<b>Drug Metabolism</b>					
Cytochrome P450: AVI-4557	NEUGENE Drug	Completed	Completed	Planned	
<b>Genetic Diseases</b>					
PKD: AVI-4126	NEUGENE Drug	Completed	Completed		
DMD: AVI-4658	NEUGENE Drug	Completed	In-progress		

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

Costs for a clinical trial typically range between \$300,000 and \$1,500,000 for a Phase I trial, between \$600,000 and \$4 million for a Phase II trial and could range between \$5 million and \$50 million for a Phase III trial. Because the scope, timing and issues encountered in each trial vary, we cannot predict the exact costs associated with a particular trial in advance. For the same reasons, we cannot predict the nature, timing, costs and quantities of future studies or trials for a product, how a product will proceed toward and through Phase III clinical trials and, if Phase III clinical trials are successful, when and if FDA approval will be sought and received. Moreover, we cannot predict whether a product will be successfully commercialized, even if regulatory approval is obtained.

**Cardiovascular Disease Program.** Resten-NG is a NEUGENE antisense drug for treating cardiovascular restenosis, i.e., the re-narrowing of a coronary artery following angioplasty.

Resten-NG targets a key regulatory gene involved in the disease process. We believe that by blocking the action of this gene, vessel wall re-narrowing will be reduced or eliminated. At the October 2006 Transcatheter Cardiovascular Therapeutics conference, our licensee and development partner, Cook Group, Incorporated (“Cook”) announced interim Phase II clinical trial data treating cardiovascular restenosis by delivering Resten-NG systemically using our

proprietary microparticle delivery technology, possibly lessening the need for, or as an adjunct to, drug eluting stents. We initiated this Phase II clinical trial at three clinical centers in Germany in 2005, and, as part of our license agreement, Cook took responsibility for completion of the study and communication of results. Cook has indicated that it is planning additional clinical studies with products based on our Resten-NG platform, possibly leading to initiating the product approval process in Europe prior to initiating clinical trials in the United States.

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

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

**Infectious Disease Program.** Our infectious disease program is currently focusing on single-stranded RNA viruses using our proprietary NEUGENE antisense compounds targeting West Nile virus, Hepatitis C virus, Influenza A virus, Dengue virus, the SARS coronavirus, and Ebola virus, as well as many of the viruses included on the Department of Homeland Security list of bioterrorism agents, including Marburg, Junin, Anthrax, and Ricin. In June 2003, we filed an IND with the FDA for our West Nile NEUGENE drug candidate, AVI-4020. Our NEUGENE drug candidate AVI-4179, designed to combat the SARS coronavirus, has been evaluated at an independent laboratory and found to be efficacious in pre-clinical studies. Due to unpredictable future demand for drugs targeting West Nile virus and the SARS coronavirus, our future efforts toward commercialization in viral diseases will focus on Hepatitis C virus and Influenza A viruses, including avian influenza (H5N1).

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

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

**Genetic Disease Program.** We completed a Phase Ib clinical trial in 2002 to evaluate the safety and pharmacokinetics of three doses of AVI-4126 in adult patients with polycystic kidney disease and with varying degrees of compromised kidney function. Results of the study showed an excellent safety profile and no adverse effect on kidney function.

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

## Business Strategy

Our strategy is to:

- focus on near-term opportunities in the cardiovascular and viral disease areas;
- select gene targets with broad or multiple disease applications;
- manage drug discovery, pre-clinical and early to mid-stage clinical development in-house; and
- initially co-develop or license products with, or to, strategic partners generally during, or after, completion of Phase II clinical trials to enhance value and share the costs of late stage clinical trials and commercialization.

## Collaborative Agreements

We believe that our NEUGENE technology is broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To exploit this core technology as fully as possible, we plan to enter into collaborative development agreements with pharmaceutical and biotechnology companies for specific molecular targets for our NEUGENE antisense technology. We will also pursue opportunities to access intellectual property rights through license agreements or other arrangements that complement our portfolio of patents and patent applications.

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

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We intend to retain manufacturing rights to our antisense products. There can be no assurance, however, that we will be able to enter into collaborative research agreements with pharmaceutical companies on terms and conditions satisfactory to us. The agreements described in this “Collaborative Agreements” section are generally only cancelable for nonperformance, including failure to make any payments and, in some cases, failure to commercially exploit the technology. There is no assurance the proposed products will be successfully developed under these collaborative arrangements or we will receive any of the potential payments noted herein.

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

#### *Chiron Agreement*

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

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

#### *Cook Group Agreement*

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

Cook is expected to fully fund the development, clinical and regulatory costs of licensed programs in the U.S. and Europe leading to commercialization. This funding is expected to result in expenditures by Cook that could reach \$100 million. The license and development agreement provides for payment to AVI of a double-digit royalty on worldwide product sales

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by Cook and a commercialization milestone. Cook also purchased 692,003 shares of AVI common stock for \$5 million under a stock purchase agreement. Cook has taken over AVI’s facilities and personnel in Colorado that were dedicated to the programs now licensed by Cook. Finally, we also entered into a supply agreement to sell Cook c-myc drugs required to support development, clinical studies, and commercialization of the licensed products.

#### *Ercole Agreement*

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

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

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

### **Manufacturing**

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

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

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

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

## Marketing Strategy

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

next several years, if at all. To market products that will serve a large, geographically diverse patient population, we expect to enter into licensing, distribution, or partnering agreements with pharmaceutical companies that have large, established sales organizations. The timing of our entry into marketing arrangements or other licensing arrangements with large pharmaceutical companies will depend on successful product development and regulatory approval within the regulatory framework established by the Federal Food, Drug and Cosmetics Act, as amended, and regulations promulgated thereunder and, to the extent our products are distributed outside of the United States, within the regulatory framework established in other countries. Although the implementation of initial aspects of our marketing strategy may be undertaken before this process is completed, the development and approval process typically is not completed in less than three to five years after the filing of an IND application and our marketing strategy therefore may not be implemented for several years. See “Drug Approval Process and Other Governmental Regulation.”

## Patents and Proprietary Rights

We have developed or acquired a comprehensive body of intellectual rights. The proprietary nature of, and protection for, our product candidates, processes and know-how are important to our business. We plan to prosecute and aggressively defend our patents and proprietary technology. Our policy is to patent the technology, inventions, and improvements that we believe are important to the development of our business and are patentable. We also depend upon trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position.

A patent estate including 202 patents (domestic and foreign) issued or licensed to us, and 198 pending patent applications (domestic and foreign) protects our technologies. We intend to protect our proprietary technology with additional filings as appropriate. Some of our patents on core technologies expire as early as 2008, including for NEUGENES. Based on patented improvements and additional support to such core patents, however, we believe our patent protection for those products and other products will extend beyond 2020.

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

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

There can be no assurance that any patents we apply for will be granted or that patents held

by us will be valid or sufficiently broad to protect our technology or provide a significant competitive advantage. Additionally, we cannot provide assurance that practice of our patents or proprietary technology will not infringe third-party patents.

## Drug Approval Process and Other Government Regulation

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

### *Drug Discovery*

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*

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

#### *Investigational New Drug Application*

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

#### *Phase I Clinical Trials*

After an IND becomes effective, Phase I human clinical trials may begin. These tests, involving usually between 20 and 80 patients or healthy volunteers, typically take approximately one year to complete and cost between \$300,000 and \$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*

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*

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

#### *New Drug Application*

After the completion of the requisite three phases of clinical trials, if the data indicate that the drug has an acceptable benefit to risk assessment and it is found to be safe and effective, a New Drug Application (NDA) is filed with 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*

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

#### *Phase IV Clinical Trials and Post Marketing Studies*

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

#### **Competition**

Several companies are pursuing the development of gene silencing technology, including Eli Lilly, Merck, Genta Incorporated, and ISIS Pharmaceuticals. All of these companies have

products in development stages, and, in some cases, are in human trials with antisense compounds similar to our NEUGENE compounds.

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

In 2006, Genta received significant negative press when its antisense drugs failed to meet primary endpoints in Phase III clinical trials in certain cancer applications. Because the underlying chemistry of our antisense is fundamentally different and distinct from the antisense chemistries of Genta, we believe that none of the clinical experiences of Genta are predictive of how an AVI NEUGENE antisense compound may fare in similar, or different, clinical trial settings. We believe that the combination of pharmaceutical properties of our NEUGENE compounds for restenosis, cancer, and drug metabolism affords us competitive advantages when compared with the antisense compounds of competitors.

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

## **Research and Development**

We expensed \$25,345,588, \$17,117,750 and \$20,738,725 on research and development activities during the years ended December 31, 2006, 2005 and 2004, respectively. Research and development (R&D) expenses include related salaries, contractor fees, materials, utilities and allocations of corporate costs. R&D expenses consist of independent R&D costs and costs associated with collaborative development arrangements. In addition, the Company funded R&D at other companies and research institutions under agreements. Research and development costs are expensed as incurred.

## **Employees**

As of December 31, 2006, we had 117 employees, 23 of whom hold advanced degrees. One hundred-three employees are engaged directly in research and development activities, and fourteen are in administration. None of our employees are covered by collective bargaining agreements, and we consider relations with our employees to be good.

## **Where You Can Find Additional Information**

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

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

## **Item 1A. Risk Factors**

### **Risks Affecting Future Operating Results**

The following factors should be considered in evaluating our business and prospects for the future. If risks described below actually occur, our operating results and financial condition would likely suffer and the trading price of our common stock may fall, causing a loss of some or all of an investment in our common stock.

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

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

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

We incurred a net loss of \$16.7 million in 2005 and \$31.1 million in 2006. As of December 31, 2006, our accumulated deficit was \$203.7 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from selling, general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our



ability to raise additional capital, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

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

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

If necessary, potential sources of additional funding could include strategic relationships, public or private sales of shares of our stock or debt or other arrangements. We may not be

able to obtain additional funding when we need it on terms that will be acceptable to us or at all. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing shareholders will be diluted. If we are unable to obtain financing when needed, our business and future prospects would be materially adversely affected.

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

All of our products are subject to extensive regulation by the United States Food and Drug Administration, or FDA, and by comparable agencies in other countries. The FDA and these agencies require new pharmaceutical products to undergo lengthy and detailed clinical testing procedures and other costly and time-consuming compliance procedures. We do not know when or if we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies.

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

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

The financial and technical resources and production and marketing capabilities of many of these entities, some of which are our competitors, exceed our resources and capabilities. Our industry is characterized by extensive research and development and rapid technological progress. Competitors may successfully develop and market superior or less expensive products which render our products less valuable or unmarketable.

*We have limited operating experience.*

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.*

While we believe that we can produce materials for clinical trials and produce products for human use at our existing and potentially expanded manufacturing facility, we may need to expand our commercial manufacturing capabilities for products in the future if we elect not to or cannot contract with others to manufacture our products. This expansion may occur in stages, each of which would require regulatory approval, and product demand could at times exceed supply capacity. We have reviewed sites for expanded facilities and do not know what the construction cost will be for such facilities and whether we will have the financing

needed for such construction. We do not know if or when the FDA will determine that such facilities comply with Good Manufacturing Practices. The projected location and construction of any facilities will depend on regulatory approvals, product development, pharmaceutical partners and capital resources, among other factors. We have not obtained regulatory approvals for any production facilities for our products, nor can we assure investors that we will be able to do so.

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

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

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

Our success will depend on our existing patents and licenses and our ability to obtain additional patents in the future. A patent estate including 202 patents (domestic and foreign) issued or licensed to us, and 198 pending patent applications (domestic and foreign) protects our technologies. We license the composition, manufacturing and use of AVICINE in all fields, except fertility regulation, from The Ohio State University. We license patents from other parties for certain complementary technologies.

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

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

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others, as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation

could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected.

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

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

Our strategic relationships are important to our success. The development, improvement and marketing of many of our key therapeutic products are or will be dependent in large part on the efforts of our strategic partners. The transactions contemplated by our agreements with strategic partners, including the equity purchases and cash payments, are subject to numerous risks and conditions. The occurrence of any of these events could severely harm our business.

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

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

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

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

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

In addition to obtaining regulatory approval, the successful commercialization of our products will depend on the ability to obtain reimbursement for the cost of the product and treatment from the consumers of or third-party payors for such products. Government authorities, private health insurers and other organizations, such as health maintenance organizations are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States, the growth of healthcare

organizations such as HMOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. The cost containment measures that healthcare providers are

instituting and any healthcare reform could affect our or our marketing partner's ability to sell our products and may have a material adverse effect on our financial results from operations. Reimbursement in the United States or foreign countries may not be available for any of our products, any reimbursement granted may be reduced or discontinued, and limits on reimbursement available from third-party payors may reduce the demand for, or the price of, our products. The lack or inadequacy of third-party reimbursements for our products would have a material adverse effect on our operations. Additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future that adversely affects our products and our business.

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

We do not intend to conduct late-stage (Phase III) human clinical trials ourselves. We anticipate entering into relationships with larger pharmaceutical companies to conduct these and later pharmaceutical trials and to market our products. We also plan to continue to use contract manufacturing for late stage clinical and commercial quantities of our products. We may be unable to enter into partnerships or other relationships, which could impede our ability to bring our products to market. Any such partnerships, if entered into at all, may be on less than favorable terms and may not result in the successful development or marketing of our products. If we are unsuccessful in establishing advantageous clinical testing, manufacturing and marketing relationships, we are not likely to generate significant revenues and become profitable.

*We use hazardous substances in our research activities*

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

## **Risks Related to Share Ownership**

*Our right to issue preferred stock, our classified Board of Directors and Oregon Anti-Takeover*

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*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 53,182,841 shares of common stock as of December 31, 2006 and all are eligible for sale under Rule 144 or are otherwise freely tradeable. In addition:

- Our employees and others hold options to buy a total of 5,571,470 shares of common stock of which 3,660,483 shares were exercisable at December 31, 2006. The options outstanding have exercise prices between \$1.76 and \$8.13 per share. The shares of common stock to be issued upon exercise of these options, have been registered, and, therefore, may be freely sold when issued;

- There are outstanding warrants to buy 8,508,103 shares of common stock at December 31, 2006 with exercise prices ranging from \$.0003 to \$35.63 per share. All of these shares of common stock are registered for resale and may be freely sold when issued;
- We may issue options to purchase up to an additional 1,710,934 shares of common stock at December 31, 2006 under our stock option plans, which also will be fully

saleable when issued except to the extent limited under Rule 144 for resales by our officers and directors;

- We are authorized to sell up to 248,144 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate; and
- We have also granted certain contractual rights to purchase (i) an additional 352,113 shares of our common stock at a price of \$7.10 per share and (ii) the right to purchase up to \$7,500,000 of our common stock based on the average closing sales price for the five days preceding the commitment to purchase. If we meet certain technological milestones, the holder of these rights is obligated to purchase shares of common stock from us. The holder of these rights may require us to register the shares issued upon the exercise of such purchase rights.

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

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

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

#### **Item 1B. Unresolved SEC Comments**

None.

#### **Item 2. Description of Property**

We occupy 53,000 square feet of leased laboratory and office space at 4575 S.W. Research Way, Suite 200, Corvallis, Oregon 97333. This lease expires in December 2020. Our executive office is located in 4,400 square feet of leased space at One S.W. Columbia, Suite 1105, Portland, Oregon 97258. This lease expires July 2009. In March 2007, we entered into an agreement to obtain a facility in Corvallis, Oregon, subject to certain conditions. If the acquisition is closed, we intend to conduct certain manufacturing of our products and components there in the future. We believe that our facilities are suitable and adequate for our present operational requirements for the foreseeable future.

#### **Item 3. Legal Proceedings**

As of March 16, 2007, there were no material, pending legal proceedings to which we are a party. From time to time, we become involved in ordinary, routine or regulatory legal proceedings incidental to our business.

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

No matters were submitted to a vote of our shareholders during the quarter ended December 31, 2006.

## **PART II**

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

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

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

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

All securities sold during 2006 by us were either previously reported on our Form 10-Qs filed with the Securities and Exchange Commission or sold pursuant to registration statements filed under the Securities Act of 1933.

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

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

### Equity Compensation Plan Information

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

#### Item 6. Selected Financial Data

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

	YEAR ENDED DECEMBER 31,				
	2006	2005	2004	2003	2002
Operations data:					
Revenues	\$ 115,291	\$ 4,783,760	\$ 430,461	\$ 969,866	\$ 836,784
Research and development	25,345,588	17,117,750	20,738,725	15,284,396	22,413,892
General and administrative	7,752,752	5,182,369	4,735,731	4,558,948	3,763,941
Interest income, net	1,910,037	840,495	266,301	491,098	460,258
Realized gain on sale of short-term securities—available-for-sale	—	—	—	3,765,752	—

Write-down of short-term securities—available-for-sale	—	—	—	—	(4,478,260)
Net loss	(31,073,012)	(16,675,864)	(24,777,694)	(14,616,628)	(29,359,051)
Net loss per share—basic and diluted	(0.59)	(0.37)	(0.69)	(0.49)	(1.14)
Balance sheet data:					
Cash and investments	\$ 33,152,132	\$ 47,051,082	\$ 19,515,316	\$ 37,599,136	\$ 19,293,645
Working capital	30,789,068	45,905,421	17,948,793	34,639,526	15,279,854
Total assets	40,862,746	56,407,982	28,518,631	47,145,023	28,603,757
Shareholders' equity	37,711,901	53,660,009	26,269,033	43,394,030	23,481,623

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

### **Forward-Looking Information**

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

- our intention to introduce new products,
- receipt of any required FDA or other regulatory approval for our products,
- our expectations about the markets for our products,
- acceptance of our products, when introduced, in the marketplace,

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- our future capital needs,
- results of our research and development efforts, and
- success of our patent applications.

Forward-looking statements are subject to risks and uncertainties, certain of which are beyond our control. Actual results could differ materially from those anticipated as a result of the factors described in the “Risk Factors” and detailed herein and in our other Securities and Exchange Commission filings, including among others:

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

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

### **Overview**

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest, license fees, grants and research contracts, we have had no material revenues from the sale of products or other sources and, other than from government grants and research contracts, and we do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue to expand our research and development efforts and enter additional collaborative efforts. As of December 31, 2006, our accumulated deficit was \$203,721,256.

## Results of Operations

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

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

*Year Ended December 31, 2005 Compared with Year Ended December 31, 2004.* Revenues, from license fees, grants and research contracts, increased from \$430,461 in 2004 to \$4,783,760 in 2005, primarily due to increases in research contract revenue, partially offset by decreases in grants revenues. In 2005, the Company recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. Operating expenses decreased from \$25,474,456 in 2004 to \$22,300,119 in 2005 due to decreases in research and development, which decreased from \$20,738,725 in 2004 to \$17,117,750 in 2005, which were partially offset by increases in general and administrative costs, which increased from \$4,735,731 in 2004 to \$5,182,369 in 2005. Approximately \$4.8 million of the research and development decrease was due to lower contracting costs for the production of GMP subunits. These research and development decreases were partially offset by increases in clinical trial expenses, lab supplies, employee costs, and clinical trial insurance. Approximately \$530,000 of this general and administrative increase was due to additional clinical and business development staff hired after the first quarter of 2004. These general and administrative increases were partially offset by decreases in accounting and legal expenses. Net interest income increased from \$266,301 in 2004 to \$840,495 in 2005 due to increases in average cash, cash equivalents and short-term securities balances and increases in average interest rates of the Company's interest earning investments.

