AVI BIOPHARMA INC
Form 10-K
March 15, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 001-14895

AVI BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Oregon	93-0797222
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3450 Monte Villa Parkway, Suite 101

Bothell, Washington	98021
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: (425) 354-5038

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.0001 par value	**The NASDAQ Stock Market LLC**
	(The NASDAQ Global Market)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

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

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 the 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. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2010 was approximately $136,667,337.

The number of outstanding shares of the registrant s common stock as of the close of business on February 28, 2011 was 112,561,377.

DOCUMENTS INCORPORATED BY REFERENCE

The issuer has incorporated into Part III of this Annual Report on Form 10-K, by reference, portions of its definitive Proxy Statement for its 2011 annual meeting.

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AVI BioPharma, Inc.

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PART I

Item 1. Business.

Forward-Looking Information

This Annual Report on Form 10-K, including the Management s Discussion and Analysis of Financial Condition and Results of Operation section in Item 7, and other materials accompanying this Annual Report on Form 10-K contain forward-looking statements or incorporate by reference forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may, and other similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other forward-looking information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to:

our expectations regarding the development and clinical benefits of our product candidates;

the results of our research and development efforts and the efficacy of our PMO chemistries and other RNA-based technology;

our expectations regarding our ability to become a leading developer and marketer of RNA-based therapeutics;

our expectations regarding the results of pre-clinical and clinical testing of our product candidates;

our ability to initiate a Phase II clinical trial for AVI-4658 in the first half of 2011 and a pivotal Phase III clinical trial for AVI-4658 in the second half of 2012;

our ability to initiate Phase I clinical trials in 2011 for our three leading anti-viral product candidates (AVI-6002, AVI-6003 and AVI-7100);

the receipt of any required approval from the U.S. Food and Drug Administration, or FDA, or other regulatory approval for our products;

the effect of regulation by FDA and other agencies;

our intention to introduce new products;

our expectations regarding the markets for our products;

acceptance of our products, if introduced, in the marketplace;

the impact of competitive products, product development, commercialization and technological difficulties;

our expectations regarding partnering opportunities and other strategic transactions;

the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;

our plans to file additional patent applications to enhance and protect our existing intellectual property portfolio;

our ability to invalidate some or all of the claims covered by patents issued to competitors;

our estimates regarding our future revenues, research and development expenses, other expenses, payments to third parties and growth in staffing levels;

our estimate regarding how long our existing cash, cash equivalents and short-term investments, exclusive of receipt of future proceeds pursuant to our contracts with the U.S. government, will be sufficient to finance our operations;

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our expectations about funding from the government and other sources; and

the adequacy of funds to support our future operations and our future capital needs.

All forward-looking statements are based on information available to us on the date of this Annual Report on Form 10-K and we will not update any of the forward-looking statements after the date of this Annual Report on Form 10-K, except as required by law. Our actual results could differ materially from those discussed in this Annual Report on Form 10-K. The forward-looking statements contained in this Annual Report on Form 10-K, and other written and oral forward-looking statements made by us from time to time, are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the following discussion and within Part I, Item 1A Risk Factors of this Annual Report on Form 10-K.

Overview

We are a biopharmaceutical company focused on the discovery and development of unique RNA-based therapeutics for the treatment of both rare and infectious diseases. Applying our proprietary, highly-differentiated and innovative platform technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. We are primarily focused on rapidly advancing the development of our potentially disease-modifying Duchenne muscular dystrophy drug candidates with the intent to realize the product opportunities of such candidates and provide significant clinical benefits. We are also focused on developing therapeutics for the treatment of infectious diseases. By building on the research under our infectious disease programs funded by the U.S. government and leveraging our highly-differentiated, proprietary technology platforms, we are seeking to further develop our research and development competencies and capabilities and identify additional product candidates. We believe that our organizational capabilities will enable us to achieve these goals and become a leading developer and marketer of RNA-based therapeutics for the treatment of both rare and infectious diseases.

Our highly-differentiated RNA-based technologies work at the most fundamental level of biology and potentially could have a meaningful impact across a broad range of human diseases and disorders. Our lead program focuses on the development of disease modifying therapeutic candidates for Duchenne muscular dystrophy, or DMD, a rare genetic muscle wasting disease caused by the absence of dystrophin, a protein necessary for muscle function. AVI-4658 is our lead therapeutic candidate for DMD and is intended to target a substantial group of individuals with DMD. If we are successful in our development efforts, AVI-4658 will address a severe unmet medical need. Data from 17 of the 19 individuals enrolled in our Phase Ib/II trial in the United Kingdom and treated systemically with AVI-4658 demonstrated some generation of novel dystrophin, and one participant exhibited the first ever reported increase in dystrophin positive muscle fibers to greater than 50% of normal. Restoration of dystrophin expression and dystrophin positive fibers is believed to be critical for successful disease modifying treatment of individuals with DMD. We intend to initiate a Phase II trial for AVI-4658 in the first half of 2011 with an objective of entering a pivotal trial in the second half of 2012.

We are also leveraging the capabilities of our RNA-based technology platforms to develop therapeutics for the treatment of infectious diseases. The U.S. Department of Defense, or DoD, has provided significant financial support for the development of therapeutics for Ebola, Marburg, Dengue and influenza. In 2010, we were awarded contracts totaling more than $300 million for the research of select therapeutic candidates. We have attracted DoD s support based in part on our ability to rapidly respond to pathogenic threats by quickly identifying, manufacturing and evaluating novel therapeutic candidates, as discussed in greater detail in the section captioned Development Programs Anti-Viral Programs Influenza Program below.

We employ our highly-differentiated and innovative RNA-based technology platforms in both our DMD and infectious disease programs. The basis for our novel RNA-based therapeutics is our phosphorodiamidate-linked morpholino oligomer, or PMO, chemistries. By applying our technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike

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other RNA-based therapeutics, our technologies can be used to selectively up-regulate or down-regulate the production of a target protein, or direct the expression of novel proteins involved in human diseases and disorders. Further, we believe the charge-neutral nature of our PMO-based molecules may have the potential to reduce untargeted immune modulatory effects often seen in alternative RNA-based technologies, as well as certain other off-target effects as seen in a recent trial. As a result of our significant scientific advances generated over years of research and development, we believe that our highly-differentiated, proprietary and innovative RNA-based technology platforms, based on charge neutral morpholino oligomers, may represent a significant improvement over traditional RNA-based technologies.

We were incorporated in the State of Oregon on July 22, 1980. Our executive office is located at 3450 Monte Villa Parkway, Suite 101, Bothell, Washington 98021 and our telephone number is (425) 354-5038. Our common stock trades on The NASDAQ Global Market under the symbol AVII.

This Annual Report on Form 10-K includes our trademarks and registered trademarks, including PMO*plus* , PMO-X , AVI BioPharma®, Cytoporter® , NeuGene® and Kepler Pharmaceuticals®. Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

Where You Can Find Additional Information

We make available free of charge through our investor relations website, www.avibio.com, our annual reports, quarterly reports, current reports, proxy statements and all amendments to those reports as soon as reasonably practicable after such material is electronically filed or furnished with the SEC. These reports may also be obtained without charge by contacting Investor Relations, AVI BioPharma, Inc., 3450 Monte Villa Parkway, Suite 101, Bothell, Washington 98021, e-mail: investorrelations@avibio.com. Our Internet website and the information contained therein or incorporated therein are not intended to be incorporated into this Annual Report on Form 10-K. In addition, the public may read and copy any materials we file or furnish with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 or may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Moreover, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

Objectives and Business Strategy

We believe that our highly-differentiated RNA-based technology platforms can be used to develop novel pharmaceutical products that treat a broad range of diseases and address key unmet medical needs. We intend to leverage our RNA-based technology platforms, organizational capabilities and resources to become a leading developer and marketer of RNA-based therapeutics, including for the treatment of both rare and infectious diseases, with a diversified portfolio of product candidates and approved products. In pursuit of this objective, we intend to pursue the following activities:

- advancing the development of AVI-4658 and our other drug candidates for the treatment of DMD to realize the product opportunities of such candidates and provide significant clinical benefits;

- successfully executing our government funded infectious disease therapeutic programs and building on and leveraging our experience with such programs to further develop our research and development competences and capabilities and garner additional external funding; and

- leveraging our highly-differentiated, proprietary RNA-based technology platforms to identify additional product candidates and explore various strategic opportunities, including potential partnering, licensing or collaboration arrangements with industry partners.

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Development Programs

Our RNA-based drug programs are being clinically evaluated for the treatment of DMD and have also demonstrated promising anti-viral activity in infectious diseases such as Ebola, Marburg, Dengue and H1N1 influenza in certain animal models. Our lead product candidates are at various stages of development summarized below.

Program	Indication	Mechanism	Chemistry	Development Stage	Developer / Collaborator
AVI-4658	DMD (exon 51)	Alternative Splicing	PMO	Phase Ib/II	Proprietary
AVI-6002	Ebola virus	Translation Suppression	PMO*plus*	Open IND	Proprietary/ U.S. Government
AVI-6003	Marburg virus	Translation Suppression	PMO*plus*	Open IND	Proprietary/ U.S. Government
AVI-6006	Dengue virus	Translation Suppression	PMO*plus*	Preclinical	Proprietary/ U.S. Government
AVI-7100	H1N1 influenza virus	Translation Suppression	PMO*plus*	Preclinical	Proprietary/ U.S. Government

In the table above, under the heading Development Stage, Phase Ib/II indicates clinical safety testing, dosage testing and initial efficacy testing in a limited participant population, Open IND indicates that the program is authorized to enter Phase I studies, but human dosing has not yet begun, and Preclinical indicates that the program is not authorized to, and has not yet, entered human clinical trials. For purposes of the table, Development Stage indicates the most advanced stage of development that has been completed or is ongoing.

Duchenne Muscular Dystrophy Program

DMD is one of the most common fatal genetic disorders affecting children around the world. DMD is a devastating and incurable muscle-wasting disease associated with specific inborn errors in the gene that codes for dystrophin, a protein that plays a key structural role in muscle fiber function. The absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. The disease occurs in approximately one in every 3,500 male births worldwide. Females are rarely affected by the disorder. Initial symptoms, which usually appear between the ages of three and five, include progressive muscle weakness of the legs and pelvis, manifested as difficulty walking, running or climbing stairs, which eventually spreads to the arms, neck, and other areas. By age ten, braces may be required for walking, and many individuals require full-time use of a wheelchair even before age 12. Eventually muscular degeneration progresses to the point of complete paralysis. Disease progression is also typically associated with respiratory muscle dysfunction and a corresponding difficulty in breathing, which may require ventilatory support, and cardiac muscle dysfunction which may lead to heart failure. DMD is ultimately fatal and death usually occurs before the age of 30. There is currently no disease modifying treatment or cure for DMD.