## Liquidity and Capital Resources

We have financed our operations since inception primarily through sales of common stock and other forms of equity totaling \$196,270,726, from grants and contract research funding of \$9,980,819 from various sources, and \$1,480,432 from shared development funding on AVICINE with SuperGen. We expect to continue to incur losses as we continue and expand our research and development activities and related regulatory work and increase our collaborative efforts. For 2007, we expect our expenditures for operations, including our collaborative efforts, and our GMP facilities to be approximately \$25 to \$28 million. This cost could increase if we undertake additional collaborative efforts. However, if need be in 2007, we believe we can reduce our expenditures because a significant amount of our costs are variable. Those estimated expenditures include amounts necessary to fulfill our obligations under our various collaborative, research and licensing agreements during 2007.

Because of the cost (up to \$1.7 billion) and timeframe (up to 15 years) generally associated with developing a potential drug or pharmaceutical product to the point of FDA approval for human use, our business strategy is to develop our products up to initial Phase III human clinical trials and then look for third parties to fund further development of the product and to market the product through strategic partnerships, license agreements or other relationships. We also look for collaborative and other efforts, such as our relationship with Cook Group, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We believe that this strategy will reduce the potential costs we would otherwise incur in developing a product and bringing it to market. Our expected costs under our various contracts and for various drug development products can be estimated for the next year or two, but not much beyond that due to the uncertainty of clinical trial results, research results and the timing of securing one or more partners to develop and market a potential drug.

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

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

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

Cook, as described in Note 4.

We do not expect any material revenues in 2007 from our business activities. We expect that our cash requirements for the balance of calendar 2007 will be satisfied by existing cash resources. To fund our operations beyond 2007, we will need to raise additional capital. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility, nor do we intend to seek one.

### CONTRACTUAL PAYMENT OBLIGATIONS

The Company's off-balance sheet arrangements are limited to operating leases and rents on certain facilities and equipment and license agreements for which it is obligated to pay the licensors a minimum annual royalty. These off-balance sheet arrangements are expensed as incurred. In 2006, these expenses totaled \$1,333,000 for operating leases and \$125,000 for royalty payments.

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

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

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term. These requirements include the progress of our research and development programs and our pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, our ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of our products. Our cash requirements are expected to continue to increase each year as we expand our activities and operations. There can be no assurance, however, that we will ever be able to generate product revenues or achieve or sustain profitability.

### New Accounting Pronouncements

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

### Critical Accounting Policies and Estimates

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

financial statements.

### Valuation of Investments

Investments in marketable securities are classified as available-for-sale under SFAS 115 and recorded at fair value in each period with changes recorded to "other comprehensive income." We periodically evaluate our investments for other than temporary impairments and record an impairment unless the evidence indicating that the carrying amount is recoverable outweighs the negative evidence to the contrary.

### Revenue Recognition

Revenue is recorded from research contracts and grants as the services are performed and payment is reasonably assured. In 2005, we recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. Revenue from license and development arrangements has been insignificant to date.

### Long-Lived Asset Impairment



We regularly evaluate long-lived assets and certain identified intangible assets for impairment in accordance with Statement of Financial Accounting Standards ("SFAS") No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," which requires us to review our long-lived assets and certain identifiable intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset might not be recoverable and exceeds its fair value. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of would be separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated. The assets and liabilities of a disposal group classified as held for sale would be presented separately in the appropriate asset and liability sections of the balance sheet. Based on this analysis, we did not recognize an impairment on long-lived assets during the year ended December 31, 2006. If circumstances related to our long-lived assets change, we may record an impairment charge in the future.

#### *Stock-based Compensation Expense*

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

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

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

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

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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

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#### **Item 8. Financial Statements**

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

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

Not applicable.

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

##### *Disclosure Controls and Procedures*

We carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer 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, 2006. Based on that review, the Chief Executive Officer and the Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Securities and Exchange Act of 1934 is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

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

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- 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, 2006. 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, 2006, the Company's internal control over financial reporting is effective.

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

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

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

Portland, Oregon  
March 14, 2007

*Report of Independent Registered Public Accounting Firm*

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

We have audited management's assessment, included in the accompanying *Management's Annual Report on Internal Control over Financial Reporting* appearing under Item 9A, that AVI BioPharma, Inc. (an Oregon corporation in the development stage) maintained effective internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Management of AVI BioPharma, Inc. is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's

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assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit

preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, management's assessment that AVI BioPharma, Inc. maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by COSO. Also, in our opinion, AVI BioPharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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, 2006 and 2005, and the related statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from July 22, 1980 (inception) through December 31, 2006 and our report dated March 16, 2007, expressed an unqualified opinion on those consolidated financial statements. The financial statements of AVI BioPharma, Inc. for the period from July 22, 1980 (inception) through December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 21, 2002. Our opinion on the statements of operations, shareholders' equity and 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.

(signed) KPMG LLP  
Portland, Oregon  
March 16, 2007

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### PART III

#### **Item 10. Directors and Executive Officers of the Registrant**

Information regarding our directors and executive officers required by this item is included in our definitive proxy statement for our 2007 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

#### **Item 11. Compensation Discussion and Analysis**

The information required by this item is included in our definitive proxy statement for our 2007 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

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

The information required by this item is included in our definitive proxy statement for our 2007 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

#### **Item 13. Certain Relationships and Related Transactions**

The information required by this item is included in our definitive proxy statement for our 2007 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

#### **Item 14. Principal Accountant Fees and Services**

The information required by this item is included in our definitive proxy statement for our 2007 annual meeting of shareholders to be filed with the Commission not later than 120 days after the end of the fiscal year covered by this Annual Report and is incorporated herein by reference.

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

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

##### **Financial Statements**

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

Report of KPMG LLP, Independent Registered Public Accounting Firm.  
Report of Arthur Andersen, Independent Auditors

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Statements of Operations	F-4
Statements of Shareholders' Equity and Comprehensive Income (Loss)	F-5
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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

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)
3.1	Third Restated Articles of Incorporation of AntiVirals Inc. (1)
3.2	Bylaws of AntiVirals Inc. (1)
3.3	First Amendment to Third Restated Articles of Incorporation (4)
3.4	Amendment to Article 2 of the Company's Third Restated Articles of Incorporation (11)
4.1	Form of Specimen Certificate for Common Stock. (1)
4.2	Form of Warrant for Purchase of Common Stock. (1)
4.3	Form of Warrant Agreement. (1)
4.4	Form of Representative's Warrant. (1)
4.5	Form of Warrant Agreement between AntiVirals Inc. and ImmunoTherapy Shareholders (3)
4.6	Form of Common Stock Purchase Warrant. (5)
4.7	Warrant to purchase 485,290 shares of the Company's common stock dated November 14, 2005 (16)
10.1	1992 Stock Incentive Plan (as amended through May 11, 2000). (1)
10.2	Employment Agreement with Denis R. Burger, Ph.D. dated November 4, 1996. (1)
10.3	Employment Agreement with Alan P. Timmins dated November 4, 1996. (1)
10.4	Employment Agreement with Dwight Weller, Ph.D. dated November 4, 1996. (1)
10.5	Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1992. (1)
10.6	Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AntiVirals Inc. dated January 20, 1996. (1)
10.7	License and Option Agreement between Anti-Gene Development Group and AntiVirals Inc., dated February 9, 1993. (1)
10.8	Commercial Lease between Research Way Investments, Landlord, and AntiVirals Inc., Tenant, dated June 15, 1992. (1)
10.9	Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated June 17, 1992.(1)
10.10	First Amendment to Lease between Benjamin Franklin Plaza, Inc., Landlord, and AntiVirals Inc., Tenant, dated July 24, 1995. (1)
10.11	Employment Agreement with Patrick L. Iversen, Ph.D. dated July 14, 1997. (2)
10.12	ImmunoTherapy Corporation 1997 Stock Option Plan (3)
10.13	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated March 12, 1996 (3)
10.14	License Agreement between ImmunoTherapy Corporation and Ohio State University, dated December 26, 1996 (3)
10.15	Amendment to License Agreement between ImmunoTherapy Corporation and Ohio State University, dated September 23, 1997 (3)
10.16	Agreement and Plan of Reorganization and Merger dated as of February 2, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.17	First Amendment to Plan of Reorganization and Merger dated as of May 27, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)
10.18	Second Amendment to Plan of Reorganization and Merger dated as of August 4, 1998, among AntiVirals Inc., AntiVirals Acquisition Corporation and ImmunoTherapy Corporation (3)

10.19	Form of Escrow Agreement among AntiVirals Inc., the Escrow Indemnitors and Jeffrey Lillard (3)
10.20	Purchase Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.21	Registration Rights Agreement, dated December 15, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.22	Purchase Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.23	Registration Rights Agreement, dated December 16, 1999, by and between AVI BioPharma, Inc. and certain Investors (5)
10.24	Subscription Agreement, dated December 1, 1999, by and between SuperGen, Inc. and AVI BioPharma, Inc. (5)
10.25	2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc. (6)
10.26	United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.27	Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.28	Registration Rights Agreement, dated April 14, 2000, between SuperGen, Inc. and AVI BioPharma, Inc. (7)
10.29	2000 Employee Share Purchase Plan (8)
10.30	Employment Agreement with Mark M. Webber dated May 11, 2000. (9)
10.31	Lease Agreement with Spieker Partners, LP dated May 8, 2001. (9)

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

10.52*	Investment Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc. (17)
10.53*	License Agreement dated January 26, 2006 by and between with Chiron Corporation and AVI BioPharma, Inc. (18)
10.54	Stock Purchase Agreement dated January 26, 2006 by and between with Chiron Corporation and AVI BioPharma, Inc. (18)
10.55	Second Lease Extension and Modification Agreement dated January 24, 2006 by and between Research Way Investments and AVI BioPharma, Inc. (19)
10.56*	Collaboration and License Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (filed herewith)
10.57	Series A-2 Preferred Stock and Common Stock Purchase Agreement, dated December 19, 2006, by and between Ercole Biotech, Inc. and AVI BioPharma, Inc. (filed herewith)
14.0	Code of Business Conduct and Ethics (13)
23.0	Consent of Independent Registered Public Accounting Firm.
31.1	Certification of the Company’s Chief Executive Officer, Denis R. Burger, Ph.D., pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Company’s Chief Financial Officer, Mark M. Webber, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.0	Certification of CEO and CFO Pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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- (1) Incorporated by reference to Exhibits to Registrant’s Registration Statement on Form SB-2, as amended and filed with the Securities and Exchange Commission on May 29, 1997 (Commission Registration No. 333-20513).
  - (2) Incorporated by reference to Exhibits to Registrant’s Annual Report on Form 10-KSB for the fiscal year ended December 31, 1997, and filed with the Securities and Exchange Commission on March 30, 1998.
  - (3) Incorporated by reference to Exhibits to Registrant’s Registration Statement on Form S-4, as amended, and filed with the Securities and Exchange Commission on August 7, 1998 (Commission Registration No. 333-60849).
  - (4) Incorporated by reference to Exhibits to Registrant’s current report on Form 8-K, as filed with the Securities and Exchange Commission on September 30, 1998 (Commission Registration No. 000-22613).
  - (5) Incorporated by reference to Exhibits to Registrant’s Registration Statement on Form S-3, as amended, and filed with the Securities and Exchange Commission on December 21, 1999 (Commission Registration No. 333-93135).
  - (6) Incorporated by reference to Exhibits to Registrant’s Registration Statement on Form S-1 and filed with the Securities and Exchange Commission on June 16, 2000 (Commission Registration No. 333-39542).
  - (7) Incorporated by reference to Exhibits to Registrant’s Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on September 15, 2000 (Commission Registration No. 333-45888).
  - (8) Incorporated by reference to Appendix A to Registrant’s Definitive Proxy Statement on Form 14-A, as amended, filed with the Securities and Exchange Commission on April 12, 2000.

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

- (10) Incorporated by reference to Exhibits to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on April 2, 2002.
- (11) Incorporated by reference to appendixes to Registrant's Definitive Proxy Statement on Schedule 14-A, as filed with the Securities and Exchange Commission on April 11, 2002.
- (12) Incorporated by reference to registrants current report on Form 8-K, as filed with the Securities and Exchange Commission on January 20, 2005.
- (13) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003, and filed with the Securities and Exchange Commission on March 15, 2004.
- (14) Incorporated by reference to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on February 28, 2005.
- (15) Incorporated by reference to Registrant's current report on Form 8-K, as filed with the Securities and Exchange Commission on November 21, 2005.
- (16) Incorporated by reference to Exhibits to Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2005, and filed with the Securities and Exchange Commission on March 16, 2006.
- (17) Incorporated by reference to Exhibits to Registrant's Registrations Statement on Form S-3, and filed with the Securities and Exchange Commission on April 11, 2006 (Commission Registration No. 333-133211).
- (18) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2006, and filed with the Securities and Exchange Commission on May 10, 2006.
- (19) Incorporated by reference to Exhibits to Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2006, and filed with the Securities and Exchange Commission on August 9, 2006.

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

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

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

## SIGNATURES

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

Dated: March 16, 2007

AVI BIOPHARMA, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in their capacities indicated on March 16, 2007:

<u>Signature</u>	<u>Title</u>
<u>/s/ DENIS R. BURGER, Ph.D.</u> Denis R. Burger, Ph.D.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)
<u>/s/ ALAN P. TIMMINS</u> Alan P. Timmins	President, Chief Operating Officer, and Director
<u>/s/ MARK M. WEBBER</u> Mark M. Webber	Chief Financial Officer and Chief Information Officer (Principal Financial and Accounting Officer)
<u>/s/ JACK L. BOWMAN</u> Jack L. Bowman	Director
<u>/s/ MICHAEL D. CASEY</u> Michael D. Casey	Director
<u>/s/ JOHN W. FARA, Ph.D.</u> John W. Fara, Ph.D.	Director
<u>/s/ K. MICHAEL FORREST</u>	Director

K. Michael Forrest

/s/ JAMES B. HICKS, Ph.D.

Director

James B. Hicks, Ph.D.

/s/ JOHN C. HODGMAN

Director

John C. Hodgman

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### Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying balance sheets of AVI BioPharma, Inc. (an Oregon corporation in the development stage) as of December 31, 2006 and 2005, and the related statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006 and for the period from July 22, 1980 (inception) through December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of AVI BioPharma, Inc. for the period from July 22, 1980 (inception) through December 31, 2001 were audited by other auditors who have ceased operations. Those auditors expressed an unqualified opinion on those financial statements in their report dated February 21, 2002. Our opinion on the statements of operations, shareholders' equity and comprehensive income (loss), and cash flows, insofar as it relates to the amounts included for the period from July 22, 1980 (inception) through December 31, 2001, is based solely on the report of the other auditors.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based on our audits and the report of other auditors, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BioPharma, Inc. as of December 31, 2006 and 2005, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2006 and for the period from July 22, 1980 (inception) through December 31, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2 to the consolidated 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), the effectiveness of AVI BioPharma's internal control over financial reporting as of December 31, 2006, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 16, 2007 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Portland, OR  
March 16, 2007

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

### Report of Independent Public Accountants

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

We have audited the accompanying balance sheet of AVI BIOPHARMA, INC. (an Oregon corporation in the development stage) as of December 31, 2001, and the related statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BIOPHARMA, INC. as of December 31, 2001, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2001 and for the period from inception (July 22, 1980) to December 31, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Portland, Oregon  
February 21, 2002

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

	December 31,	
	2006	2005
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 20,159,201	\$ 34,597,734
Short-term securities—available-for-sale	12,992,931	12,453,348
Accounts receivable	51,498	1,236,446
Other current assets	736,283	365,866
<b>Total Current Assets</b>	<b>33,939,913</b>	<b>48,653,394</b>
Property and Equipment, net of accumulated depreciation and amortization of \$10,174,712 and \$8,396,923	4,329,583	5,599,269
Patent Costs, net of accumulated amortization of \$1,496,699 and \$1,270,881	2,558,541	2,117,710
Other Assets	34,709	37,609
<b>Total Assets</b>	<b>\$ 40,862,746</b>	<b>\$ 56,407,982</b>
<b>Liabilities and Shareholders' Equity</b>		
Current Liabilities:		
Accounts payable	\$ 1,401,584	\$ 1,861,604
Accrued employee compensation	1,371,353	886,369
Other liabilities	377,908	—
<b>Total Current Liabilities</b>	<b>3,150,845</b>	<b>2,747,973</b>
Commitments and Contingencies		
Shareholders' Equity:		
Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$.0001 par value, 200,000,000 shares authorized; 53,182,841 and 51,182,751 issued and outstanding	5,318	5,118
Additional paid-in capital	241,409,421	226,290,167
Accumulated other comprehensive income	18,418	12,968
Deficit accumulated during the development stage	(203,721,256)	(172,648,244)
<b>Total Shareholders' Equity</b>	<b>37,711,901</b>	<b>53,660,009</b>
<b>Total Liabilities and Shareholders' Equity</b>	<b>\$ 40,862,746</b>	<b>\$ 56,407,982</b>

See accompanying notes to financial statements.

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

	Year ended December 31,			July 22, 1980 (Inception) through December 31, 2006
	2006	2005	2004	
Revenues from license fees, grants and research contracts	\$ 115,291	\$ 4,783,760	\$ 430,461	\$ 9,980,819
Operating expenses:				
Research and development	25,345,588	17,117,750	20,738,725	147,647,215
General and administrative	7,752,752	5,182,369	4,735,731	40,820,528
Acquired in-process research and development	—	—	—	19,545,028
	<b>33,098,340</b>	<b>22,300,119</b>	<b>25,474,456</b>	<b>208,012,771</b>



Other income (loss):				
Interest income, net	1,910,037	840,495	266,301	7,449,542
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)
	<u>1,910,037</u>	<u>840,495</u>	<u>266,301</u>	<u>(5,689,304)</u>
Net loss	<u>\$ (31,073,012)</u>	<u>\$ (16,675,864)</u>	<u>\$ (24,777,694)</u>	<u>\$ (203,721,256)</u>
Net loss per share - basic and diluted	<u>\$ (0.59)</u>	<u>\$ (0.37)</u>	<u>\$ (0.69)</u>	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	<u>52,660,711</u>	<u>44,655,008</u>	<u>35,994,976</u>	

See accompanying notes to financial statements.