The yearly cost of care for individuals with DMD is high and increases with disease progression. Although DMD is a rare disease, it represents a substantial product opportunity due to the severity and inexorable progression of the symptoms.

Our lead program is designed to address specific gene mutations that result in DMD by forcing the genetic machinery to skip over an adjacent contiguous piece (i.e., one or more exons) of RNA and, thus, restore the ability of the cell to express a new truncated, but functional, dystrophin protein. We believe that the expression of the dystrophin protein may restore, prevent or slow deterioration of muscle function. In addition to our lead product candidate, AVI-4658, which skips exon 51, we have a second product candidate, AVI-4038, which skips exon 50, and contains the identical sequence that was previously being studied preclinically with the PPMO AVI-5038, and we are confirming potential drug candidates for skipping other exons, including 44, 45 and 53.

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AVI-4658. AVI-4658 is a PMO-based therapeutic in clinical development for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that can be treated by skipping exon 51. AVI-4658 targets the most frequent series of mutations that cause DMD. It is estimated that these mutations affect approximately 18% of the DMD population that is potentially treatable with exon skipping therapeutics (approximately 85% of the total DMD population). AVI-4658 has been granted orphan drug designation in the United States and European Union. See Government Regulation Orphan Drug Designation and Exclusivity for additional information.

In October 2010, we announced results from the most recently completed clinical trial of AVI-4658, AVI Study 28. AVI Study 28 was a Phase Ib/II open label, dose-ranging, clinical trial assessing the safety, tolerability, pharmacokinetics and exploratory efficacy of AVI-4658 in ambulatory individuals with DMD. Participants in AVI Study 28 were between the ages of five and 15 with an error in the gene coding for dystrophin, which was amenable to treatment by skipping exon 51. Participants were dosed once per week for 12 weeks. A total of 19 participants were enrolled and these individuals were assigned to one of six dose cohorts of 0.5, 1.0, 2.0, 4.0, 10.0 or 20.0 mg/kg. Of the 19 participants enrolled, 18 received at least ten of the 12 doses planned in this trial. After completion of dosing, participants were followed for an additional 14 weeks. Muscle biopsies were taken before treatment and 17 participants had a second biopsy at week 14, two weeks after administration of the final dose. The primary objective of the trial was to assess the safety of AVI-4658 at these doses over the 26-week duration of the trial. Secondary trial objectives included assessment of plasma pharmacokinetics, urinary elimination and exploratory endpoints evaluating biological activity and clinical performance. This trial was conducted by investigators in the United Kingdom at the University College London Institute of Child Health / Great Ormond Street Hospital in London and at the Royal Victoria Infirmary in Newcastle-Upon-Tyne. Based on AVI Study 28, we have announced that:

- AVI-4658 was well-tolerated in all participants;
- no drug-related serious adverse events or severe adverse events were detected, except that one participant exhibited deteriorating cardiac function, which was considered probably disease related;
- adverse events were mostly mild or moderate in intensity, not dose-related, and none were considered probably or definitely related to AVI-4658;
- there was substantial and novel dystrophin expression and dystrophin-positive fiber generation in three participants (reaching up to 55% of normal in one subject), which tended to be greatest in the highest two dosing cohorts (10.0 and 20.0 mg/kg);
- new dystrophin expression was correctly localized in muscle cells and was accompanied by restoration of the dystrophin-associated glycoprotein complex, or DGC, a protein complex necessary for the proper function of muscle cells;
- reductions in key inflammatory markers, including the presence of inflammatory cells found in tissues, potentially suggest a favorable alteration in the underlying degenerative disease process;
- no immune response to newly made dystrophin was detected; and
- there was general stability in exploratory markers of participant clinical performance, including cardiac, pulmonary and muscle functional assessments.

We are currently planning the initiation of a Phase II trial for AVI-4658 in the first half of 2011. Clinical Study 4658-US-201, or AVI Study 201, is currently planned as an open-label, single center, dose-finding study to assess safety, tolerability and efficacy of 12 once-weekly intravenous doses of AVI-4658 in ambulatory individuals with genotypically-confirmed DMD who have an error in the gene coding for dystrophin that can be treated by skipping exon 51. We are seeking approval to increase the number of once-weekly doses from 12 to 24. A total of up to 16 participants will be enrolled in parallel into one of three cohorts. The first cohort will be composed of four participants who will receive a

weekly dose of 50 mg/kg. The second cohort will be composed of four participants who will receive a weekly dose of 30 mg/kg. The third and final cohort will be composed of up to eight participants who will serve as an untreated, matched comparison group over 24 weeks. Muscle

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biopsies of all participants receiving AVI-4658 will be performed prior to study treatment. Participants receiving the 50 mg/kg dose will receive a second biopsy at 12 weeks after initiation of treatment, and participants receiving 30 mg/kg will receive a second biopsy at 24 weeks after initiation of treatment. Exploratory clinical measures of ambulation, muscle function and strength will also be captured and evaluated during the course of the trial. The study will occur at the Nationwide Children s Hospital in Columbus, Ohio. We intend to initiate enrollment in mid-2011 and complete the study in 2012.