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

	Partnership Units	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Deficit Accumulated During the Development Stage	Total Shareholders' Equity
BALANCE AT JULY 22, 1980 (Inception)	—	—	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of partnership units, warrants and common stock	3,615	8,272,916	828	33,732,654	—	—	33,733,482
Compensation expense related to issuance of warrants for common stock and partnership units	—	—	—	537,353	—	—	537,353
Exercise of warrants for partnership units and common stock	42	1,530,858	152	1,809,165	—	—	1,809,317
Exercise of options for common stock	—	730,547	73	3,153,387	—	—	3,153,460
Issuance of common stock for ESPP	—	99,421	10	481,484	—	—	481,494
Issuance of common stock and warrants for cash and securities, net of offering costs	—	19,928,020	1,993	116,832,608	—	—	116,834,601
Issuance of common stock and warrants for the acquisition of ImmunoTherapy Corporation	—	2,132,592	213	17,167,199	—	—	17,167,412
Issuance of common stock and warrants for services	—	192,848	20	919,243	—	—	919,263
Compensation expense related to issuance of options for common stock	—	—	—	619,714	—	—	619,714
Conversion of debt into common stock and partnership units	9	9,634	1	87,859	—	—	87,860
Issuance of common stock in exchange for partnership units	(1,810)	1,632,950	163	(163)	—	—	—
Withdrawal of partnership net assets upon conveyance of technology	(1,856)	—	—	(176,642)	—	—	(176,642)
Common stock subject to rescission, net	—	(64,049)	(6)	(288,789)	—	—	(288,795)
Comprehensive income (loss):							
Write-down of short-term securities—available-for-sale	—	—	—	—	17,001,348	—	17,001,348
Realized gain on sale of short- term securities—available-for- sale	—	—	—	—	(3,765,752)	—	(3,765,752)
Unrealized loss on short-term securities—available-for-sale	—	—	—	—	(13,525,399)	—	(13,525,399)
Net loss	—	—	—	—	—	(131,194,686)	(131,194,686)
Comprehensive loss	—	—	—	—	—	(131,194,686)	(131,484,489)
BALANCE AT DECEMBER 31, 2003	—	34,465,737	3,447	174,875,072	(289,803)	(131,194,686)	43,394,030
Exercise of options for common stock	—	4,121	—	14,986	—	—	14,986
Issuance of common stock for ESPP	—	49,918	5	94,553	—	—	94,558
Compensation expense related to issuance of options for common stock	—	—	—	421,635	—	—	421,635
Issuance of common stock and warrants for cash, net of offering costs	—	1,623,377	162	6,964,194	—	—	6,964,356
Comprehensive income (loss):							
Unrealized gain on short-term securities—available-for-sale, net	—	—	—	—	157,162	—	157,162
Net loss	—	—	—	—	—	(24,777,694)	(24,777,694)
Comprehensive loss	—	—	—	—	—	(24,777,694)	(24,620,532)
BALANCE AT DECEMBER 31, 2004	—	36,143,153	\$ 3,614	\$ 182,370,440	\$ (132,641)	\$ (155,972,380)	\$ 26,269,033
Exercise of options for common stock	—	37,029	4	94,950	—	—	94,954
Issuance of common stock for ESPP	—	60,854	6	110,724	—	—	110,730
Compensation expense related to issuance of options for common stock	—	—	—	394,225	—	—	394,225

Issuance of common stock and warrants for cash, net of offering costs	—	14,941,715	1,494	43,319,828	—	—	43,321,322
<b>Comprehensive income (loss):</b>							
Unrealized gain on short-term securities—available-for-sale, net	—	—	—	—	145,609	—	145,609
Net loss	—	—	—	—	—	(16,675,864)	(16,675,864)
Comprehensive loss	—	—	—	—	—	—	(16,530,255)
<b>BALANCE AT DECEMBER 31, 2005</b>	<b>—</b>	<b>51,182,751</b>	<b>\$ 5,118</b>	<b>\$ 226,290,167</b>	<b>\$ 12,968</b>	<b>\$ (172,648,244)</b>	<b>\$ 53,660,009</b>
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
<b>Comprehensive income (loss):</b>							
Unrealized gain on short-term securities—available-for-sale, net	—	—	—	—	5,450	—	5,450
Net loss	—	—	—	—	—	(31,073,012)	(31,073,012)
Comprehensive loss	—	—	—	—	—	—	(31,067,562)
<b>BALANCE AT DECEMBER 31, 2006</b>	<b>—</b>	<b>53,182,841</b>	<b>\$ 5,318</b>	<b>\$ 241,409,421</b>	<b>\$ 18,418</b>	<b>\$ (203,721,256)</b>	<b>\$ 37,711,901</b>

See accompanying notes to financial statements

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

	Year ended December 31,			For the Period July 22, 1980 (Inception) through December 31, 2006
	2006	2005	2004	
<b>Cash flows from operating activities:</b>				
Net loss	\$ (31,073,012)	\$ (16,675,864)	\$ (24,777,694)	\$ (203,721,256)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	2,090,375	1,997,672	1,888,008	12,820,239
Loss on disposal of assets	192,369	35,862	86,947	315,178
Realized gain on sale of short-term securities—available-for-sale	—	—	—	(3,862,502)
Write-down of short-term securities—available-for-sale	—	—	—	17,001,348
Issuance of common stock to vendors	1,375,000	—	—	1,375,000
Compensation expense on issuance of common stock and partnership units	—	—	—	861,655
Compensation expense to non-employees on issuance of options and warrants to purchase common stock or partnership units	525,126	394,225	421,635	2,643,053
Stock-based compensation	4,881,470	—	—	4,881,470
Conversion of interest accrued to common stock	—	—	—	7,860
Acquired in-process research and development	—	—	—	19,545,028
(Increase) decrease in:				
Accounts receivable and other current assets	814,531	(919,237)	108,308	(787,781)
Other assets	2,900	—	(7,762)	(34,709)
Net increase (decrease) in accounts payable, accrued employee compensation, and other liabilities	577,872	498,375	(1,501,395)	3,445,845
Net cash used in operating activities	(20,613,369)	(14,668,967)	(23,781,953)	(145,509,572)
<b>Cash flows from investing activities:</b>				
Purchase of property and equipment	(767,282)	(1,070,801)	(1,070,338)	(15,298,511)
Patent costs	(686,607)	(397,081)	(462,591)	(4,475,030)
Purchase of marketable securities	(14,969,926)	(13,140,581)	(13,123,205)	(112,865,796)
Sale of marketable securities	14,435,793	3,693,329	35,494,101	104,800,437
Acquisition costs	—	—	—	(2,377,616)
Net cash provided by (used in) investing activities	(1,988,022)	(10,915,134)	20,837,967	(30,216,516)
<b>Cash flows from financing activities:</b>				
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	8,162,858	43,527,006	7,073,900	196,270,726
Buyback of common stock pursuant to rescission offering	—	—	—	(288,795)
Withdrawal of partnership net assets	—	—	—	(176,642)
Issuance of convertible debt	—	—	—	80,000
Net cash provided by financing activities	8,162,858	43,527,006	7,073,900	195,885,289

Increase (decrease) in cash and cash equivalents	(14,438,533)	17,942,905	4,129,914	20,159,201
Cash and cash equivalents:				
Beginning of period	34,597,734	16,654,829	12,524,915	—
End of period	<u>\$ 20,159,201</u>	<u>\$ 34,597,734</u>	<u>\$ 16,654,829</u>	<u>\$ 20,159,201</u>

**SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:**

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

See accompanying notes to financial statements.

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**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.

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**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the valuation of investments, long-lived asset impairment, and revenue recognition.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. The Company held cash and cash equivalents of \$20,159,201 and \$34,597,734 as of December 31, 2006 and 2005, respectively which consist primarily of money market funds.

#### *Short-Term Securities—Available-For-Sale*

The Company accounts for its short-term securities in accordance with Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities" (SFAS 115). Short-term securities include certificates of deposit, commercial paper and other highly liquid investments with original maturities in excess of 90 days at the time of purchase and less than one year from the balance sheet date. The Company classifies its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value with unrealized gains (losses) recorded as a separate component of shareholders' equity and comprehensive income (loss). The Company's investments in marketable securities had gross unrealized gains of \$18,418 and \$12,968 as of December 31, 2006 and 2005, respectively.

#### *Accounts Receivable*

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

<u>As of December 31,</u>	<u>2006</u>	<u>2005</u>
Research contract	\$ 45,846	\$ 1,200,000
Grant	5,652	36,446
Accounts receivable	<u>\$ 51,498</u>	<u>\$ 1,236,446</u>

#### *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.

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Amounts included in property and equipment are as follows:

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

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

#### *Patent Costs*

Patent costs consist primarily of legal and filing fees incurred to file patents on proprietary technology developed by the Company. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the legal lives of the patents, generally 17 years. Patent amortization was \$245,776, \$248,385 and \$209,835 for the years ended December 31, 2006, 2005 and 2004, respectively. Estimated aggregate amortization expense over the five succeeding fiscal years is expected to be \$1,300,000.

#### *Revenue Recognition*

The Company records revenue from research contracts and grants as the services are performed and payment is reasonably assured. In 2005, the Company recognized \$4,600,000 in research contracts revenue from government funding for work performed on viral disease research projects. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with performance milestones under license and development arrangements is recognized based upon the achievement of the milestones, as defined in the respective agreements. To date revenue from license and development arrangements has not been significant.

#### *Research and Development*

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.

#### *Other Current Assets*

Amounts included in other current assets are as follows:

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

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

#### Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered and settled. A valuation allowance is recorded to reduce the net deferred tax asset to zero because it is more likely than not the deferred tax asset will not be realized.

#### Net Loss Per Share

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

Year Ended December 31,	2006	2005	2004
Net loss	\$ (31,073,012)	\$ (16,675,864)	\$ (24,777,694)
Weighted average number of shares of common stock and common stock equivalents outstanding:			
Weighted average number of common shares outstanding for computing basic earnings per share	52,660,711	44,655,008	35,994,976
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*	*
Weighted average number of common shares outstanding for computing diluted earnings per share	52,660,711	44,655,008	35,994,976
Net loss per share - basic and diluted	\$ (0.59)	\$ (0.37)	\$ (0.69)

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

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#### Stock-based Compensation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

<u>For the Year Ended December 31,</u>	<u>2005</u>	<u>2004</u>
Net loss, as reported	\$ (16,675,864)	\$ (24,777,694)



Deduct: Total stock-based employee compensation expense determined under fair value based method, for all awards not previously included in net loss	(2,219,446)	(2,011,753)
Net loss, as adjusted	<u>\$ (18,895,310)</u>	<u>\$ (26,789,447)</u>
Basic and diluted net loss per share:		
As reported	<u>\$ (0.37)</u>	<u>\$ (0.69)</u>
As adjusted	<u>\$ (0.42)</u>	<u>\$ (0.74)</u>

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

	<u>As reported following SFAS No. 123R</u>	<u>If reported following APB 25</u>
Net loss	<u>\$ (31,073,012)</u>	<u>\$ (27,025,042)</u>
Basic and diluted net loss per share	<u>\$ (0.59)</u>	<u>\$ (0.51)</u>

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

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

During the year ended December 31, 2006, the total compensation expense for stock-based compensation recognized in accordance with SFAS 123R and for acceleration of the vesting of certain stock options was \$4,881,470, respectively.

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with EITF 96-18 "Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." The fair value of the options granted are expensed when the measurement date is known. The performance for services was satisfied on the grant date for stock options granted to non-employees. The total fair value of the options granted to non-employees in 2006, 2005 and 2004 was \$525,126, \$394,225 and \$421,635, respectively, which was expensed to research and development.

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

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

### 3. LIQUIDITY:

The Company is in the development stage. Since its inception in 1980 through December 31, 2006, the Company has incurred losses of approximately \$204 million, substantially all of which resulted from expenditures related to research and development, general and administrative expenses, non-cash write-downs in 2002 of \$4,478,260 and in 2001 of \$12,523,088 on short-term securities—available-for-sale that had an other than temporary impairment as defined by SEC accounting rules and a one-time charge of \$19,545,028 for acquired in-process research and development reflecting the acquisition of ImmunoTherapy Corporation. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company expects to incur operating losses over the next several years.

The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on completing product development of its antisense products, obtaining regulatory approvals for such products, and bringing these products to market. During the period required to develop these products, the Company will require substantial additional financing. There is no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. On March 13, 2006, the Company announced that it had entered into agreements with Cook Group Inc. ("Cook") for Cook's development and commercialization of products for vascular and cardiovascular diseases. Under a stock purchase agreement with Cook, the Company received net proceeds of \$4,955,623. The Company sold 692,003 shares of common stock at \$7.23 per share to Cook, as described in Note 4. The Company believes it has sufficient cash to fund operations through 2007. For 2007, the Company expects expenditures for operations, including collaborative efforts and GMP facilities to be approximately \$25 to \$28 million. Expenditures for 2007 could increase if the Company undertakes additional collaborative efforts. If necessary, however, the Company's management has the ability to significantly curtail certain expenditures because a significant amount of the Company's costs are variable.

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

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

#### 4. SHAREHOLDERS' EQUITY:

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 2000, the Board of Directors and the Company's shareholders approved the Employee Stock Purchase Plan under which the Company is authorized to sell up to 250,000 shares of common stock to its full-time employees, nearly all of whom are eligible to participate. Under the terms of the Plan, employees may elect every six months to have up to 10% of their compensation withheld to purchase the Company's common stock. The purchase price of the stock is 85% of the lower of the beginning-of-plan period or end-of-plan period market price of the Company's common stock. During 2006, employees elected to purchase a total of 41,663 shares of the Company's common stock at \$2.95 per share. During 2005, employees elected to purchase a total of 60,854 shares of the Company's common stock at \$1.82 per share. During 2004, employees elected to purchase a total of 49,918 shares of the Company's common stock at \$1.89 per share. At December 31, 2006, 248,144 shares remained available to purchase.

The Company has two stock option plans, the 2002 Equity Incentive Plan and the 1997 Stock Option Plan (the Plans). The 2002 Plan provides for the issuance of incentive stock options to employees and nonqualified stock options, stock appreciation rights and bonus rights to employees, directors of the Company and consultants. The 1997 Plan provides for the assumption of the ImmunoTherapy Options under the Merger Agreement. The Company has reserved 7,282,404 shares of common stock for issuance under the Plans. Options issued under the Plans generally vest ratably over four years and expire five to ten years from the date of grant. At December 31, 2006, 4,167,981 options are outstanding at a weighted-average exercise price of \$5.36 under equity compensations plans approved by security holders. At December 31, 2006, 1,959,078 shares were available to issue under equity compensation plans approved by security holders.

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



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

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

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

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

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The Company has also issued warrants for the purchase of common stock in conjunction with financing and compensation arrangements. The 2,645,921, and 389,611 warrants granted in 2005 and 2004, respectively, have not been considered in the fair value based method of accounting defined in SFAS 123 as such warrant grants related to the raising of additional equity. A summary of the status of the Company's warrants and changes are presented in the following table:

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

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

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

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## 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 Inc. ("Cook") for Cook's development and commercialization of products for vascular and cardiovascular diseases. See Note 4.

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

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## 6. INCOME TAXES:

As of December 31, 2006 the Company has net operating loss carryforwards of approximately \$150,482,000, available to reduce future taxable income, which expire 2007 through 2026. Of this \$150,482,000, approximately \$2,600,000 relates to net operating losses assumed as part of the ImmunoTherapy Corporation acquisition. Utilization of these ImmunoTherapy Corporation net operating losses is limited to approximately \$1,200,000 per year. In addition, the Internal Revenue Code rules under Section 382 could limit the future use of the remaining \$147,882,000 in losses based on ownership changes and the value of the Company's stock. Approximately \$3,923,000 of the Company's carryforwards were generated as a result of deductions related to exercises of stock options. When utilized, this portion of the Company's carryforwards, as tax effected, will be accounted for as a direct increase to contributed capital rather than as a reduction of that year's provision for income taxes. The principal differences between net operating loss carryforwards for tax purposes and the accumulated deficit result from depreciation, amortization, investment write-downs, treatment of research and development costs, limitations on the length of time that net operating losses may be carried forward, and differences in the recognition of stock-based compensation.

The Company had net deferred tax assets of \$79,398,000 and \$67,629,000 at December 31, 2006 and 2005, primarily from net operating loss carryforwards. A valuation allowance was recorded to reduce the net deferred tax asset to zero because it is more likely than not the deferred tax asset will not be realized. The net change in the valuation allowance for deferred tax assets was an increase of approximately \$11,769,000, \$9,056,000 and \$12,093,000 for the years ended December 31, 2006, 2005 and 2004, respectively, mainly due to the increase in the net operating loss carryforwards, research and development tax credits and write-down of short-term securities.

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

<u>December 31,</u>	<u>2006</u>	<u>2005</u>
Net operating loss carryforwards	\$ 58,688,000	\$ 50,079,000
Difference in depreciation and amortization	1,413,000	1,031,000
Capital loss carryforward	5,007,000	5,007,000
Research and development tax credits	12,575,000	10,935,000
FAS 123R stock compensation	946,000	0
Stock options for consulting services	765,000	560,000
Other	4,000	17,000
	<u>79,398,000</u>	<u>67,629,000</u>
Valuation allowance	<u>(79,398,000)</u>	<u>(67,629,000)</u>
	<u>\$ —</u>	<u>\$ —</u>

## 7. RELATED PARTY TRANSACTIONS:

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

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## 8. COMMITMENTS:

### *Lease Obligations*

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

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

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

### *Royalty Obligations*

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

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

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

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## 9. FINANCIAL INFORMATION BY QUARTER (UNAUDITED):

<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
<b>Operating expenses:</b>				
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
	<u>8,789,748</u>	<u>7,285,981</u>	<u>7,437,640</u>	<u>9,584,971</u>
<b>Other income (loss):</b>				
Interest income, net	443,042	492,083	517,053	457,859
Net loss	<u>\$ (8,329,187)</u>	<u>\$ (6,780,646)</u>	<u>\$ (6,902,029)</u>	<u>\$ (9,061,150)</u>
Net loss per share, basic and diluted	<u>\$ (0.16)</u>	<u>\$ (0.13)</u>	<u>\$ (0.13)</u>	<u>\$ (0.18)</u>
Shares used in per share calculations	<u>53,000,236</u>	<u>52,964,049</u>	<u>52,946,054</u>	<u>51,715,050</u>
<b>2005 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	\$ 1,417,446	\$ 3,281,805	\$ 39,317	\$ 45,192
<b>Operating expenses:</b>				
Research and development	4,913,490	4,147,201	3,915,155	4,141,904
General and administrative	1,409,066	1,052,244	1,272,529	1,448,530
	<u>6,322,556</u>	<u>5,199,445</u>	<u>5,187,684</u>	<u>5,590,434</u>
<b>Other income (loss):</b>				
Interest income, net	353,538	225,169	215,725	46,063
Net loss	<u>\$ (4,551,572)</u>	<u>\$ (1,692,471)</u>	<u>\$ (4,932,642)</u>	<u>\$ (5,499,179)</u>
Net loss per share, basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.04)</u>	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>
Shares used in per share calculations	<u>47,838,357</u>	<u>44,184,293</u>	<u>44,167,565</u>	<u>42,455,512</u>

#### 10. SUBSEQUENT EVENTS:

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

Portions of this document have been redacted. Redacted sections marked with “\*\*\*\*\*.”

## COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the “**Agreement**”) between **AVI BioPharma, Inc.** of One S.W. Columbia, Suite 1105, Portland OR 97258 (“**AVI**”) and **ERCOLE BIOTECH, INC.**, of 79 TW Alexander Dr., Bldg 4401, Suite 200, Research Triangle Park, NC 27709 (“**Ercole**”) is entered into and made effective this 19th day of December 2006 (the “**Effective Date**”).

### OVERVIEW

#### Collaboration and Cross Licenses

AVI owns or controls certain patents related to morpholino chemistry (the “**AVI Patents**”), including those licensed under that certain Agreement between AVI and Anti-Gene Development Group effective May 19, 1993 and amended March, 2000 (the “**AGDG Agreement**”).

Ercole controls certain patents (the “**Isis Splicing Patents**”, as identified on Exhibit 5) related to RNA splicing licensed under that certain Collaboration and License Agreement between Ercole and Isis Pharmaceuticals effective May 16, 2003 (the “**Isis CLA**”).

Ercole controls certain patents (the “**Ercole Splicing Patents**”) related to RNA splicing licensed under that certain License Agreement between Ercole and The University of North Carolina at Chapel Hill effective October 15, 2001 (the “**UNC License**”).

The Parties wish to collaborate in the areas of drug discovery and medicinal chemistry, as further described below and in the Research Plan. Each Party will choose a fixed pool of exclusive Gene Targets for their research and development efforts and will receive an exclusive license to practice under specified patents owned or controlled by the other Party to discover and develop Products that modify such exclusive Gene Targets (either “**Ercole-AVI Exclusive Products**” or “**AVI Exclusive Products**,” each as further defined below). In exchange for these exclusive licenses and the contribution of each Party to the other Party’s efforts to develop Splicing Modulators, each Party will pay royalties and milestones on the development and sale of Products.

Ercole and AVI will design and identify morpholino and morpholino peptide conjugate splice switching oligomers that modulate the splicing of Ercole-AVI Exclusive Targets and the AVI Exclusive Targets. For each Ercole-AVI Exclusive Target, AVI will provide Splicing Modulators to be tested for their ability to modulate splicing.

Ercole will collaborate with AVI regarding AVI Exclusive Target drug discovery and development as requested by AVI, including but not limited to: compound identification, mRNA binding locations, in vitro assays and preclinical testing.

Capitalized terms used in this Agreement have the meanings set forth in Exhibit 1.

In consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

### **Article 1. COLLABORATIVE RESEARCH PLAN**

#### **1.1 General; Collaboration Term.**

- (a) Ercole and AVI will work together under the direction of the Steering Committee to execute the Research Plan to develop Splicing Modulators.
- (b) The Collaboration Term will begin on the Effective Date and will continue for three (3) years unless earlier terminated due to termination of the Agreement under Sections 8.2 or 8.3, or unless terminated or extended upon mutual agreement of the Parties. Expiration or earlier termination of the Collaboration will not affect the other provisions of this Agreement.

#### **1.2 Targets: General.**

Ercole and AVI will each select \*\*\*\*\* exclusive Gene Targets (“**Exclusive Targets**”) for their research and development efforts. The Exclusive Targets selected by Ercole will be “**Ercole-AVI Exclusive Targets**” hereunder and will be designated Ercole Exclusive Targets under the Isis CLA. The Exclusive Targets selected by AVI will be “**AVI Exclusive Targets**” hereunder and will also be designated Ercole Exclusive Targets under the Isis CLA. Exhibit 2 hereto contains a list of the initial Ercole-AVI Exclusive Targets and, subject to the Isis CLA, the initial AVI Exclusive Targets as of the Effective Date. Promptly following the Effective Date, Ercole will propose the initial AVI Exclusive Targets as “**Ercole Exclusive Targets**” under the Isis CLA in accordance with the procedures provided for in Article 1 of the Isis CLA and will cooperate with AVI to select a replacement in the event that any such proposed target is rejected by Isis. Gene Targets may be added to and removed from Exhibit 2 in accordance with the terms of this Section and Section 1.3.

#### **1.3 Targets: Designation, Approval and Replacement.**

- (a) **Number of Exclusive Targets.** Pursuant to Section 1.3(b), each Party may increase its respective Gene Target limit beyond the initial \*\*\*\*\* Gene Targets by paying \*\*\*\*\* per each additional Gene Target. Subject to the Isis CLA, if AVI desires to increase its Gene Target limit, it will pay Ercole \*\*\*\*\* for each additional Gene Target, which Ercole will pay to Isis in order to designate the additional Gene Target as an Ercole Exclusive Target under the Isis CLA. If Ercole desires to increase its Gene Target limit, Ercole will pay Isis as required by the Isis CLA for each additional Gene Target in order to designate the additional Gene Target as an Ercole Exclusive Target under the Isis CLA.
- (b) **Exclusive Target Substitutions or Additions.** The Parties will designate any additional or substitute Exclusive Targets as follows:

(1) **Target Request.** The Party who wishes to designate a new Gene Target as one of its Exclusive Targets (the “Requesting Party”) will provide the other Party (the “Reviewing Party”) with written notice (the “Request Notice”) of the Gene Target it wishes to designate as an Exclusive Target (the “Proposed Exclusive Target”). The Request Notice will include the gene name and the NCBI accession number, ENSEMBL number or nucleic acid sequence for the Proposed Exclusive Target.

(2) **Target Review.** Within thirty (30) days of receiving the Request Notice, the Reviewing Party will notify the Requesting Party in good faith and in writing regarding (A) whether the Proposed Exclusive Target is subject to the Reviewing Party’s own Active Program and (B) the nature of any contractual obligations to a Third Party, including under the Isis CLA, in effect at the time of the Request Notice that would preclude the Reviewing Party from granting a license under Section 2 or collaborating with the Requesting Party with respect to the Proposed Exclusive Target (the “Review Notice”).

(3) **Target Rejection due to Active Program.** If the Proposed Exclusive Target is subject to the Reviewing Party’s own Active Program, the Proposed Exclusive Target will be rejected and will not become an Exclusive Target of the Requesting Party. If the Proposed Exclusive Target is not rejected under this subsection (3), the Proposed Exclusive Target will become an Exclusive Target of the Requesting Party and will be added to the Requesting Party’s list of Exclusive Targets on Exhibit 2.

(4) **Target Acceptance; Limitations.** If the Proposed Exclusive Target is subject to contractual limitations as identified in the Review Notice under Section 1.3(b)(2), then within fifteen (15) days of receiving the Review Notice, the Requesting Party must notify the Reviewing Party whether or not it accepts the Proposed Exclusive Target subject to the contractual limitations set forth in the Review Notice. If the Requesting Party accepts the Proposed Exclusive Target, then the accepted Proposed Exclusive Target will become an Exclusive Target of the Requesting Party and will be added to the Requesting Party’s list of Exclusive Targets on Exhibit 2; *provided, however* that, with respect to such accepted Exclusive Target, the licenses granted under Section 2 below will be limited as described in the Review Notice.

### (c) Exclusive Target Removal.

(1) After the Effective Date, a Party may remove Gene Targets from its list of Exclusive Targets on Exhibit 2, by (i) providing the other Party written notice of its election to do so and (ii) updating the list on Exhibit 2 to remove the Gene Target; *provided, however*, that each Party may only remove up to \*\*\*\*\* Gene Targets from its list of Exclusive Targets in any six month period. In addition, once a Party removes a Gene Target from its list of Exclusive Targets, such Party cannot attempt to re-designate the removed Gene Target as an Exclusive Target until two years have passed from the date such Gene Target was removed other than by operation of Section 1.3(b)(3).

(2) The Parties shall use commercially reasonable efforts to develop and commercialize Products against each of its Exclusive Targets. If a Party is not making

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such an effort, it must provide a sufficient written justification to the other Party or enter into discussions with the other Party, if requested, regarding surrender of its license hereunder to such Exclusive Targets.

### 1.4 Collaborative Research Plan.

**General Overview.** Ercole and AVI will identify and develop Splicing Modulators that modulate the splicing of Ercole-AVI Exclusive Targets and AVI Exclusive Targets, as more specifically described in the Research Plan. All data and information generated as a result of either Party’s identification of Splicing Modulators that modulate the splicing of Ercole-AVI Exclusive Targets shall be owned by Ercole. All data and information generated as a result of either Party’s identification of Splicing Modulators that modulate the splicing of AVI Exclusive Targets shall be owned by AVI. Ownership of Splicing Modulators and any resultant patents will be determined pursuant to Section 4.1(d).

### 1.5 Steering Committee.

(a) **Members.** The Parties shall establish a Steering Committee within thirty (30) calendar days from the Effective Date. The Steering Committee will be the key management, decision making and liaison body in relation to the Research Plan and shall:

(i) consist of two (2) representatives of Ercole and two (2) representatives of AVI, as notified by such Party to the other Party from time to time in writing. Each representative of a Party shall have one vote;

(ii) be chaired by a representative chosen by AVI;

(iii) hold meetings in person or over the telephone as frequently as the members of the Steering Committee may agree shall be necessary during the period of the Research Program or more frequently upon the reasonable request of either Party but in no event less than once every six (6) months. Dates of meetings to be held in person shall be agreed by the Parties not less than thirty (30) days beforehand. Responsibility for arranging the meetings, including providing notice and an agenda shall rest with the chairman;

(iv) appoint a secretary who shall be responsible for sending draft minutes of each meeting without undue delay (but in no event more than thirty (30) days after the applicable meeting).

(b) **Duties.** The Steering Committee shall be in charge of the matters described below:

(i) managing, reviewing and/or amending the Research Plan, provided however, that the Steering Committee shall have no authority to decide any substantial change in the scope of the Research Plan which would materially increase the costs thereof. Such change shall require a written agreement between the Parties;

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- (ii) managing, reviewing and/or amending the development plan for each AVI Exclusive Product until an IND is filed, after which time the Steering Committee will no longer have oversight responsibility for that AVI Exclusive Product;
- (iii) managing, reviewing and/or amending the development plan for each Ercole-AVI Exclusive Product until an IND is filed, after which time the Steering Committee will no longer have oversight responsibility for that Ercole-AVI Exclusive Product;
- (iv) making proposals to the Parties to review and approve regarding amendment of the terms of this Agreement;
- (v) shall perform such other functions and responsibilities as are given to it under the express provisions of this Agreement or as it shall determine for the purpose of performing the duties set forth above.

**(c) Operation.**

- (i) The Steering Committee shall form a quorum when two (2) representatives of each Party are present. Decisions of the Steering Committee require unanimous consent. If any issue is unresolved after formal consideration by the Steering Committee, either Party may by written notice to the other refer that issue for dispute resolution pursuant to Section 12.6.
- (ii) For the avoidance of doubt, notwithstanding any failure of the Steering Committee and/or the respective officers of each Party to reach an agreement pursuant to Section 12.6, and until such disagreement is finally resolved, the provisions of this Agreement shall continue to be in full force and effect and the Parties shall be obligated to perform their respective obligations and be entitled to their respective rights under this Agreement.
- (iii) Each Party shall be responsible for its own expenses incurred in connection with Steering Committee meetings. The location of the meetings of Steering Committee shall alternate at sites selected by each Party. Unless one Party objects in writing, the Steering Committee may conduct their meetings via teleconference or videoconference.

**Article 2. License Grants and Other Rights**

**2.1 License Term.** As used herein, "License Term" shall begin on the Effective Date and, unless earlier terminated as herein provided, shall end on the later of (i) the expiration of the last to expire patent included in the Patents, or (ii) if all the patents listed in subpart (i) are found to be either invalid or unenforceable, ten (10) years from the Effective Date.

**2.2 AVI License Grants.** Subject to the AGDG Agreement and the limitations set forth in Section 1.3(b)(4) and termination provisions set forth in Sections 2.2(b) below, AVI grants Ercole the following licenses:

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- (a) License Grants. AVI grants Ercole an exclusive worldwide license to the AVI Patents solely to research, develop, offer for sale, sell, import and export Ercole-AVI Exclusive Products.
  - (b) Termination of Licenses. The licenses granted under Section 2.2(a) shall automatically terminate with respect to any Ercole-AVI Exclusive Target which has been removed from the Ercole-AVI Exclusive Targets pursuant to Section 1.3(c).

**2.3 Sublicenses Under AVI Patent Rights.**

- (a) Subject to the terms and conditions of this Agreement and during the License Term, Ercole will have the right to grant sublicenses under the licenses from AVI set forth in Section 2.2 to Third Parties solely for the purposes of enabling such Third Party to discover, develop and commercialize Ercole-AVI Exclusive Products.
- (b) Any sublicense granted by Ercole under this Agreement is subject to and will be consistent with the terms and conditions of this Agreement. The grant of any such sublicense hereunder will not relieve Ercole of its obligations under this Agreement. Ercole will promptly notify AVI of all sublicenses granted by Ercole, as well as sublicensee contact information.
- (c) In the event of a material default by any sublicensee under an Ercole sublicense, Ercole will (i) inform AVI, (ii) hold AVI harmless, and (iii) take any action reasonably necessary to prevent such default from giving AGDG the right to terminate the AGDG Agreement. Such actions may include, but are not limited to, causing the sublicensee promptly to cure the default and terminating the sublicense.

**2.4 Ercole License Grants.** Subject to the UNC License and Isis CLA and the limitation set forth in Section 1.3(b)(4), Ercole grants AVI the following licenses:

- (a) License Grants. Ercole grants to AVI an exclusive worldwide license to the Splicing Patents solely to research, develop, make and have made, offer for sale, sell, import and export AVI Exclusive Products.
- (b) Termination of Licenses. The licenses granted under Section 2.4(a) shall automatically terminate with respect to any AVI Exclusive Target which has been removed from the AVI Exclusive Targets pursuant to Section 1.3(c).

**2.5 Sublicenses Under Splicing Patents.**

- (a) Subject to the terms and conditions of this Agreement and during the License Term, AVI may grant a sublicense to a Third Party collaborator under the Splicing Patents solely for the purposes of enabling such Third Party to develop and commercialize AVI Exclusive Products.
- (b) Any sublicense granted by AVI under this Agreement is subject to and will be consistent with the terms and conditions of this Agreement, the Isis CLA and the UNC License.

Without limiting the generality of the foregoing, as required by the Isis CLA, AVI shall not be permitted to grant any sublicenses to an AVI Exclusive Product until an IND has been submitted for that AVI Exclusive Product. The grant of any such sublicense hereunder will not relieve AVI of its obligations under this Agreement. AVI will promptly notify Ercole of all sublicenses granted by AVI, as well as sublicensee contact information.

- (c) In the event of a material default by any sublicensee under an AVI sublicense, AVI will (i) hold Ercole harmless and (ii) take any action reasonably necessary to prevent such default from giving UNC or Isis the right to terminate the UNC License or the Isis CLA, as the case may be. Such actions may include, but are not limited to, causing the sublicensee promptly to cure the default and terminating the sublicense.

## 2.6 Other Rights.

If the sale or use of a Product that bears a royalty payable to the other Party under this Agreement would infringe patent rights owned or controlled by the other Party (other than Patents expressly licensed hereunder), the Party controlling such patents covenants not to seek an injunction against infringement or otherwise enforce such patents in a manner that would prevent the other Party or its Affiliates or sublicensees from developing or commercializing the relevant Product and will, upon request, negotiate a commercially reasonable license to such patents.

## Article 3. ROYALTIES AND PAYMENTS

### 3.1 Royalties Payable to AVI by Ercole on Sales of Products by Ercole.

(a) **Ercole-AVI Exclusive Products.** The royalty payable to AVI by Ercole for sales by Ercole, its Affiliates or sublicensees of any Ercole-AVI Exclusive Products shall be equal to \*\*\*\*\* percent of Net Sales plus an amount equal to the royalty payable by AVI under the AGDG Agreement as a result of the sale of such Ercole-AVI Exclusive Products, provided that in no event shall Ercole be responsible for royalties payable under the AGDG Agreement in excess of the amounts specified in this subsection 3.1(a). Royalties shall be payable on a country-by-country basis until the later of expiration of the AVI Patents and Ercole Invention Patents Covering a particular Ercole-AVI Exclusive Product or the tenth anniversary of first commercial sale (the “AVI Royalty Period”) of such Ercole-AVI Exclusive Product. On a country-by-country basis, if the last AVI Patent and Ercole Invention Patent Covering a particular Ercole-AVI Exclusive Product expires prior to the tenth anniversary of first commercial sale of such Ercole-AVI Exclusive Product, then the applicable royalty shall be reduced by \*\*\*\*\* percent for the remainder of the AVI Royalty Period. As of the Effective Date, the applicable royalty rate payable under the AGDG Agreement on Ercole-AVI Exclusive Products is \*\*\*\*\* percent \*\*\*\*\* of Net Sales once cumulative net sales of “Therapeutic Products” (as defined in the AGDG Agreement) by AVI and its licensees exceed \*\*\*\*\* dollars \*\*\*\*\*. Ercole’s royalty payment obligation will be reduced by the amount of any future reduction in AVI’s royalty obligation under the AGDG Agreement. AVI will provide Ercole with information reasonably requested related to current and cumulative net sales of PMO Products. This payment obligation shall survive any expiration or earlier termination of this Agreement or any of the licenses granted hereunder.

### 3.2 Royalties Payable to Ercole by AVI on Sales of Products by AVI.

(a) **AVI Exclusive Products.** The royalty payable to Ercole by AVI for sales by AVI, its Affiliates or sublicensees of any AVI Exclusive Products shall be equal to \*\*\*\*\* percent of Net Sales plus an amount equal to the royalties payable by Ercole under the UNC License and the Isis CLA as a result of the sale of such AVI Exclusive Products, provided that in no event shall AVI be responsible for royalties payable under the UNC License or the Isis CLA in excess of the amounts specified below in this subsection 3.2(a). Royalties shall be payable on a country-by-country basis until the later of expiration of all Splicing Patents and AVI Invention Patents Covering a particular AVI Exclusive Product or the tenth anniversary of first commercial sale (the “Ercole Royalty Period”) of such AVI Exclusive Product. On a country-by-country basis, if the last Splicing Patent and AVI Invention Patent Covering a particular AVI Exclusive Product expires prior to the tenth anniversary of first commercial sale of such AVI Exclusive Product, then the applicable royalty shall be reduced by \*\*\*\*\* for the remainder of the Ercole Royalty Period. As of the Effective Date, the applicable royalty rate payable under the UNC License on AVI Exclusive Products is \*\*\*\*\* percent \*\*\*\*\* and the applicable royalty rate payable under the Isis CLA on AVI Exclusive Products is \*\*\*\*\* percent \*\*\*\*\*. This amount will be reduced by the amount of any future reduction in Ercole’s royalty obligation under the UNC License or the Isis CLA. This payment obligation shall survive any expiration or earlier termination of this Agreement or any of the licenses granted hereunder.

### 3.3 Development Milestones.

(a) **Ercole-AVI Exclusive Products.** Ercole will pay or will cause its Affiliates or sublicensees to pay to AVI the following milestone payments for each Ercole-AVI Exclusive Product within sixty (60) days after achievement of each of the following events in the specified jurisdiction, or where no jurisdiction is specified, in the first Major Market Country:

Milestone Event	Milestone Payment
Start of IND-Enabling GLP Tox Studies	US \$*****
Filing of IND	US \$*****
First Initiation of Phase II Trial	US \$*****
US NDA Approval	US \$*****
EC Approval	US \$*****
Japanese Approval	US \$*****



(b) **AVI Exclusive Products.** AVI will pay or will cause its Affiliates or sublicensees to pay to Ercole the following milestone payments for each AVI Exclusive Product within sixty (60) days after achievement of each of the following events in the specified jurisdiction, or where no jurisdiction is specified, in the first Major Market Country:

<b>Milestone Event</b>	<b>Milestone Payment</b>
Start of IND-Enabling GLP Tox Studies	US \$*****
Filing of IND	US \$*****
First Initiation of Phase II Trial	US \$*****
US NDA Approval	US \$*****
EC Approval	US \$*****
Japanese Approval	US \$*****

### 3.4 Commercial Success Milestones.

In order to satisfy Ercole's obligation under the Isis CLA, AVI, its Affiliates or sublicensees will pay Ercole a one-time milestone payment equal to \*\*\*\*\* dollars \*\*\*\*\* for each AVI Exclusive Product that has Net Sales of \*\*\*\*\* dollars \*\*\*\*\* or more in a Calendar Year. For clarity, such payment shall only be due once per AVI Exclusive Product in the first Calendar Year in which Net Sales total or exceed \*\*\*\*\* dollars \*\*\*\*\* and not in any subsequent years when Net Sales meet or exceed this amount. Any commercial success milestone due hereunder will be payable in quarterly installments of \*\*\*\*\* dollars \*\*\*\*\* over the \*\*\*\*\* years following the year in which the milestone was met.

### 3.5 Payment of Royalties and Milestones; Reports.

Each Party will make royalty payments to the other Party for each Product sold during a Calendar Quarter within sixty (60) days of the last day of that Calendar Quarter. Each royalty payment will be accompanied by a written report for that Calendar Quarter showing the calculation of Net Sales of the Product sold by such Party, its Affiliates and its sublicensees worldwide during the quarterly reporting period and the calculation of the royalties and Milestones payable under this Agreement, all on a country-by-country and Product-by-Product basis.

### 3.6 Payment Modalities; Foreign Currency Conversion; Late Payment Charges; Offset.

- (a) **Payments.** All payments by a Party under this Agreement will be made in United States Dollars by bank wire transfer in next day available funds to such bank account in the United States designated in writing by Ercole or AVI, from time to time.
- (b) **Late Payments; Collections.** In the event that any payment, including royalty or milestone payments, due hereunder is not made when due, the payment will bear interest from the date due at the lesser of (i) one and one-half percent (1.5%) per month,

compounded monthly, or (ii) the highest rate permitted by law. If a Party disputes in writing the amount of an invoice presented by the other Party within thirty (30) days of receipt of such invoice, the late fees will only apply to the correct amount as later determined or agreed. The payment of such interest will not limit a Party from exercising any other rights it may have as a consequence of the lateness of any payment. In addition, each Party agrees to pay all costs of collection, including reasonable attorneys' fees, incurred by the other Party in enforcing the payment obligations after a due date has passed under this Agreement.

- (c) **Conversion.** If a Party receives any revenues in currency other than U.S. dollars, then for purposes of making royalty payments required hereunder, such revenues shall be converted into U.S. dollars at the conversion rate for the foreign currency as published in the eastern edition of The Wall Street Journal as of the last business day of the applicable calendar quarter in which the corresponding sales of Products were made.
- (d) **Offset.** If a Party suffers a loss as a result of a breach of this Agreement by the other Party, the non-breaching Party may offset such loss against any amounts payable hereunder.

### 3.7 Audits Rights.

- (a) Upon the written request of AVI or Ercole, as the case may be, and not more than once in each Calendar Year, AVI or Ercole will permit the other Party's independent certified public accountant to have access during normal business hours to its records as may be reasonably necessary to verify the accuracy of the royalty reports and the Party's compliance in other respects with this Agreement for the current year and the preceding three years prior to the date of such request, provided however that any given calendar year will be subject to audit no more than once. The accounting firm will disclose to the auditing Party only whether the royalty reports are correct or incorrect, the specific details concerning any discrepancies or other non-compliance, and the corrected amount of Net Sales and royalty payments. No other information will be provided to the auditing Party.
- (b) If such accounting firm concludes that additional royalties were owed during such period, the delinquent Party will pay the additional royalties within sixty (60) days of the date such Party receives the accounting firm's written report. The fees charged by such accounting firm will be paid by the auditing Party unless the additional royalties, milestones or other payments owed by the audited Party exceed five percent (5%) of the royalties, milestones or other payments paid for the time period subject to the audit, in which case the audited Party will pay the reasonable fees and expenses charged by the accounting firm.

- (c) Each Party will treat all financial information subject to review under this Section 3.7 or under any sublicense agreement in accordance with the confidentiality provisions of Article 5, and will cause its accounting firm to enter into an acceptable confidentiality agreement obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement. Notwithstanding the foregoing, it is expressly
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agreed that a royalty report provided hereunder may be provided, in whole or in pertinent part, to UNC or Isis by Ercole to the extent required by the UNC License or the Isis CLA, as the case may be, or to AGDG by AVI to the extent required by the AGDG Agreement.

### **3.8 Taxes.**

If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 3, each Party will make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article 3. Each Party will submit appropriate proof of payment of the withholding taxes to the other Party within a reasonable period of time.

## **Article 4. INTELLECTUAL PROPERTY**

### **4.1 Ownership of Inventions.**

- (a) Neither Party hereto will be deemed by this Agreement to have been granted any license or other rights to the other Party's rights in any inventions, technology, discoveries, or other proprietary property (collectively, "Inventions") existing as of the Effective Date of this Agreement, except as expressly provided herein.
- (b) Subject to Section 4.1(d), any Inventions made under the Research Plan, either solely by Ercole or jointly with AVI, which (i) relate to the Splicing Patents and do not relate to the AVI Patents or (ii) are Covered by the Splicing Patents and are not Covered by the AVI Patents, will be assigned to Ercole. Any Inventions made under the Research Plan, either solely by AVI or jointly with Ercole, which (x) relate to the AVI Patents and do not relate to the Splicing Patents or (y) are Covered by the AVI Patents and are not Covered by the Splicing Patents, will be assigned to AVI. Such an Invention will be an "Ercole Invention" or an "AVI Invention," as the case may be, and Patents claiming such Inventions will be "Ercole Invention Patents" or "AVI Invention Patents," respectively.
- (c) Subject to Section 4.1(d), AVI and Ercole will jointly hold title to all Inventions, whether or not patentable, that are made by either or both Parties under the Research Plan that relate to or are Covered by both the AVI Patents and the Splicing Patents, as well as to Patents filed thereon. Such Inventions will be "Jointly Owned Inventions," and Patents claiming such Jointly Owned Inventions will be "Jointly Owned Invention Patents." AVI and Ercole will promptly provide each other with notice whenever a Jointly Owned Invention is made. The Parties agree and acknowledge that, except insofar as this Agreement provides otherwise, the default rights conferred on joint owners under US patent law as of the Effective Date, including the right of each Party to independently practice, license and use a joint patent, will apply in relation to the Jointly Owned Invention Patents throughout the world as though US patent law applied worldwide.
- (d) Any invention claiming the composition of matter of a Splicing Modulator or an analog thereof and any invention related to the use of such compounds shall be referred to as a "Compound Invention". All Compound Inventions arising from activities under the Research Plan and related to a Splicing Modulator designed to modulate the splicing of
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an Ercole-AVI Exclusive Target shall be solely owned by Ercole and shall be designated as Ercole Inventions. All Compound Inventions arising from activities under the Research Plan and related to a Splicing Modulator designed to modulate the splicing of an AVI Exclusive Target shall be solely owned by AVI and shall be designated as AVI Inventions.

- (e) The Parties agree, upon reasonable request, to execute any documents reasonably necessary to effect and perfect each other's ownership of any Invention.

### **4.2 Filing, Prosecution, Maintenance, Enforcement and Defense of Patents Owned or Controlled by AVI.**

- (a) AVI will have the sole and exclusive right, in its sole discretion and at its expense, to file, prosecute, maintain, enforce and defend any Patents within the AVI Patents and the AVI Invention Patents. Ercole shall provide such assistance, at AVI's expense, as AVI may reasonably request in pursuing such legal action.
- (b) Ercole will promptly advise AVI if Ercole becomes aware of any suspected or actual infringement of the AVI Patents and the AVI Invention Patents by any person.
- (c) AVI will be entitled to all damages and monetary awards recovered as a result of its enforcement of the AVI Patents and the AVI Invention Patents. Notwithstanding the foregoing, if AVI's enforcement of the AVI Patents and AVI Invention Patents results from a Third Party's unauthorized development, sale or other commercialization of a Splicing Modulator that targets an Ercole-AVI Exclusive Target, then Ercole shall be entitled to receive \*\*\*\*\* percent of any damages or monetary awards recovered and remaining after deduction of each Parties' expenses associated with the enforcement action.

### **4.3 Filing, Prosecution, Maintenance, Enforcement and Defense of Patents Owned or Controlled by Ercole.**

- (a) Ercole will have the sole and exclusive right and responsibility at its own expense, to file, prosecute, maintain, enforce and defend the Ercole Splicing Patents and the Ercole Invention Patents. AVI shall provide such assistance, at Ercole's expense, as Ercole may reasonably request in pursuing such legal action.

- (b) AVI will promptly advise Ercole if AVI becomes aware of any suspected or actual infringement of such Ercole Splicing Patents or the Ercole Invention Patents by any person.
- (c) Ercole will be entitled to all damages and monetary awards recovered as a result of enforcing the Ercole Splicing Patents and the Ercole Invention Patents. Notwithstanding the foregoing, if Ercole's enforcement of the Ercole Patents and Ercole Invention Patents results from a Third Party's unauthorized development, sale or other commercialization of a Splicing Modulator that targets an AVI Exclusive Target, then AVI shall be entitled

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to receive \*\*\*\*\* percent of any damages or monetary awards recovered and remaining after deduction of each Parties' expenses associated with the enforcement action.

#### 4.4 Filing, Prosecution, Maintenance, Enforcement and Defense of Jointly Owned Invention Patents.

Ercole and AVI will negotiate in good faith an appropriate arrangement for the use, prosecution, maintenance and enforcement of any Jointly Owned Invention Patents.

#### 4.5 Third Party Patents.

- (a) **Notice and Control.** If either Party becomes aware of a patent assigned to a Third Party that includes one or more claims which could potentially be infringed by activities conducted by either Party under this Agreement, it will immediately inform the other Party, and representatives of AVI and Ercole will meet to discuss whether any action is warranted and, if so, possible courses of action. If the Third Party patent claim relates primarily to AVI technology, AVI will take the lead in any negotiations or legal actions with the Third Party, taking into consideration suggestions made by Ercole and Ercole's counsel, and AVI shall have final say in any settlement or business arrangement with the Third Party. If the Third Party patent claim relates primarily to Ercole technology, Ercole will take the lead in any negotiations or legal actions with the Third Party, taking into consideration suggestions made by AVI and AVI's counsel, and Ercole shall have final say in any settlement or business arrangement with the Third Party. Each party will be responsible for its own legal expenses related to such actions.
- (b) **New Third Party Royalty Payments.** If any license agreement or settlement is entered into pursuant to Section 4.5 (a) that establishes a royalty obligation to a Third Party on sales of Products, such royalty payment will be made by the Parties as follows.
- (i) **Ercole-AVI Exclusive Products** - If the Third Party patent for which a royalty is due relates primarily to Ercole technology (and has therefore been agreed to directly by Ercole pursuant to Section 4.5 (a)), Ercole shall bear full responsibility for the Third Party royalty payment. If the Third Party patent for which the royalty is due relates primarily to AVI technology, Ercole may deduct half of the Third Party royalty payment from the royalty payments due AVI, provided, however, that the royalty rate paid to AVI (net of payments due to AGDG) shall not be less than \*\*\*\*\* of Net Sales of the Ercole-AVI Exclusive Product on which the Third Party royalty is being paid.
- (ii) **AVI-Exclusive Products** - If the Third Party patent for which a royalty is due relates primarily to AVI technology (and has therefore been agreed to directly by AVI pursuant to Section 4.5 (a)), AVI shall bear full responsibility for payment of the Third Party royalty payment. If the Third Party patent for which the royalty is due relates primarily to Ercole technology, AVI may deduct half of the Third Party royalty payment from the royalty payments due Ercole, provided, however, that the royalty rate paid to Ercole (net of payments due to Isis and the University of North Carolina) shall not be less than \*\*\*\*\* of Net Sales of the respective AVI Exclusive Product on which the Third Party royalty is being paid.

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## Article 5. CONFIDENTIALITY

### 5.1 Nondisclosure Obligation.

All Confidential Information disclosed by one Party to the other Party hereunder will be maintained in confidence by the receiving Party and will not be disclosed to a Third Party or Affiliate or used for any purpose except as set forth below.

### 5.2 Permitted Disclosures.

Except as otherwise provided herein, a Party may disclose Confidential Information received from the other Party:

- (a) to governmental or other regulatory agencies in order to obtain Patents or approval to conduct clinical trials, or to gain marketing approval; provided that such disclosure may be made only to the extent reasonably necessary to obtain such patents or approvals;
- (b) to Affiliates, sublicensees, agents, consultants, and/or other Third Parties for the development, manufacturing and/or marketing of the Product (or for such parties to determine their interest in performing such activities) in accordance with this Agreement on the condition that such Affiliates, sublicensees and Third Parties agree to be bound by the confidentiality obligations contained in this Agreement; or
- (c) if such disclosure is required by law or court order.
- (d) Either Party may disclose (i) a copy of this Agreement on a confidential basis to prospective investors and (ii) a mutually agreed upon redacted copy of this Agreement on a confidential basis to prospective collaborators; *provided, however*, that a Party can never disclose the other Party's Exclusive Targets without the express prior written consent of such Party, it being understood that Ercole may disclose the Exclusive Targets to Isis.

## Article 6. PUBLICATION AND PUBLICITY

### 6.1 Publication.

- (a) The Parties agree that it is customary in the industry to publish results obtained from clinical trials and other studies of a Product, and that each Party may publish such information obtained, subject to the provisions of this Section.
- (b) Except as provided otherwise herein, the Parties will be entitled to publish or present on the results of the Research Plan hereunder and any Product, provided that the Party seeking to publish will deliver to the other Party for its review a copy of any proposed publication, poster or an abstract of any oral presentation at scientific meetings involving any Product hereunder, or the Confidential Information of the other Party, at least 45 days prior to submission of scientific publications or abstracts of oral presentations. The reviewing Party will have the right to request that any of its Confidential Information be deleted from such publication or presentation, and the disclosing Party will comply with

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that request. If the disclosing Party does not receive any feedback from the reviewing Party within that 45-day period, the disclosing Party will be free to proceed with the publication or presentation *except* that neither Party may publish on the other Party's Products without the prior written approval of the other Party, which may be given at that Party's sole discretion.

## 6.2 Publicity.

Except as otherwise provided herein or required by law, neither Party will originate any publication, news release or other public announcement, written or oral, whether in the public press, or stockholders' reports, or otherwise, relating to this Agreement, and neither Party will use the name, trademark, trade name, logo or likeness of the other Party or its employees in any publicity, news release or disclosure relating to this Agreement, or its subject matter, without the prior permission of the other Party.

## Article 7. INDEMNIFICATION

### 7.1 Indemnification by Ercole.

Ercole will indemnify, defend and hold AVI and its agents, employees, officers and directors (the "AVI Indemnitees") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees) arising out of Third Party claims or suits related to (a) Ercole's performance of its obligations under this Agreement; (b) breach by Ercole of its representations and warranties set forth in Article 9; (c) Ercole's choice of Ercole-AVI Exclusive Targets pursuant to Article 1; or (d) the manufacture, use, importation or commercialization (including marketing) of Ercole-AVI Exclusive Products; *provided, however*, that Ercole's obligations pursuant to this Section 7.1 will not apply to the extent such claims or suits result from (y) the gross negligence or willful misconduct of any of the AVI Indemnitees or (z) a breach by AVI of its representations and warranties set forth in Section 9. Ercole shall also indemnify AGDG to the extent required by the AGDG Agreement.

### 7.2 Indemnification by AVI.

AVI will indemnify, defend and hold Ercole and its agents, employees, officers and directors (the "Ercole Indemnitees") harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorney's fees) arising out of Third Party claims or suits related to (a) AVI's performance of its obligations under this Agreement; (b) breach by AVI of its representations and warranties set forth in Article 9; (c) AVI's choice of AVI Exclusive Targets pursuant to Article 1; or (d) the manufacture, use, importation or commercialization (including marketing) of AVI Exclusive Products; *provided however*, that AVI's obligations pursuant to this Section 7.2 will not apply to the extent that such claims or suits result from (y) the gross negligence or willful misconduct of any of the Ercole Indemnitees or (z) a breach by Ercole of its representations and warranties set forth in Article 9. AVI shall also indemnify UNC and Isis to the extent required by the UNC License or the Isis CLA, as the case may be.

### 7.3 Notification of Claims; Conditions to Indemnification Obligations.

As a condition to a Party's right to receive indemnification under this Article 7, it will (i) promptly notify the other Party as soon as it becomes aware of a claim or action for which indemnification may be sought pursuant hereto, (ii) cooperate with the indemnifying Party in the defense of such claim or suit, and (iii) permit the indemnifying Party to control the defense of such claim or suit, including without limitation the right to select defense counsel. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party without the prior written consent of the indemnified Party. The indemnifying Party will have no liability under this Article 7 with respect to claims or suits settled or compromised without its prior written consent.

## Article 8. TERM AND TERMINATION OF AGREEMENT

### 8.1 Termination of Agreement.

This Agreement shall continue in full force and effect for the License Term unless terminated as set forth in this Article 8.