AVI-5038. AVI-5038 is a PMO-based therapeutic in pre-clinical development for the treatment of individuals with DMD who have an error in the gene coding for dystrophin that can be treated by skipping exon 50. AVI-5038 uses our peptide conjugated phosphorodiamidate morpholino oligomers, or PPMO, chemistry. AVI-5038 targets a series of mutations estimated to be present in approximately 5% of the DMD population that is potentially treatable with exon skipping therapeutics (approximately 85% of the total DMD population). AVI-5038 has been granted orphan drug designation in the United States and European Union. See Government Regulation Orphan Drug Designation and Exclusivity for additional information.

Previously, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038. Based on those findings, we conducted additional preclinical studies and have not alleviated the toxicity problem. We are currently evaluating alternatives regarding the development of AVI-5038, but in parallel the PMO-based therapeutic, AVI-4038, which contains the same base sequence as AVI-5038, and the identical PMO backbone chemistry, but lacks the conjugated peptide, is being considered for further development options.

Anti-Viral Programs

We are implementing our RNA-based technology platforms in our anti-viral programs for the development of therapeutics to treat viruses, such as Ebola, Marburg, Dengue and influenza. We currently have several contracts with the DoD and its agencies funding these anti-viral programs. Our arrangement with DoD supporting the development of our Ebola and Marburg virus drug candidates provides funding through to approval of a New Drug Application, or NDA, by the U.S. Food and Drug Administration, or FDA. Similarly, our arrangement with DoD supporting the development of our H1N1 influenza drug candidate provides funding for both preclinical studies supporting an Investigational New Drug, or IND, application with the FDA and the entry into a Phase I clinical trial. Without continued funding of these programs we may be unable to continue our development efforts and future funding is subject to availability of budgeted funds from DoD. As of December 31, 2010, we had contracts with the U.S. government pursuant to which we are entitled to receive up to an aggregate of $157.1 million for development of our product candidates, of which $76.1 million had been billed or recognized as revenue and $81.0 million of which relates to development that has not yet been completed and has not been billed or recognized as revenue. For a more detailed description of our contracts with the U.S. government, see Management s Discussion and Analysis of Financial Condition and Results of Operation U.S. Government Contracts below and Note 7 U.S. Government Contracts of the financial statements included elsewhere in this Annual Report on Form 10-K.

Hemorrhagic Fever Virus Programs. Our anti-viral therapeutic programs use our translation suppression technology and apply our proprietary PMO*plus* chemistry backbone, an advanced generation of our base PMO chemistry backbone that selectively introduces positive charges to its backbone to improve selective interaction between the drug and its target. Our translation suppressing technology is based on Translation Suppressing Oligomers, or TSOs, which are PMO-based compounds that stop or suppress the translation of a specific protein by binding to their specific target sequence in mRNA. We plan to pursue development and regulatory approval of our Ebola and Marburg hemorrhagic fever virus product candidates under the FDA s Animal Rule. The Animal Rule provides that under certain circumstances where it is unethical or not feasible to conduct human efficacy studies, the FDA may grant marketing approval based on adequate and well-controlled animal studies when the results of those studies establish that the drug or biological product is reasonably likely to produce clinical benefit in humans. Demonstration of the product s safety in humans is still required. See Government Regulation Animal Rule for additional information. Our lead product candidates in our hemorrhagic fever virus program include AVI-6002 (for the Ebola virus infection), AVI-6003 (for Marburg virus infection) and AVI-6006 (for Dengue virus infection).

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Ebola virus. AVI-6002 is designed to treat Ebola virus infection. The hemorrhagic fever caused by the Ebola virus is severe and often fatal in humans. The disease was first recognized in 1976 and is one of two members of a family of RNA viruses called Filoviridae. The disease is generally understood to be endemic to parts of Africa. Onset of illness from Ebola virus is abrupt and symptoms include fever, headache, muscle ache, vomiting and stomach pain. Internal and external bleeding may also be observed in some individuals. There are currently no treatments for Ebola virus infection beyond supportive care.

Marburg virus. AVI-6003 is designed to treat Marburg virus infection. Marburg hemorrhagic fever is another severe and potentially fatal disease in humans that was first recognized in 1967. It is also caused by an RNA virus of the filovirus family and is understood to be endemic to Africa. Onset of the disease is often sudden and the symptoms include fever, chills, nausea, vomiting, chest pain and diarrhea. Increasingly severe symptoms may also include massive hemorrhaging and multiple organ dysfunction. There are currently no treatments for Marburg virus infection beyond supportive care.

Treatment of primates infected with Ebola virus with AVI-6002 achieved up to 80% survival and treatment of primates infected with Marburg virus with AVI-6003 achieved 100% survival, compared to control groups where both viruses were universally lethal. In addition to survival, primates treated with AVI-6002 and AVI-6003 demonstrated improvements in levels of viremia, harmful inflammatory indicators and measurements of virus induced liver damage.

Dengue virus. AVI-6006 is designed to treat Dengue virus infection and Dengue hemorrhagic fever, or DHF, which are caused by one of four closely related viruses. DHF is a more severe form of Dengue infection and can be fatal. Dengue virus is spread via the bite of mosquitoes and is now endemic to at least 100 countries in Asia, the Pacific, the Americas, Africa, and the Caribbean. It is estimated that there are up to 100 million cases of DHF worldwide each year. Symptoms of Dengue infection include high fever, severe headache, joint pain, rash and mild bleeding. Symptoms of DHF include a vascular leak and other symptoms similar to Dengue. When the fever declines, additional symptoms may occur including vomiting, severe abdominal pain and difficulty breathing. The fever decline may also mark a period of time when blood vessels start to leak and cause bleeding. We identified effective viral targeting strategies in cell culture studies conducted in collaboration with laboratories that are experts in the Dengue field. The lead compounds were found to be effective in a mouse lethal challenge model and ferret disease model studies.

Influenza Program.

Our anti-viral therapeutic programs are also focused on the development of our product candidates designed to treat pandemic influenza viruses. AVI-7100 is our lead product candidate for the treatment of influenza and employs our PMO*plus* technology. In June 2010, we were awarded a contract under DoD s Transformational Medical Technologies, or TMT, program. This contract funds our activities to develop AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus. The contract provides for funding to advance the development of AVI-7100 including studies enabling an IND application with the FDA, the study of a pilot intranasal delivery formulation, and the funding of the entry into a Phase I clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization, or EUA. Additional funding under an earlier contract awarded to us via the TMT program is supporting continued preclinical evaluation of AVI-7100 against H1N1 as well as expanded preclinical evaluation against H5N1 (avian flu) and drug resistant H1N1 and H3N2 flu strains. See Management s Discussion and Analysis of Financial Condition and Results of Operations U.S. Government Contracts for additional information.

In June 2009, the World Health Organization, or WHO, declared a pandemic of H1N1 influenza. The virus was first detected in people in the United States in April 2009 and was referred to as swine flu because many of the genes in the virus were very similar to those found in flu viruses that circulate in pigs. The severity of the illness associated with the 2009 H1N1 virus ranged from mild to severe. Symptoms of H1N1 influenza include fever, cough, runny nose, headache, chills and fatigue. Many people infected with H1N1 also have respiratory symptoms without a fever. Severe illness and deaths have also occurred. The Centers for Disease Control and

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Prevention, or CDC, estimated that between April 2009 and April 2010 there were up to 89 million cases of H1N1 infection in the United States. The CDC also estimated that there were up to 403,000 H1N1-related hospitalizations in the U.S. during the same time period.

The TMT program established a contract with us to conduct a rapid response exercise against a real-world emerging threat like the pandemic H1N1 virus. The intent of the exercise was to demonstrate our capability to efficiently respond to a real-world emerging viral threat by rapidly designing and producing multiple therapeutic candidates and evaluating preclinical efficacy.

Initially the exercise involved identifying target sequences against H1N1, designing several drug candidates utilizing proprietary derivatives of our PMO chemistry, and then manufacturing the candidates in sufficient quantity for limited preclinical testing. We successfully accomplished these steps in approximately one week, demonstrating our ability to rapidly respond to a real-world viral threat utilizing our RNA-based technology platforms. Additionally, we successfully completed a second formal rapid response exercise commissioned by TMT for our Dengue development program. In 11 days, we demonstrated our capability to efficiently respond to a real-world threat. This exercise involved identifying target sequences against the Dengue virus, designing several drug candidates utilizing proprietary derivatives of our PMO chemistry, and then manufacturing the candidates in sufficient quantity for limited preclinical testing.

Subsequently, we evaluated our RNA-based drug candidates in preclinical studies using a mouse model of seasonal flu and identified two lead candidates, including AVI-7100. The two lead candidates were tested in the more advanced ferret model utilizing a fully virulent human pandemic H1N1 virus. The ferret studies included various treatment groups employing the lead candidates administered via intraperitoneal and intranasal dosing routes, a saline control group, a scrambled RNA sequence control group and a control group dosed with Tamiflu, a standard of care drug. While both lead candidates and routes of administration were indicative of activity versus all controls, AVI-7100 demonstrated overall superiority over our other H1N1 candidate.

On March 11, 2011, we received a letter from the FDA indicating that our initial response to a clinical hold letter from the FDA for AVI-7100 was incomplete. The letter requested additional information related to our background technology to clarify information that we provided in our previous response to the clinical hold letter. We are working to respond on an expedited basis to provide the FDA with this information. If the FDA is satisfied with our follow-up response we believe we will be able to initiate our Phase I clinical trial on AVI-7100 in the first half of 2011.

Discovery Stage Program Overview

Our PMO-chemistries work at a fundamental level of biology through distinct mechanisms by targeting RNA, the carrier of genetic information. Our RNA-based platform technologies are highly-differentiated from other RNA technologies, including antisense, siRNA and RNAi. Unlike these technologies, which result in down-regulation of gene expression, ours can be used to selectively up-regulate or down-regulate the expression of proteins involved in human diseases and disorders, or direct the production of novel proteins with clinically relevant properties.

In the research we have conducted using our RNA-based technologies we have evaluated compounds against diseases and disorders including:

- select genetic diseases;
- viruses, including Dengue and polio;
- gram negative and positive bacteria, including burkholderia and anthrax; and
- toxins, including ricin.

One of our drug candidates is in clinical development, while our others are at preclinical or discovery stage. Additional potential applications include therapeutics against infectious diseases, dermatological disorders,

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cancer, inflammatory disease and other applications with significant relevance to human health. Our technologies may also have applications in connection with other therapeutic approaches such as stem cell therapy.