**8.2 Termination upon Breach.** If one Party is in breach of this Agreement and has not cured such breach within ninety (90) days after receipt of written notice requesting cure of the breach, then the non-breaching Party may upon written notice to the breaching Party terminate the rights and licenses granted hereunder to the breaching party. In such event, the rights and licenses granted to the terminating Party with respect to Gene Targets that are exclusive targets at the time of termination shall remain exclusive, such that the breaching Party upon such termination grants to the non-breaching Party an exclusive, royalty-free (as to the breaching Party), worldwide license, with the right to sublicense, to practice the other Party's Patents as described under Sections 2.2 and 2.3 (in the case where AVI is the breaching Party) or Sections 2.4 and 2.5 (in the case where Ercole is the breaching Party). Any royalty, milestone or other payment obligations of the non-breaching Party to the breaching Party shall cease as of the date of such termination except to the extent such payments are required under a Third Party license agreement (e.g., the AGDG Agreement, the UNC License or the Isis CLA). Alternatively, if one Party breaches this Agreement and such breach jeopardizes the rights of the other Party under a Third Party license agreement (e.g., the AGDG Agreement, the UNC License or the Isis CLA), then the non-breaching Party may, at its sole discretion, elect in writing to terminate only those Third Party rights granted to the other Party hereunder, without terminating the remainder of this Agreement. In such instance, the breaching party shall have only such cure rights as are expressly provided for in the applicable Third Party license agreement.

### 8.3 Termination upon Bankruptcy; Rights in Bankruptcy.

This Agreement may be terminated with written notice by either Party at any time during the License Term upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings by the other Party or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; *provided, however*, in the case of any involuntary bankruptcy proceeding such right to terminate will only become effective if the party consents to the involuntary bankruptcy or such proceeding is not dismissed within 90 days of the filing thereof.

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All rights and licenses granted under or pursuant to this Agreement by AVI or Ercole are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code.

### 8.4 Accrued Rights and Surviving Obligations.

- (a) Expiration or termination of the Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination, including, but not limited to, obligations to pay royalties and/or milestones under Article 3, Sections 3.6 through 3.9, 4.1, and Articles 5, 6, 7, 8, 9, 10, 11, 12.
- (b) The rights of any sublicensee under any permitted sublicense granted pursuant to Section 2.3 or 2.4 will survive the termination of this Agreement to the extent provided in the sublicense, and the licensor therein agrees to assign all such sublicenses to the other Party hereto. All payments then or thereafter due to such licensor from each surviving sublicense shall become owed directly to the other Party hereto; provided that such Party shall remit to the other Party the amount by which any such payments exceed the corresponding amount that would have been payable hereunder.

## Article 9. REPRESENTATIONS AND WARRANTIES; DISCLAIMER

### 9.1 Representations and Warranties of the Parties.

Each Party represents and warrants to the other Party that, as of the Effective Date:

- (a) Such Party is duly organized and validly existing under the laws of the state of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;
- (b) Such Party has taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- (c) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement. The execution, delivery and performance of this Agreement by such Party does not conflict with any agreement, instrument or understanding, oral or written, to which such Party is a Party or by which such Party may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over such Party. All consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with this Agreement have been obtained;
- (d) Such Party has the full and exclusive right, power and authority to enter into this Agreement, to perform its obligations under this Agreement (including the Research Plan) and to grant the licenses granted hereunder;

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- (e) AVI expressly acknowledges the limitations and restrictions that apply to sublicensees under the UNC License and Isis CLA and warrants that it will adhere to such limitations and restrictions.

Ercole represents and warrants that, as of the date of this Agreement:

- (a) Other than the Isis CLA and that UNC License, there are no agreements between Ercole and any Third Parties which would preclude or otherwise limit its ability to conduct its tasks and obligations under the Research Plan or otherwise fulfil its obligations under this Agreement;
- (b) The Isis CLA and the UNC License are in full force and effect, and the copies attached hereto are accurate and complete. Ercole shall not amend these agreements in a way that would adversely affect the rights of AVI hereunder to practice the sublicensed technology without AVI's express written consent, provided that adding, removing or replacing Exclusive Targets under the Isis CLA (other than AVI Exclusive Targets) does not constitute a change requiring notice to or consent of AVI.

AVI represents and warrants that, as of the date of this Agreement:

- (a) Other than the AGDG Agreement, there are no agreements between AVI and any Third Parties which would preclude or otherwise limit AVI's ability to conduct its tasks and obligations under the Research Plan or otherwise fulfil its obligations under this Agreement;
- (b) The AGDG Agreement is in full force and effect, and the copy attached hereto is accurate and complete. AVI may not amend the AGDG Agreement in a way that would adversely affect the rights of Ercole hereunder to practice the sublicensed technology without Ercole's express written consent.

### 9.2 Disclaimers.

THE SPLICING MODULATORS AND SERVICES PROVIDED UNDER THE RESEARCH PLAN ARE PROVIDED “AS IS” AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF

MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

THE PARTIES EXPRESSLY DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OF THIRD PARTY RIGHTS, UNLESS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT.

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## Article 10. NOTICE

### 10.1 Notice.

All notices which are required or permitted hereunder will be in writing and sufficient if delivered personally, sent by facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

if to AVI, to:  
One S.W. Columbia, Suite 1105  
Portland OR 97258  
Attention: President  
Fax No:503-227-0751

if to Ercole, to:  
79 TW Alexander Dr., Bldg 4401, Suite 200  
Research Triangle Park, NC 27709  
Attention: President  
Fax No: (919) 536-1700

with a copy to:

Hutchison Law Group PLLC  
5410 Trinity Road, Suite 400  
Raleigh, North Carolina 27607  
Attn: William N. Wofford  
Fax No: 1 (919) 829 9696

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given when delivered if personally delivered or sent by facsimile on a business day, on the business day after dispatch if sent by nationally-recognized overnight courier and on the third business day following the date of mailing if sent by mail.

## Article 11. RECORDS

### 11.1 Records.

Each Party will maintain records, in sufficient detail and in good scientific manner, which will fully and properly reflect all work done and results achieved in the performance of its responsibilities under the Research Plan hereunder. Each Party will have the right, during normal business hours and upon reasonable prior notice, to inspect and copy those records of the other Party referred to herein that are necessary or useful to the inspecting Party for the purposes of making any required filings with Regulatory Authorities in order to obtain manufacturing approvals and/or marketing approvals. Each Party will maintain such records and the information disclosed therein in confidence in accordance with Article 5.

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## Article 12. MISCELLANEOUS PROVISIONS

### 12.1 Relationship of the Parties.

It is expressly agreed that AVI and Ercole will be independent contractors and that the relationship between the two Parties will not constitute a partnership, joint venture or agency. Neither AVI nor Ercole will have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party.

### 12.2 Successors and Assigns.

Neither this Agreement nor any interest hereunder may be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred by either Party without the prior written consent of the other Party; *provided, however*, that either Party may, without such consent, assign the Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates (whether by sale of stock, sale of assets or merger). Any permitted assignee will assume all obligations of its assignor under the Agreement. This Agreement will be binding upon the successors and permitted assigns of the Parties. Any attempted assignment not in accordance with this Section 12.2 will be void. For clarification, in no event will any proper assignment or other transfer of this Agreement cause an increase in the obligations of the assigning party or its successor or assign (e.g., no intellectual property rights owned or controlled by such successor or assign shall be licensed or assigned under this Agreement except as expressly provided for in Section 2.6).

### 12.3 Entire Agreement; Amendments.

This Agreement contains the entire understanding of the Parties with respect to the license, development and commercialization of Products hereunder. All express or implied agreements and understandings, either oral or written, heretofore made by the Parties on the same subject matter are expressly superseded by this Agreement. The Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties hereto.

#### **12.4 Force Majeure.**

Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached the Agreement for failure or delay in fulfilling or performing any term of the Agreement when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, without limitation, embargoes, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, or acts of God. The affected Party will notify the other Party of such force majeure circumstances as soon as reasonably practical and will make every reasonable effort to mitigate the effects of such force majeure circumstances.

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#### **12.5 Applicable law**

The Agreement will be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts of law principles.

#### **12.6 Dispute Resolution**

(a) The Parties recognize that disputes may from time to time arise between the Parties during the term of this Agreement. In the event of such a dispute, either Party, by written notice to the other Party, may have such dispute referred to the Parties' respective executive officers designated below, for attempted resolution by good faith negotiations within 30 days after such notice is received. Said designated officers are as follows:

For AVI:	President
For Ercole:	Chairman

(b) If the executive officers are unable to reach unanimous consent with respect to activities conducted under Sections 1.5(b)(i) or 1.5(b)(ii), then Ercole or AVI, respectively, shall have the final decision making authority with respect to matters regarding Ercole-AVI Exclusive Products or AVI Exclusive Products.

(c) In the event the designated executive officers are not able to resolve such dispute after such 30-day period, each Party may pursue its rights and remedies in law or equity in any court of competent jurisdiction.

#### **12.7 No consequential damages**

IN NO EVENT WILL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING, BUT NOT LIMITED TO, LOSS OF PROFITS OR REVENUE, OR CLAIMS OF CUSTOMERS OF ANY OF THEM OR OTHER THIRD PARTIES FOR SUCH OR OTHER DAMAGES. Notwithstanding the foregoing, if Ercole materially breaches its obligations with respect to the AGDG Agreement, then Ercole may be liable for damages arising as a consequence of such breach and if AVI materially breaches its obligations with respect to the UNC License or the Isis CLA, then AVI may be liable for damages arising as a consequence of such breach.

#### **12.8 Captions**

The captions to the several Articles and Sections hereof are not a part of the Agreement, but are merely a convenience to assist in locating and reading the several Articles and Sections hereof.

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#### **12.9 Waiver**

The waiver by either Party hereto of any right hereunder, or the failure to perform, or a breach by the other Party will not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.

#### **12.10 Compliance with law**

Nothing in this Agreement will be deemed to permit a Party to export, re-export or otherwise transfer any Product sold under this Agreement without compliance with applicable laws.

#### **12.11 Severability.**

In the event any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the substantive rights of the Parties. The Parties will in such an instance use their best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, maintains the balance of the rights and obligations of the Parties under this Agreement.

#### **12.12 Construction.**

Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting Party will not apply.

## 12.13 Counterparts.

This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

**Ercole Biotech, Inc.**

**AVI BioPharma, Inc.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

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### EXHIBIT 1

#### DEFINITIONS

**1.1 “Active Program”** means with respect to a Gene Target, an Ercole-AVI Exclusive Target or an AVI Exclusive Target, any reasonable (as defined below) ongoing research, development, or commercialization (including research, development or commercialization activities conducted by a Third Party pursuant to a valid sublicense under this Agreement), of a Product directed to such Gene Target.

For purposes of clarification, research, development and commercialization efforts with respect to an Ercole-AVI Exclusive Target or an AVI Exclusive Target or Product shall be deemed reasonable if the applicable Party’s research and development efforts with respect to such Gene Target or Product are reasonably comparable with other projects in such Party’s portfolio at a similar stage of development and of similar market potential. Reasonable research, development and commercialization efforts should include preclinical studies, human clinical studies and development aimed at obtaining regulatory approval for marketing a Product that modulates such Gene Target.

**1.2 “Affiliate”** with respect to either Party means any person, organization, corporation or other business entity (collectively, “Person”) controlling, controlled by, or under common control with such Party. For purposes of this definition, “control” refers to the possession, directly or indirectly, of the power to direct the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise, of a Person.

**1.3 “AVI Exclusive Product”** means a Splicing Modulator that modulates an AVI Exclusive Target and is Covered by the Splicing Patents and/or an AVI Invention Patent.

**1.4 “AVI Exclusive Target”** has the meaning set forth in Section 1.2.

**1.5 “AVI Invention”** has the meaning set forth in Section 4.1(b).

**1.6 “AVI Invention Patent”** has the meaning set forth in Section 4.1(b).

**1.7 “AVI Patents”** means the Patents listed in Exhibit 6.

**1.8 “Calendar Quarter”** means the respective periods of 3 consecutive calendar months ending on March 31, June 30, September 30 and December 31.

**1.9 “Calendar Year”** means each successive period of 12 months commencing on January 1 and ending on December 31.

**1.10 “Collaboration Term”** means the term of the Research Plan as set forth in Section 1.1.

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**1.11 “Confidential Information”** means information which is (a) of a confidential and proprietary nature; and (b) not readily available to that Party’s competitors and which, if known by a competitor of that Party, might lessen any competitive advantage of that Party or give such competitor a competitive advantage.

For the purposes of this Agreement, “Confidential Information” includes, without limitation, (a) information that is proprietary or confidential or which is treated by that Party as confidential and which relates either directly or indirectly to the business of that Party regardless of the form in which that information is constituted, and which is not lawfully in the public domain; and (b) any confidential information in relation to Patents, technology, know-how, or any improvements owned or controlled by a Party hereto.

“Confidential Information” will not include any information that the receiving Party can establish by written records:

(i) was known by it prior to the receipt of Confidential Information from the disclosing Party;



- (ii) was disclosed to the receiving Party by a Third Party having the right to do so;
  - (iii) was, or subsequently became, in the public domain through no fault of the receiving Party, its officers, directors, employees or agents;
  - (iv) was concurrently or subsequently developed by personnel of the receiving Party without having had access to the disclosing Party's Confidential Information;
  - (v) was disclosed with the prior written consent of the disclosing Party; or
  - (vi) was disclosed by the receiving Party pursuant to any judicial or governmental request, requirement or order.
- 1.12** **“Covered”, “Covering” or “Cover”** mean any process, method, organism or part thereof, composition of matter, biological compound or part thereof which when made, used, practiced or sold would, but for the applicable license granted pursuant to this Agreement constitute an infringement of any valid claim, or claims, in the referenced Patent.
- 1.13** **“EC Approval”** means approval of a Product for marketing in the European Union by the European Commission (“EC”) or, if a Party seeks approval through mutual recognition therein, by the Ministry of Health of the United Kingdom, France, Germany, Italy or Spain (each a “Major European Country”), without the requirement for price having been approved. If a Product can be sold in a Major European Country without EC or Ministry of Health approval, EC Approval will be deemed to have been obtained on the first sale of a Product in a Major European Country.
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- 1.14** **“Ercole-AVI Exclusive Product”** means a Splicing Modulator that modulates an Ercole-AVI Exclusive Target and that is Covered by the AVI Patents and/or an Ercole Invention Patent.
- 1.15** **“Ercole-AVI Exclusive Target”** has the meaning set forth in Section 1.2.
- 1.16** **“Ercole Invention”** has the meaning set forth in Section 4.1(b).
- 1.17** **“Ercole Invention Patent”** has the meaning set forth in Section 4.1(b).
- 1.18** **“Ercole Splicing Patents”** means the Patents listed in Exhibit 4.
- 1.19** **“Exclusive Targets”** means either or both of the Ercole-AVI Exclusive Targets and the AVI Exclusive Targets.
- 1.20** **“Gene Target”** means a transcriptional unit of a gene, and any protein product of such transcriptional unit, including all splice variants.
- 1.21** **“IND”** means an Investigational New Drug Application or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a Regulatory Authority in conformity with applicable Regulatory Authority regulations.
- 1.22** **“IND-Enabling GLP Tox Studies”** means, at a minimum, the pharmacokinetic and toxicology studies required to meet the safety regulations for filing an IND, as well as any additional studies required by a Regulatory Authority as a prerequisite to filing an IND.
- 1.23** **“Initiation of Phase II Trial”** means the dosing of the first patient in the first human clinical trial conducted in patients and designed to indicate a statistically significant level of efficacy for a Product in the desired indication, as well as to obtain some indication of the dosage regimen required.
- 1.24** **“Invention”** has the meaning set forth in Section 4.1(a) herein.
- 1.25** **“Isis CLA”** means that certain Collaboration and License Agreement between Ercole and Isis Pharmaceuticals effective May 16, 2003, attached (as redacted) hereto as Exhibit 8.
- 1.26** **“Jointly Owned Invention”** has the meaning set forth in Section 4.1(d).
- 1.27** **“Jointly Owned Invention Patent”** has the meaning set forth in Section 4.1(d).
- 1.28** **“License Term”** has the meaning set forth in Section 2.1.
- 1.29** **“Major Market”** means any one of the following countries: the United States, Japan, the United Kingdom, France, Germany, Italy or Spain.
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- 1.30** **“NDA”** means a New Drug Application or similar application or submission for approval to market and sell a new pharmaceutical product filed with or submitted to a Regulatory Authority in conformity with applicable Regulatory Authority regulations.
- 1.31** **“Net Sales”** means the gross amount invoiced for sales, leases and other dispositions of Products by a Party, its Affiliates, and sublicensees, to an independent Third Party in an arms-length transaction, less:
- (a) Trade, quantity and cash discounts allowed;
  - (b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances which effectively reduce the net selling price;
  - (c) Credits for actual Product returns;

- (d) Any tax imposed on the production, sale, delivery or use of the Product, including, without limitation, sales, use, excise or value added taxes;
- (e) allowance for bad debt expense that are more than ninety (90) days old and that Licensee reasonably believes are uncollectible,

“Net Sales” excludes:

- (a) the transfer of reasonable and customary quantities of free samples of Product(s) and the transfer of Product(s) as clinical trial materials, other than for subsequent resale;
- (b) Sales or transfers of Product(s) among Ercole or AVI and their respective Affiliates, unless the receiving Party is the consumer or user of the Product;
- (c) Use by Ercole or AVI or their respective Affiliates or sublicensees of Product for any use connected with the securing of regulatory approval or validating of a manufacturing process or the obtaining of other necessary Marketing Approvals for Product (unless such Product is subsequently sold); and

Notwithstanding the foregoing, if (i) a Party enters an arms-length license agreement with a Third Party with respect to a Product and (ii) the definition of Net Sales is different in such license agreement than as described above, then, the Parties will use the definition described in the third party license for the calculation of royalties hereunder.

1.32 “AGDG Agreement” means that certain agreement between AVI and Anti-Gene Development Group effective May 19, 1993 and amended in March, 2000 and attached hereto (as redacted) as Exhibit 7.

1.33 “Party” means either Ercole or AVI, as the case may be and “Parties” means both Ercole and AVI.

1.34 “Patent” or “Patents” means the AVI Patents, Isis Patents, UNC Patents, AVI Invention Patents, and Ercole Invention Patents, together with any (a) patent applications (including provisional applications) included therein; (b) any patents issuing from such patent applications; (c) any continuations-in-part, but only to the extent that they Cover the same invention claimed in the foregoing, (d) all patents and patent applications worldwide based on, corresponding to, or claiming the priority date(s) of any of the foregoing; (e) any reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, requests for continued examination, or divisions of or to any of the foregoing; and (f) term extension or other governmental action which provide exclusive rights to a Product beyond the original patent expiration date.

1.35 “Product” means an Ercole-AVI Exclusive Product or an AVI Exclusive Product, or both.

1.36 “Regulatory Authority” means any applicable government regulatory authority involved in granting approvals for the marketing and/or pricing of a Product worldwide including, without limitation, the United States Food and Drug Administration (“FDA”) and any successor government authority having substantially the same function, and foreign equivalents thereof.

1.37 “Research Plan” is the plan attached hereto as Exhibit 3.

1.38 “Royalty Period” has the meaning set forth in Section 3.1(a) for Ercole-AVI Exclusive Products and 3.2(a) for AVI Exclusive Products.

1.39 “Splicing Modulator” means an oligonucleotide or analog thereof that selectively modulates RNA Splicing or polyadenylation by a non-Rnase dependent mechanism at the nucleic acid level by specifically binding to the sequence of a selected messenger or viral ribonucleic acid (RNA) by base-pairing, thus causing a selective pattern of gene expression.