AVI Chemistry Technology

Our core chemistry is based on phosphorodiamidate-linked morpholino oligomers, or PMOs. PMOs are synthetic molecules based on a fundamental redesign of the natural nucleic acid structure of DNA and RNA. PMOs bind to complementary sequences of RNA by standard Watson-Crick nucleic acid base-pairing. Structurally, the key difference between PMOs and naturally occurring DNA and RNA is that while PMOs have standard nucleic acid bases, those bases are bound to synthetic morpholine rings instead of deoxyribose (in DNA) or ribose (in RNA) rings, and they are linked through phosphorodiamidate groups instead of phosphate groups. Replacement of anionic phosphates with the neutrally charged phosphorodiamidate groups eliminates ionization in the usual physiological pH range, thus PMOs in organisms or cells are uncharged molecules. Because of these modifications, PMOs are very resistant to degradation by plasma and intracellular enzymes and control gene expression by steric blockade of targeted RNA. Unlike other RNA-based technologies, including siRNAs, PMOs do not need to interact with RNA-Induced Silencing Complex, or RISC, or the RNase H enzyme to be biologically active. In this way, PMOs operate fundamentally differently from other RNA-based technologies.

We have developed three new PMO-based chemistry platforms in addition to our original PMO-based technology. These new modified chemistries have been specifically designed to allow for molecular modulation and dial-in of desired performance attributes in drug candidates that align to specific therapeutic applications. We believe that the novel, favorable characteristics intrinsic in these new platforms will allow for the development of drug candidates with superior drug-like properties.

PPMO. The first of these novel chemistries is based on peptide conjugated phosphorodiamidate morpholino oligomers, or PPMOs, in which cellular uptake of the active PMO s component, as well as its potency and specificity of tissue targeting, may be significantly enhanced.

PMOplus . The second of these chemistries, PMO*plus* , includes the addition of selectively introduced positive charges to certain monomers in the core PMO backbone. We believe that while PMO*plus* has potentially broad therapeutic applications, it may be particularly effective in overcoming the viral mutations that make certain RNA viruses drug-resistant.

PMO-X . The third of these chemistries, PMO-X , further enhances the favorable properties of our core PMO chemistries by introducing novel, selective, and proprietary backbone chemistry modifications which allow us to physicochemically tune the biologic performance properties of new oligomers. We believe PMO-X may provide enhanced in vivo potency for our drug candidates and provide greater flexibility in modulation of their tissue targeting, cellular delivery and uptake.

We intend to continue to support our internal research and development efforts in order to advance our proprietary chemistries and to develop new analogues that may provide additional benefits in key characteristics of drug performance.

AVI Mechanisms

The Human Genome Project revealed that humans have far fewer genes than would have been predicted from the number of unique proteins that are expressed in the human proteome. The genetic information stored in human DNA is not contiguous. Short DNA stretches, called exons that code for fragments of the protein are separated by long non-coding pieces of DNA called introns. During processing of precursor or pre-mRNA, which is copied from the DNA template, introns are removed and exons spliced together to create the mature mRNA. Thus, in mRNA, the genetic information is contiguous in spliced together exons and from this a functional protein can be made. Pre-mRNA splicing can also follow alternative paths, such that different exons are combined, creating multiple mRNAs from the same pre-mRNA and, hence, generate multiple proteins, all from the same gene. Latest estimates

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indicate that approximately 90% of all human genes are alternatively spliced and therefore code for a number of different proteins from a single gene. Thus, for the majority of genes, alternative splicing produces multiple proteins that can have slightly or profoundly different functions. Some pairs of splice variants code for proteins that have exactly opposite effects. Alternative splicing pathways are involved in many different diseases such that pathological protein isoforms are overproduced and the physiological isoforms are decreased.

Our PMO-based molecules have intrinsic design flexibility and therefore can be constructed for distinct bio-mechanistic purposes. Our programs currently apply our PMO technologies to bind to either specifically targeted pre-mRNAs or mRNAs. Through this selective targeting, two distinct biologic mechanisms of action can be initiated: (1) modulation of pre-mRNA splicing (also commonly described as splice switching, exon skipping or directed alternative splicing) and (2) inhibition of mRNA translation (also commonly described as translation suppression). Further, our PMO-based molecules are neutrally charged, which reduces untargeted immune modulatory effects often seen in alternative RNA-based technologies.

Splice Switching Oligomers. Splice Switching Oligomers, or SSOs, are PMO-based compounds that can direct the natural alternative splicing mechanism of pre-mRNA by forcing the cellular splicing machinery towards specific desired splicing outcomes and producing an mRNA for a desired protein. We believe that the emerging field of directed alternative splicing represents a novel and very promising mechanism for gene regulation. Our SSOs exploit pre-mRNA splicing to control gene function and may produce a therapeutic benefit by both systemically or locally suppressing the production of targeted disease-associated proteins, as well as systemically or locally increasing production of favorable proteins, changing the quantitative balance of different protein isoforms in vivo, or directing the expression of novel human proteins (i.e., proteins that are structurally and immunologically fully human, but which are not natively seen in the human body). For example, our SSO technology application is being used in our DMD program and data from 17 of the 19 individuals enrolled and treated systemically with AVI-4658 in our Phase Ib/II clinical trial demonstrated some generation of novel dystrophin, and one participant exhibited the first ever reported increase in dystrophin positive muscle fibers to greater than 50% of normal. We believe this powerful mechanism may provide significant benefits when used for intervention in disease-causing processes.

By targeting elements in pre-mRNA that are essential for splicing, SSO compounds force the cellular machinery to skip over targeted exons, creating an altered mRNA template. SSOs can be designed to prevent formation of harmful proteins and/or help to restore beneficial proteins. For example, when an exon contains a disease-causing mutation or when one or more exons are missing from the gene sequence entirely, directed skipping of targeted exons in the pre-mRNA may allow for production of an altered protein with a desired therapeutic functionality. This approach represents a potential approach to overcome the devastating consequences of certain disease-causing mutations, such as those found in DMD.

Directed alternative splicing has emerged as a ubiquitous and dynamic mechanism for gene regulation. Supported by a growing stream of new insights and discoveries derived from the fields of genomics, bioinformatics and molecular biology, we believe that this area promises to be a rich source of therapeutic applications. The ability to repair mRNA and restore missing essential protein is unique to SSO technology. Antisense and siRNA based technologies can only reduce the level of undesirable proteins.

Translation Suppressing Oligomers. Translation Suppressing Oligomers, or TSOs, are PMO-based compounds that interfere with gene expression and other RNA-dependent cellular processes by binding to their specific target sequence in mRNA. The primary application of TSOs is to stop or suppress the translation of a specific protein through this binding process, thus selectively inhibiting the translation of the targeted protein and thereby reducing its harmful effect. Our TSO compounds demonstrate tight and selective RNA binding and act by a direct steric-blocking mechanism instead of by RNAse H-mediated or RISC-mediated RNA degradation.

Material Agreements and Strategic Alliances

We believe that our RNA-based technology could be broadly applicable for the potential development of pharmaceutical products in many therapeutic areas. To further exploit our core technology, we may periodically

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enter into research, development or commercialization alliances with pharmaceutical and biotechnology companies for specific molecular targets or selected disease indications. We may also selectively pursue opportunities to access certain intellectual property rights that complement our internal portfolio through license agreements or other arrangements.

U.S. Department of Defense Agreements

We currently have several contracts with the U.S. Department of Defense, or DoD, and its agencies funding our programs. For a more detailed description of our contracts with the U.S. government, see Management s Discussion and Analysis of Financial Condition and Results of Operation U.S. Government Contracts below and Note 7 U.S. Government Contracts of the financial statements included elsewhere in this Annual Report on Form 10-K.

University of Western Australia

In November 2008, we entered into an exclusive license with the University of Western Australia, or UWA, for certain patents and technical information relating to the use of certain antisense sequences for the treatment of DMD. The license grants us specific rights to the treatment of DMD by inducing the skipping of certain exons defined in the agreement. Unless earlier terminated in accordance with the terms of the agreement, such agreement will expire on the expiration date of the last to expire patent within the patents licensed to us under the agreement. Our clinical candidate, AVI-4658, falls under the scope of this agreement. Any future drug candidates developed for the treatment of DMD by exon skipping may or may not fall under the scope of this agreement.

Under the agreement, we are required to meet certain performance diligence obligations related to development and commercialization of products developed under license. We believe we are currently in compliance with these obligations. We made an initial upfront payment to UWA on execution of the license. We may be required to make additional payments to UWA of up to $150,000 based on successful achievement of certain regulatory-related milestones and also may be required to pay royalties ranging from a fraction of a percent to the low single digits on net sales of products covered by issued patents licensed from UWA during the term of the agreement. As of December 31, 2010, we have not made, and are not under any current obligation to make, any such milestone or royalty payments to UWA. We believe, however, that a milestone payment obligation of $10,000 to UWA may be triggered in 2011.

Strategic Alliances

Isis Ercole Agreement

In May 2003, Ercole Biotechnology, Inc., or Ercole, and Isis Pharmaceuticals, or Isis, entered into a collaboration and license agreement related to RNA splicing. We assumed Ercole s obligations under this agreement when we acquired Ercole in March 2008. This agreement contains several cross-licenses between the parties granting each party certain exclusive and nonexclusive rights under a selected set of the other parties patents and patent applications for the research, development, and commercialization of antisense therapeutics using RNA splicing with respect to certain gene targets.

Subject to the satisfaction of certain milestones triggering the obligation to make any such payments, we may be obligated to make milestone payments to Isis of up to $23.4 million in the aggregate for each product developed under a licensed patent under this agreement.

As of December 31, 2010, we have not made, and are not under any current obligation to make, any such milestone payments, as the conditions triggering any such milestone payment obligations have not been satisfied. The range of percentage royalty payments required to be made by us under the terms of this agreement is from a fraction of a percent to mid single digits. We believe that our DMD, Ebola, Marburg and influenza programs will not fall under the scope of this agreement and therefore will not be subject to milestone or royalty obligations under its provisions.

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Subject to the satisfaction of certain milestones triggering the obligation to make any such payments, Isis may be obligated to make milestone payments to us of up to $21.1 million in the aggregate for each product developed under a licensed patent under this agreement. As of December 31, 2010, Isis has not made, and is not under any current obligation to make, any such milestone payments, as the conditions triggering any such milestone payment obligations have not been satisfied. The percentage royalty payments required to be made by Isis under the terms of this agreement is a fraction of a percent. As to any product commercialized under the agreement, the agreement will terminate on the expiration date of the last to expire licensed patent covering such product. Research collaboration activity defined in the agreement expired in 2006.