1.40 “Splicing Patents” means the Isis Splicing Patents and the Ercole Splicing Patents.

1.41 “Third Party” means any Party other than AVI or Ercole and their respective Affiliates.

1.42 “UNC License” means that certain License Agreement between Ercole and The University of North Carolina at Chapel Hill effective October 15, 2001, attached hereto (as redacted) as Exhibit 9.

## Exhibit 2

### AVI Exclusive Targets and Ercole-AVI Exclusive Targets

#### AVI Exclusive Targets

<u>Gene Name</u>	<u>ENSEMBL Gene ID</u>
*****	*****
*****	*****
*****	*****
*****	*****
*****	*****

#### Ercole-AVI Exclusive Targets

<u>Gene Name</u>	<u>ENSEMBL Gene ID</u>
*****	*****
*****	*****
*****	*****
*****	*****
*****	*****

### Exhibit 3

#### Research Plan

##### 1. Overview

Ercole and AVI wish to collaborate to develop oligonucleotides that modulate RNA splicing (Splicing Modulators). As such, Ercole and AVI will work together under the direction of the Steering Committee to identify morpholino and morpholino peptide conjugate oligomers that modulate RNA splicing of therapeutically relevant genes of interest. These oligomers will be also used to help address the mechanisms by which Splicing Modulators can modulate RNA processing and act as therapeutic agents. Ercole and AVI will also collaborate to identify additional oligomer modifications that can be exploited to modulate RNA splicing.

##### 2. Drug Discovery

- A. Ercole and AVI will design and identify morpholino and morpholino peptide conjugate Splicing Modulators that modulate the splicing of Ercole-AVI Exclusive Gene Targets and the AVI Exclusive Gene Targets (The “Modulator Commitment”).
  - For each Ercole-AVI Exclusive Target, AVI will provide up to 30 Splicing Modulators, requested by Ercole, to be tested in a cell-based assay for their ability to modulate splicing. Ercole will perform preclinical drug discovery pharmacology on morpholino and morpholino peptide conjugate Splicing Modulators supplied by AVI for Ercole-AVI Exclusive Targets.
  - For each AVI Exclusive Target, AVI will perform preclinical drug discovery pharmacology on morpholino and morpholino peptide conjugate Splicing Modulators supplied by AVI. Ercole will collaborate with AVI regarding AVI Exclusive Targets, including but not limited to: Splicing Modulators identification, selection and targeting, in vitro assays and preclinical drug development.
- B. Although the desired efficacy and potency will vary for different targets and cell lines which express the target, it is generally desired that the Splicing Modulator promotes at least a \*\*\*\*\* decrease in the targeted mRNA splice variant at a concentration of \*\*\*\*\* or lower using electroporation or scrape-loading for delivery in cell culture.
- C. For Splicing Modulators selected for further drug development, AVI will provide morpholino and morpholino peptide conjugates, including negative and positive control sequences, in sufficient amounts to carry out required rodent pharmacology studies, not to exceed \*\*\*\*\* grams per gene target (the “Study Materials”). The initial \*\*\*\*\* of Study Materials will be free of charge. For additional amounts, the Study Materials will be provided by AVI at cost.
- D. AVI and Ercole will transfer bioanalytical methods as needed to one another to support preclinical pharmacology/pharmacokinetics studies and will provide collaborative advice in these areas.

- E. Under direction of the Steering Committee and for their respective Gene Targets, Ercole and AVI will perform preclinical toxicology/PK studies required for IND filing and early clinical trial design.

##### 3. Medicinal Chemistry

- A. To facilitate improvements of morpholino and morpholino peptide conjugate oligomers as Splicing Modulators, Ercole will evaluate morpholino and morpholino peptide conjugate oligomers in Ercole’s RNA processing models. The oligomers will include molecules containing modifications as suggested and agreed to by the parties. AVI will provide over the term of the agreement, but not less than two years, up to 30 different oligomers for cell-based assays (\*\*\*\*\*) and for in vivo experiments (\*\*\*\*\*).
- B. Ercole will evaluate efficacy of oligomers in Ercole’s cellular and animal RNA processing model systems.
- C. AVI and Ercole will discuss and confer on any plans for evaluation in RNA processing model systems of any additional oligonucleotide modifications.
- D. Those Splicing Modulators with modifications that show promise in model systems will be shared by both parties in their application to therapeutically relevant targets.

##### 4. Further Development

Any time that Ercole decides to develop an Ercole-AVI Exclusive Product beyond the stage covered in this Research Plan (for example, to conduct formal GLP toxicology and clinical testing), Ercole will so notify AVI, and Ercole and AVI will negotiate and execute a Supply Agreement covering the manufacture of that particular oligomer to support Ercole’s development and commercial needs (“Supply Plan”). The Supply Agreement will provide for either: a) the supply of material to Ercole by AVI (with financial terms to include industry-standard manufacturing margins); or b) the transfer of the

manufacturing process to an acceptable third-party contract manufacturer (with payment of an industry-standard royalty to AVI on manufacturing patents and know-how).

## 5. Use Of Materials, Data and Information

- A. Unless provided otherwise herein, all Splicing Modulators and any related research materials delivered to Ercole under this Agreement will not be used in research or testing involving human subjects. The Splicing Modulators and any related research materials supplied under this Agreement must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known. Ercole agrees to comply with all applicable laws, rules and regulations in connection with its use of Splicing Modulators and related research materials provided hereunder.
- B. Ercole may use data and information generated pursuant to the testing and evaluations, or otherwise provided to Ercole by AVI hereunder, for internal drug discovery purposes only, consistent with the terms of this Agreement. AVI acknowledges that Ercole may

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wish to provide such data and/or information to a Third Party in connection with a permitted investment, sublicense or partnering activity under this Agreement.

- C. AVI may use data and information generated pursuant to the testing and evaluations, or otherwise provided to AVI by Ercole hereunder, for internal drug discovery purposes only, consistent with the terms of this Agreement. Ercole acknowledges that AVI may wish to provide such data and/or information to a Third Party in connection with a permitted investment, sublicense or partnering activity under this Agreement.
- D. Consistent with the foregoing provisions, if Ercole conducts studies comparing the chemistry Covered By the AVI Patents with the chemistry of a Third Party, all data and information incorporating or relating to the chemistry Covered By the AVI Patents that result from such studies is confidential and proprietary to AVI and will not be disclosed to Third Parties, consistent with the provisions of Article 4 of the Agreement; provided, however, that Ercole may disclose such data and information to Third Parties under the terms of a confidentiality agreement to the extent necessary to enable Ercole to compare the relative performance or properties of specific Splicing Modulators but only so long as Ercole does not disclose the chemistry or sequence of such Splicing Modulator.

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### Exhibit 4

#### Ercole Splicing Patents

US Patent No. \*\*\*\*\* entitled \*\*\*\*\*.

US Patent No. \*\*\*\*\* entitled \*\*\*\*\*.

US Patent No. \*\*\*\*\* entitled \*\*\*\*\*.

US Patent No. \*\*\*\*\* entitled \*\*\*\*\*.

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### Exhibit 5

#### Isis Splicing Patents

US Patent No. \*\*\*\*\* entitled \*\*\*\*\*.

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### Exhibit 6

#### AVI Patents

##### Morpholino Backbone Patents

1. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. Patent No. \*\*\*\*\*

2. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. Patent No. \*\*\*\*\*

3. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. Patent No. \*\*\*\*\*

4. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. Patent No. \*\*\*\*\*

5. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - CA \*\*\*\*\* , JP \*\*\*\*\* , AU \*\*\*\*\* , EP \*\*\*\*\* , KR \*\*\*\*\*

6. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* –EP \*\*\*\*\*

7. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – US Provisional Application \*\*\*\*\*

**ESPRIT**

8 - - 10. Attorney Docket Nos. \*\*\*\*\* entitled \*\*\*\*\* – U.S. Patent \*\*\*\*\* and pending US applications \*\*\*\*\*; corresponding CA, JP, AU, EP applications

**Delivery Technology**

11 & 12. Attorney Docket Nos. \*\*\*\*\* entitled \*\*\*\*\* – U.S. application \*\*\*\*\* pending; corresponding CA, JP, AU, EP, KR applications

13. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. application \*\*\*\*\* pending; corresponding PCT application

14. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – U.S. application \*\*\*\*\* pending; corresponding PCT application

15. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – U.S. application \*\*\*\*\* pending; corresponding CA, AU, EP applications

16. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – US Application \*\*\*\*\* pending; corresponding PCT application

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**Licensed Intellectual Property**

17 & 18. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – U.S. Patent Nos. \*\*\*\*\*; EP Patent No. \*\*\*\*\*; corresponding CA, JP applications \*\*\*\*\*

19. Attorney Docket No. \*\*\*\*\* – U.S. Patent No. \*\*\*\*\*

20. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* - U.S. Patent No. \*\*\*\*\*; AU Patent No. \*\*\*\*\*; EP Patent No. \*\*\*\*\*

21. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – U.S. Patent No. \*\*\*\*\*

22. Attorney Docket No. \*\*\*\*\* entitled \*\*\*\*\* – U.S. Patent No. \*\*\*\*\*

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**Exhibit 7**

**AGDG Agreement**

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**Exhibit 8**

**Isis CLA**

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**Exhibit 9**

**UNC License**

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**SERIES A-2 PREFERRED STOCK  
AND COMMON STOCK PURCHASE AGREEMENT**

This Series A-2 Preferred Stock and Common Stock Purchase Agreement (this “**Agreement**”) is entered into as of December 19, 2006 by and among Ercole Biotech, Inc., a Delaware corporation (the “**Ercole**”), and AVI BioPharma, Inc. (“**AVI**”).

WHEREAS, Ercole and AVI are parties to that certain Collaboration and License Agreement, dated of even date herewith (the “**Collaboration Agreement**”);

WHEREAS, in connection with entering into the Collaboration Agreement with Ercole, AVI desires to acquire shares of Ercole’s Series A-2 Preferred Stock, par value \$0.001 per share (the “**Series A-2 Preferred**”); and Ercole desires to sell such shares of Series A-2 Preferred upon the terms set forth herein; and

WHEREAS, AVI has agreed to issue to Ercole, as consideration to be paid for the Series A-2 Preferred, shares of freely tradeable common stock of AVI, par value \$.0001 per share (the “**AVI Common Stock**”), which shares have been registered in a shelf offering registration on a Form S-3 registration statement declared effective by the SEC and currently in effect, SEC No. 333-109015 (the “**Shelf Registration**”), pursuant to the terms set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, representations, warranties, covenants and conditions set forth in this Agreement, Ercole and AVI mutually agree as follows:

1. Authorization and Sale of Stock.

1.1 Authorization. Ercole has authorized the issuance and sale of up to an aggregate of Six Hundred Twenty-Five Thousand (625,000) shares of the Series A-2 Preferred (the “**Ercole Shares**”).

1.2 Sale and Payment for Ercole Shares. Subject to the terms and conditions of this Agreement, Ercole hereby agrees to issue and sell to AVI and AVI hereby agrees to purchase from Ercole all of the Ercole Shares for an aggregate purchase price of \$675,000 (the “**Purchase Price**”) consisting of one hundred ninety-two thousand, eight hundred fifty-seven (192,857) registered and freely tradeable shares of AVI Common Stock (the “**AVI Shares**”).

1.3 Sale of AVI Shares by Ercole. Ercole may sell the AVI Shares at its discretion, provided, however, that Ercole shall sell in any single trading day no more than 60,000 shares and no single trade shall involve the sale of more than 20,000 shares.

2. Closing; Delivery.

2.1 Closing. The closing of the sale and issuance of the Ercole Shares to AVI and of the AVI Shares to Ercole (the “**Closing**”), shall take place at 10:00 a.m. (ET) on December 22, 2006, or such earlier date as mutually agreed by the parties (the “**Closing Date**”),

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at the offices of Hutchison Law Group PLLC, 5410 Trinity Road, Suite 400, Raleigh, North Carolina 27607 by electronic transmission or hand delivery of documents, or at such other time and place as Ercole and AVI agree.

2.2 Delivery. At the Closing, subject to the terms and conditions hereof, Ercole will deliver to AVI a certificate, in such denomination and registered in such name or names as AVI may designate by notice to Ercole prior to the Closing, representing the Ercole Shares to be purchased by AVI from Ercole at the Closing, dated the date of the Closing against delivery of the AVI Shares. AVI will deliver or cause to be delivered via DWAC or other common means of electronic share transfer to Ercole’s designated brokerage account the AVI Shares registered in such name or names as Ercole may designate by notice to AVI prior to Closing.

3. Representations and Warranties of Ercole. Subject to and except as disclosed by Ercole in the Schedule of Exceptions attached hereto and incorporated herein by reference (the “**Ercole Schedule of Exceptions**”), Ercole represents and warrants to AVI that:

3.1 Organization and Standing. Ercole is a corporation duly organized, validly existing, and in good standing under the laws of its state of incorporation, and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now conducted and as currently proposed to be conducted. Ercole is duly qualified and authorized to do business, and is in good standing as a foreign corporation, in each jurisdiction where the nature of its activities and of its properties (both owned and leased) makes such qualification necessary, except where the failure to be so qualified would not have a material adverse effect upon the business, financial condition or results of operation (a “**Material Adverse Effect**”) of Ercole.

3.2 Capitalization. The authorized capital of Ercole immediately prior to the Closing is as set forth on Schedule 3.1.

3.3 Corporate Power. Ercole has the requisite corporate power and authority to execute, deliver and perform its obligations under this Agreement, including without limitation, to issue the Ercole Shares.

3.4 Authorization. All corporate action on the part of Ercole and its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement and the Certificate (as defined in Section 5.5), the performance of all of Ercole’s obligations thereunder, and the authorization, issuance, sale and delivery of the Ercole Shares and the securities issuable upon the conversion of the Ercole Shares (collectively, the “**Securities**”) has been or will be taken prior to Closing. This Agreement when executed by Ercole and the parties hereto shall constitute a valid and legally binding obligation of Ercole enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors, rules and laws governing specific performance, injunctive relief and other equitable remedies.

3.5 Valid Issuance of Securities. The Ercole Shares, when issued, sold and delivered in accordance with the terms of this Agreement and the Certificate of Incorporation, as amended (the “**Certificate of Incorporation**”), will be duly and validly issued, fully paid and

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nonassessable and free of restrictions on transfer other than restrictions on transfer under applicable state and federal securities laws. The Securities issuable upon conversion of the Ercole Shares have been duly and validly reserved for issuance, and upon issuance in accordance with the Certificate of Incorporation, will be duly and validly issued, fully paid and nonassessable and free of restrictions on transfer other than restrictions on transfer under applicable federal and state securities laws.

3.6 Governmental Consent. All consents, approvals, orders or authorizations of, or registrations, qualifications, designations, declarations or filings with any federal or state governmental authority on the part of Ercole required in connection with the valid execution and delivery of this Agreement the offer, sale or issuance of the Ercole Shares or the consummation of any other transaction contemplated hereby have been obtained, except for notices which may be required to be filed with certain state and federal securities commissions after the sale or issuance of the Ercole Shares, and a Form D to be filed pursuant to Rule 503 under the Securities Act of 1933, as amended, (the “1933 Act”), which notices will be filed on a timely basis.

3.7 Compliance with Laws. To its knowledge, Ercole is not in violation of any applicable statute, rule, regulation, order or restriction of any domestic or foreign government or any instrumentality or agency thereof in respect of the conduct of its business or the ownership of its properties, the violation of which would have a Material Adverse Effect.

3.8 Compliance with Other Instruments. Ercole is not in violation or default of any term of its Certificate of Incorporation or bylaws, or of any provision of any mortgage, indenture or material contract to which it is a party and by which it is bound or of any judgment, decree, order or writ, other than such violation(s) that would not have a Material Adverse Effect on Ercole. The execution, delivery and performance of this Agreement, the issuance of the Ercole Shares and the consummation of the transactions contemplated hereby will not result in any such violation or be in conflict with, or constitute, with or without the passage of time and giving of notice, either a default under any such provision, instrument, judgment, decree, order or writ or an event that results in the creation of any lien, charge or encumbrance upon any assets of Ercole or the suspension, revocation, impairment, forfeiture, or nonrenewal of any material permit, license, authorization or approval applicable to Ercole, its business or operations or any of its assets or properties. Without limiting the foregoing, Ercole has obtained all waivers reasonably necessary with respect to any preemptive rights, rights of first refusal or similar rights, including any notice or offering periods provided for as part of any such rights, in order for Ercole to consummate the transactions contemplated hereunder without any third party obtaining any rights to cause Ercole to offer or issue any securities of Ercole as a result of the consummation of the transactions contemplated hereunder.

3.9 Offering. Based in part on the accuracy of the representations and warranties of AVI contained in Section 4.10 hereof, and subject to such filings with the Securities and Exchange Commission (“SEC”) and any applicable state securities commissions as may be required in connection therewith, the offer, issue and sale of the Ercole Shares are and will be exempt from the registration and prospectus delivery requirements of the 1933 Act, and have been registered or qualified (or are exempt from registration and qualification) under the registration, permit or qualification requirements of all applicable state securities laws.

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3.10 Litigation. Except as set forth on Schedule 3.10 to the Ercole Schedule of Exceptions, there is no claim, action, suit, proceeding, arbitration, complaint, charge or investigation pending or to its knowledge, threatened against Ercole. Neither Ercole nor any of its officers or directors is a party to or is named as subject to the provisions of any order, writ, injunction, judgment or decree of any court or government agency or instrumentality. There is no action, suit, proceeding or investigation by Ercole and pending or proceedings which Ercole intends to initiate. The foregoing includes, without limitation, actions, suits, proceedings or investigations pending or threatened in writing involving the use by any of Ercole’s former employees, in the course of performing services as an employee for Ercole, of any information or techniques allegedly proprietary to any of such employees, former employers, or their obligations under any agreements with prior employers.

3.11 Intellectual Property. Other than the Collaboration and License Agreement (the “**Isis CLA**”) between Ercole and Isis Pharmaceuticals, Inc. effective May 16, 2003, and the License Agreement (the “**UNC License**”) between Ercole and The University of North Carolina at Chapel Hill effective October 15, 2001, there are no agreements between Ercole and any third parties which would preclude or otherwise limit Ercole’s ability to conduct its tasks and obligations under Collaboration and License Agreement entered into between the parties concurrent with the execution of this Agreement. The Isis CLA and the UNC License are in full force and effect, and the copies provided to AVI are accurate and complete. Ercole has not received any communications alleging that it has violated or, by conducting its business as proposed, would violate any of the patents, trademarks, service marks, trade names, domain names, copyrights, trade secrets or other proprietary rights or processes of any other person or entity, except, in either case, for standard end-user, object code, internal-use software license and support/maintenance agreements. To Ercole’s knowledge, no employee is obligated under any contract (including licenses, covenants or commitments of any nature) or other agreement, or subject to any judgment, decree or order of any court or administrative agency, that would interfere with the use of such employee’s best efforts to promote the interest of Ercole or that would conflict with its business. Ercole does not believe it is or will be necessary to use any inventions of any of its employees made prior to or outside the scope of their employment by Ercole, except for any such inventions licensed to Ercole under the UNC License.

3.12 Material Liabilities. Ercole has no material liability or obligation, and to its knowledge, no contingent liability or obligation (individually or in the aggregate) that is not disclosed in its financial statements as of and for the year ended December 31, 2005 (the “**Financial Statements**”), copies of which have been provided to AVI, except (i) obligations and liabilities incurred in the ordinary course of business subsequent to the date of the Financial Statements that are not materially adverse, individually or in the aggregate, (ii) obligations and liabilities identified in Section 3.12 of the Ercole Schedule of Exceptions, and (iii) obligations under contracts made in the ordinary course of business that would not be required to be reflected in financial statements prepared in accordance with generally accepted accounting principles.

3.13 Corporate Documents. The Second Amended and Restated Certificate of Incorporation and Bylaws of Ercole are in the form provided to AVI. The minute books of the Company contain minutes of all meetings of directors and stockholders and all actions by written consent without a meeting by the directors and stockholders since the date of incorporation and

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accurately reflect in all material respects all actions by the directors (and any committee of directors) and stockholders with respect to all transactions referred to in such minutes.

3.14 Disclosure. Ercole has provided AVI with all of the information AVI has requested for deciding whether to purchase the Ercole Shares. To Ercole's knowledge, no certificates made or delivered in connection with this Agreement contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein not misleading in light of the circumstances under which such statements were made or given.

3.15 Investment Representations. Ercole represents that it has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment hereunder, and has the ability to bear the economic risks of such investment. In making its investment decision hereunder, Ercole and its advisors have relied on the representations and warranties of AVI contained herein and AVI's public filings as filed with the SEC. Ercole has not traded in AVI Common Stock or derivative securities in the 30-day period prior to the Closing Date.

4. Representations and Warranties of AVI. AVI hereby represents and warrants to Ercole as follows:

4.1 Organization and Standing. AVI is a corporation duly formed, validly existing, and in good standing under the laws of the jurisdiction of its incorporation and has all requisite corporate power and authority to own, lease and operate its properties and assets and to carry on its business as now conducted and as currently proposed to be conducted.

4.2 Authorization. AVI has the requisite power and authority to enter into this Agreement, to purchase the Ercole Shares subject to all of the terms hereof, to issue and deliver the AVI Shares and to otherwise carry out and perform its obligations under the terms of this Agreement. All corporate or other action on the part of AVI and its officers, directors and stockholders necessary for the authorization, execution and delivery of this Agreement, the performance of all AVI's obligations hereunder, and the authorization, issuance and delivery of the AVI Shares, has been taken. This Agreement when executed and delivered by AVI and the parties hereto shall constitute the valid and legally binding obligation of AVI enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors, rules and laws governing specific performance, injunctive relief and other equitable remedies.

4.3 Valid Issuance of Securities. The AVI Shares, when issued, sold and delivered in accordance with the terms of this Agreement and the Certificate of Incorporation, as amended of AVI (the "**AVI Charter**"), will be duly and validly issued, fully paid and nonassessable and free of restrictions on transfer other than restrictions on transfer under applicable state and federal securities laws and as set forth in Section 1.3 hereunder.

4.4 Governmental Consent. All consents, approvals, orders or authorizations of, or registrations, qualifications, designations, declarations or filings with any federal or state governmental authority on the part of AVI required in connection with the valid execution and delivery of this Agreement, the offer or issuance of the AVI Shares or the consummation of any other transaction contemplated hereby have been obtained.

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4.5 SEC Documents.

(a) Since January 1, 2006, AVI has timely made all filings required to be made by it under the Exchange Act (the "SEC Documents"), and the securities laws of any state, and any rules and regulations promulgated thereunder. The SEC Documents comply in all material respects with the requirements of the Securities Exchange Act or the Act of 1934, as amended (the "**Exchange Act**") or the 1933 Act, as applicable, and none of the SEC Documents contains any untrue statement of a material fact or omits to state a material fact required to be stated therein or necessary in order to make the statements made therein, in light of the circumstances under which they were made, not misleading, as of their respective filing dates, except to the extent corrected by a subsequently filed SEC Document filed prior to the date hereof.

(b) AVI meets all requirements for the use of the Shelf Registration and the Shelf Registration statement has been declared effective by the SEC and is effective as of the date hereof. No stop order suspending the effectiveness of the Registration Statement has been issued, no proceedings for that purpose are pending before or, to AVI's knowledge, threatened by the SEC and AVI is not aware of any basis for the issuance of such a stop order. The Registration Statement complies in all material respects with the applicable requirements of the 1933 Act and the regulations thereunder. AVI has no present intention to withdraw the Registration Statement, cease issuing shares under the Registration Statement or place a stop order or otherwise instruct its transfer agent to prohibit the transfer of shares issued pursuant to the Registration Statement. A sufficient number of shares of AVI Common Stock are, and will be as of the Closing, available to permit the issuance of the AVI Shares by AVI pursuant to the Registration Statement.

4.6 Material Liabilities. AVI has no material liability or obligation (individually or in the aggregate) that is not disclosed in the SEC Documents, including without limitation the financial statements contained therein, or incurred in the ordinary course of business consistent with AVI's past practices.

4.7 Compliance with Other Instruments. AVI is not in violation or default of any term of its certificate of incorporation or bylaws, or of any provision of any mortgage, indenture or material contract to which it is a party and by which it is bound or of any judgment, decree, order or writ, other than such violation(s) that would not have a Material Adverse Effect on AVI. The execution, delivery and performance of this Agreement, the issuance of the AVI Shares and the consummation of the transactions contemplated hereby will not result in any such violation or be in conflict with, or constitute, with or without the passage of time and giving of notice, either a default under any such provision, instrument, judgment, decree, order or writ or an event that results in the creation of any lien, charge or encumbrance upon any assets of AVI or the suspension, revocation, impairment, forfeiture, or nonrenewal of any material permit, license, authorization or approval applicable to AVI, its business or operations or any of its assets or properties.

4.8 Nasdaq National Market. The AVI Common Stock is listed on The Nasdaq National Market, and there are no proceedings to revoke or suspend such listing. The issuance of the AVI Shares will not contravene any NASDAQ Marketplace Rule. The AVI

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Common Stock is registered pursuant to Section 12(g) of the Exchange Act. AVI has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the AVI Common Stock under the Exchange Act or delisting the AVI Common Stock from The Nasdaq National Market. AVI has not received any notification that, and has no knowledge that, the SEC or the NASD is contemplating terminating such listing or



registration. The issuance of the AVI Shares does not require stockholder approval, including, without limitation, as may be required pursuant to the Nasdaq Marketplace Rules. The AVI Shares, as of the date of issuance, will be listed and available for trading on the Nasdaq National Market.

4.9 Disclosure. Neither this Agreement nor the SEC Documents taken together contain any untrue statement of a material fact nor omit to state a material fact necessary in order to make the statements contained herein or therein, in light of the circumstances under which they were made, not misleading.

4.10 Investment Representations.

(a) This Agreement is made with AVI in reliance upon AVI's representations to Ercole, which by its acceptance hereof AVI hereby confirms, that the Ercole Shares to be received by it will be acquired for investment for its own account, not as a nominee or agent, and that it has no present intention of selling, granting participation in, or otherwise distributing the same in a manner that will violate the registration provisions of the 1933 Act or any applicable state securities laws. By executing this Agreement, AVI further represents that it does not have any contract, undertaking, agreement, or arrangement with any person to sell, transfer or grant participations to any third person, with respect to any of the Ercole Shares.

(b) AVI understands that the Ercole Shares have not been registered under the 1933 Act or any applicable state securities laws, based upon Ercole's determination, on the grounds that the sale provided for in this Agreement and the issuance of securities hereunder are exempt from such registration, and that Ercole's reliance on such exemption is predicated in part on AVI's representations set forth herein.

(c) AVI represents that it is an accredited investor, as defined under Regulation D of the 1933 Act, and has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investment hereunder, and has the ability to bear the economic risks of its investment.

(d) AVI understands that the Ercole Shares may not be sold, transferred or otherwise disposed of without registration under the 1933 Act or any applicable state securities laws, or an exemption therefrom, and that in the absence of an effective registration statement covering the Ercole Shares or an available exemption from such registration, the Ercole Shares must be held indefinitely. In particular, AVI represents that it is aware that the Ercole Shares may not be sold pursuant to Rule 144 promulgated under the 1933 Act unless all of the conditions of that Rule are met. Among the conditions for use of Rule 144, prior to the time sales may be made under paragraph (k) of Rule 144, is the availability of current information to the public about Ercole. Such information is not now available and Ercole has no present plans to make such information available. AVI represents that, in the absence of an effective registration statement covering the Ercole Shares, it will sell, transfer, or otherwise

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dispose of the Ercole Shares only in a manner that does not violate the 1933 Act and any applicable state securities laws and then only in accordance with the provisions of Section 4.10 (e) hereof, the provisions of the Registration Rights contained herein and the provisions of Ercole's Bylaws.

(e) Prior to such time, if ever, as Ercole becomes subject to the reporting provisions of Section 13(a) or 15(d) of the Exchange Act, AVI agrees that in no event will it make a transfer or disposition of any of the Ercole Shares (other than pursuant to an effective registration statement under the 1933 Act or, to Ercole's reasonable satisfaction, pursuant to Rule 144), unless and until (i) AVI shall have notified Ercole of the proposed disposition and (ii) if reasonably requested by Ercole, at the expense of AVI or transferee, it shall have furnished to Ercole an opinion of counsel, reasonably satisfactory to Ercole, to the effect that such transfer may be made without registration under the 1933 Act or any applicable state securities laws.

(f) AVI understands that each certificate representing the Ercole Shares will be endorsed with a legend substantially as follows:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS. COPIES OF THE STOCK PURCHASE AGREEMENT PROVIDING FOR RESTRICTIONS ON TRANSFER OF THESE SECURITIES MAY BE OBTAINED UPON WRITTEN REQUEST BY THE HOLDER OF RECORD OF THIS CERTIFICATE TO THE SECRETARY OF THE COMPANY AT THE PRINCIPAL EXECUTIVE OFFICES OF THE COMPANY."

4.11 No Public Market. AVI understands that no public market now exists for any of the securities issued by Ercole and that there is no assurance that a public market will ever exist for the Ercole Shares or any such securities.

4.12 Government Consents. No consent, approval or authorization of or designation, declaration or filing with any state, federal, or foreign governmental authority on the part of AVI is required in connection with the valid execution and delivery of this Agreement by AVI, and the consummation by AVI of the transactions contemplated hereby; provided, however, that AVI makes no representations as to Ercole's compliance with applicable law.

5. Conditions to Closing. Unless otherwise provided in this Section 4.12, or as waived by AVI or Ercole, as applicable, the obligations of Ercole to issue and sell the Ercole Shares at the Closing and to accept delivery of the AVI Shares in payment therefor, the obligations of AVI to purchase the Ercole Shares at the Closing and to issue and deliver the AVI

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Shares in payment of the Ercole Shares, are subject to the fulfillment on or before such Closing of each of the following conditions:

5.1 Representations and Warranties. The representations and warranties contained in Sections 3 and 4 shall be true in all material respects on and as of the date of the Closing.

5.2 Performance. Each party shall have performed and complied in all material respects with all agreements and conditions contained in this Agreement required to be performed or complied with by it on or before the Closing.

5.3 Qualifications; Filings. All authorizations, filings, approvals or permits, if any, of any governmental authority or regulatory body of the United States or any agency thereof or of any state that are required prior to and in connection with the lawful issuance and sale of the Ercole Shares and the lawful issuance and delivery to Ercole of the AVI Shares pursuant to this Agreement, including, without limitation, the filing with the SEC by AVI of a prospectus supplement to the Registration Statement with respect to the AVI Shares, which prospectus supplement shall be in compliance in all material respects with applicable requirements, shall have been duly made or obtained and shall be effective on and as of the date of the Closing, except for notices required to be filed by Ercole with the SEC and certain state securities commissions as applicable after the Closing, which notices will be filed on a timely basis.

5.4 Proceedings and Documents. All corporate and other proceedings in connection with the transactions contemplated hereby at the Closing hereunder and all related documents shall be reasonably satisfactory in substance and form to Ercole and its counsel and to AVI and its counsel, as applicable, and AVI and its counsel and Ercole and its counsel, as applicable, shall have received all such counterpart originals or certified or other copies of such documents as they may reasonably request.

5.5 Filing of Certificate of Designation to the Second Amended and Restated Certificate of Incorporation. The Certificate of Designation to Second Amended and Restated Certificate of Incorporation of Ercole attached hereto as **Exhibit A** (the "**Certificate**") shall have been duly filed by Ercole with the Secretary of State of the State of Delaware.

6. Miscellaneous.

6.1 Entire Agreement. This Agreement and the Ercole Schedule of Exceptions constitute the entire agreement between the parties, and no party shall be liable or bound to any other party in any manner by any warranties, representations or covenants or agreements except as specifically set forth herein or therein. The terms and conditions of this Agreement shall inure to the benefit of and be binding upon the successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any third party any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement (including the Schedule of Exceptions which is part of this Agreement).

6.2 Headings. The headings used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

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6.3 Notice. Any notice required or permitted under this Agreement shall be given in writing and shall be deemed effectively given upon personal delivery, if sent via facsimile (with confirmed receipt), or five business days after deposit with the United States Post Office, by registered or certified mail, postage prepaid, addressed

(a) if to Ercole, at:

Ercole Biotech, Inc.  
P.O. Box 12295  
79 Alexander Drive, Bldg. 4401, Suite 200  
Research Triangle Park, North Carolina 27709  
Attention: President  
Phone: (919) 883-7118  
Fax: (919) 536-1700

With a copy to:

William N. Wofford, Esq.  
Hutchison Law Group PLLC  
5410 Trinity Road  
Suite 400  
Raleigh, North Carolina 27607  
Phone: (919) 829-9600  
Fax: (919) 829-9696

or at such other address as Ercole shall have furnished to AVI in writing in accordance with procedures set forth in this Section, and

(b) if to AVI, at

AVI BioPharma, Inc.  
One SW Columbia, Suite 1105  
Portland, Oregon 97258  
Attention: President  
Phone: (503) 227-0554  
Fax: (503) 227-0751

With a copy to:

Michael Phillips, Esq.  
Davis Wright Tremaine LLP  
1300 SW 5<sup>th</sup> Avenue, Suite 2300  
Portland, OR 97201  
Phone: (503) 231-2300  
Fax: (503) 778-5499

or at such other address as AVI shall have furnished to Ercole in writing in accordance with procedures set forth in this Section.

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6.4 Expenses. Each party shall pay all costs and expenses that it incurs with respect to the negotiation, execution, delivery and performance of this Agreement and any schedules or exhibits hereto.

6.5 Severability. Any invalidity, illegality or limitation of the enforceability with respect to any one or more of the provisions of this Agreement, or any part thereof, shall in no way affect or impair the validity, legality or enforceability of any other provisions of this Agreement. In case any provision of this Agreement shall be invalid, illegal or unenforceable, it shall, to the extent practicable, be modified so as to make it valid, legal and enforceable and to retain as nearly as practicable the intent of the parties, and the validity, legality, and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

6.6 Delays or Omissions. No delay or omission to exercise any right, power or remedy accruing to Ercole, AVI or any subsequent holder of any Ercole Shares upon any breach, default or noncompliance of Ercole, AVI, or any such holder under this Agreement, shall impair any such right, power or remedy, nor shall it be construed to be a waiver of any such breach, default or noncompliance, or any acquiescence therein, or of any similar breach, default or noncompliance thereafter occurring. It is further agreed that any waiver, permit, consent or approval of any kind or character on the part of Ercole, AVI or any subsequent holder of any Ercole Shares of any breach, default or noncompliance under this Agreement or any waiver on Ercole's, AVI's or such subsequent holders' part of any provisions or conditions of this Agreement must be in writing and shall be effective only to the extent specifically set forth in such writing and that all remedies under this Agreement, by law, or otherwise afforded to Ercole, AVI or any subsequent holder of any Ercole Shares, shall be cumulative and not alternative.

6.7 Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, either retroactively or prospectively and either for a specified period of time or indefinitely) upon the written agreement of Ercole and AVI. Any amendment or waiver effected in accordance with this Section 6.6 shall be binding upon AVI and each transferee of the Ercole Shares.

6.8 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

6.9 Governing Law. This Agreement shall be governed by and construed under the laws of the State of Delaware as applied to agreements among Delaware residents, made and to be performed entirely within the State of Delaware.

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IN WITNESS WHEREOF, the undersigned has caused this Series A-2 Preferred Stock and Common Stock Purchase Agreement to be executed and delivered effective as of the date first written above.

**ERCOLE BIOTECH, INC.**

By: \_\_\_\_\_  
Ryszard Kole, President

**AVI BIOPHARMA, INC.**

By: \_\_\_\_\_  
Name: Alan P. Timmins  
Title: President and Chief Operating Officer

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## CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders  
AVI BioPharma, Inc.

We consent to the incorporation by reference in the registration statement Nos. 333-86778, 333-105412, 333-10915, 333-68502, 333-45888, 333-93135 and 333-86039 on Forms S-3 and Nos. 333-101826, 333-49996, 333-49994 and 333-34047 on Forms S-8 of AVI BioPharma, Inc. of our report dated March 16, 2007, with respect to the balance sheets of AVI BioPharma, Inc. (an Oregon corporation in the development stage) as of December 31, 2006 and 2005 and the related statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2006, management's assessment of the effectiveness of internal control over financial reporting and the effectiveness of internal control over financial reporting as of December 31, 2006, which reports appear in the December 31, 2006 annual report on Form 10-K of AVI BioPharma, Inc.

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

/s/ KPMG LLP

Portland, Oregon,  
March 16, 2007

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

I, Denis R. Burger, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15 (f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2007

By:

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

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

I, Mark M. Webber, certify that:

1. I have reviewed this quarterly report on Form 10-K of AVI BioPharma, Inc. (the "Registrant");
  2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15 (f) and 15d-15 (f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2007

By:

\_\_\_\_\_  
/s/ Mark M. Webber  
**Mark M. Webber,**  
**Chief Financial Officer and Chief Information**  
**Officer**  
**(Principal Financial and Accounting Officer)**

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

In connection with the Annual Report of AVI BioPharma, Inc. (the "Company") on Form 10-K for the period ended December 31, 2006 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Denis R. Burger, as Chief Executive Officer of the Company, and Mark M. Webber, as Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge,:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

/s/ Denis R. Burger

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Denis R. Burger  
Chairman and Chief Executive Officer  
AVI BioPharma, Inc.  
March 16, 2007

/s/ Mark M. Webber

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Mark M. Webber  
Chief Financial Officer and Chief Information Officer  
AVI BioPharma, Inc.  
March 16, 2007

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

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

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