Eleos Agreement

In January 2007, we entered into a cross-license agreement with Eleos Inc., or Eleos, for the development of antisense products targeting p53, a well-studied human protein that controls cellular response to genetic damage. Under the terms of the agreement, we granted Eleos an exclusive license to certain of our intellectual property related to treatment of cancer with p53-related drugs. In return, Eleos granted us an exclusive license to its intellectual property related to treatment of most viral diseases with drugs that target p53. The companies are sharing rights under their respective intellectual property rights licensed under the agreement in other medical fields where targeting p53 may be therapeutically useful. Subject to the satisfaction of certain development and commercialization milestones, Eleos may be obligated to make milestone payments of up to $19.5 million in the aggregate with respect to products resulting from Eleos use of our intellectual property licensed to Eleos under the agreement. Additionally, subject to the satisfaction of certain development and commercialization milestones, we may be obligated to make milestone payments of up to $19.5 million in the aggregate with respect to products resulting from our use of the intellectual property Eleos licensed to us under the agreement. As of December 31, 2010, neither we nor Eleos have made, and neither we nor Eleos are under any current obligation to make, any such milestone payments, as the conditions triggering any such milestone payment obligations have not been satisfied. Percentage royalty payments required to be made by Eleos to us under the terms of this agreement range from low single digits to the low double digits on net sales of products covered by or otherwise resulting from Eleos use of our intellectual property licensed to Eleos under the agreement. We are required to pay to Eleos a low double digits percentage royalty on net sales of products covered or otherwise resulting from our use of Eleos intellectual property licensed to us under the agreement. We recognized $125,000 in revenue from this agreement in each of the fiscal years ending December 31, 2010, 2009 and 2008. This agreement will terminate as of the later of (1) the expiration date of the last to expire patent licensed under the agreement having claims covering a product resulting from the use of the AVI or Eleos intellectual property licensed under the agreement, and (2) 10 years from the date of the first commercial sale of a product using either our or Eleos intellectual property licensed under the agreement.

Charley s Fund Agreement

In October 2007, Charley s Fund, Inc., or Charley s Fund, a nonprofit organization that funds drug development and discovery initiatives specific to DMD, awarded us a $2.45 million research grant. Pursuant to the related sponsored research agreement, the grant would support the development of product candidates using our proprietary exon skipping technologies to overcome the effects of certain genetic errors in the dystrophin gene. The sponsored research agreement was amended in May 2009. Under the terms of the May 2009 amendment, subject to the satisfaction of certain milestones, Charley s Fund agreed that it would pay up to an additional $3.0 million over and above the $2.0 million it had already paid to us at the time of the execution of the amendment. As of December 31, 2010, Charley s Fund has made an aggregate of $3.3 million in payments to us. Revenue associated with this research and development arrangement is recognized based on proportional performance method, using the payment received method. We recognized $0, $0 and $23,000 in revenue from Charley s Fund for the years ended December 31, 2010, 2009 and 2008, respectively.

Under the terms of the sponsored research agreement, as amended, if we and any of our strategic partners elect to discontinue the development and commercialization of any product containing any molecular candidate arising or derived from the research sponsored by Charley s Fund for reasons other than safety or efficacy, we must grant to Charley s Fund an exclusive, royalty-bearing, fully-paid, worldwide license, with right of

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sublicense, to any such product. Depending on whether and when Charley s Fund obtains a license to any such product, percentage royalty payments on net sales required to be made by Charley s Fund to us under the terms of the sponsored research agreement, as amended, would be in the mid single digits. Under the terms of the sponsored research agreement, as amended, if we are able to successfully commercialize any molecular candidate arising or derived from the research sponsored by Charley s Fund either through sales of products or through licensing or partnership arrangements with a third party that include rights for such third party to sell, distribute, promote or market such products or the underlying intellectual property, then we are obligated to repay the research funds paid to us by Charley s Fund, up to an amount equal to the total amount of funds provided by Charley s Fund to us. In connection with this repayment obligation, we agreed that we would pay a mid range single-digit percentage royalty on net sales of products containing any molecular candidate arising or derived from the research sponsored by Charley s Fund and a mid-teens amount of any upfront cash and/or milestone payments received from a licensing or partnership arrangement with a third party with respect to such products (in each case, up to an amount equal to the total amount of funds provided by Charley s Fund to us). This agreement will terminate by its own terms at the completion of the research being sponsored by Charley s Fund. The AVI technology upon which the agreement is based is covered by certain patents, the last of which expires following the termination of the agreement.

Previously, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038. We have conducted additional preclinical studies and have not alleviated the toxicity problem. Pursuant to the terms of our agreement with Charley s Fund, the receipt of additional funds is tied to the satisfaction of certain clinical milestones. Because of the toxicity issues with AVI-5038, satisfaction of the additional milestones under the agreement is unlikely. We are currently evaluating alternatives regarding the development of AVI-5038, but in parallel the PMO-based therapeutic, AVI-4038, which contains the same base sequence as AVI-5038, and the identical PMO backbone chemistry, but lacks the conjugated peptide, is being considered for further development options.

Manufacturing

We believe we have developed proprietary manufacturing techniques that could allow synthesis and purification of our product candidates to support up to Phase II clinical development. We have entered into certain manufacturing and supply arrangements with third party suppliers which will in part utilize these techniques to support development of certain of our product candidates. We have additionally contracted with several suppliers of commercial active pharmaceutical ingredients, or APIs, to develop, scale-up the manufacture process, and ultimately manufacture our products to support commercialization. We do not have, and do not intend to establish in the near term, any of our own internal manufacturing capability to support our product candidates.

For our Ebola and Marburg hemorrhagic fever virus development programs, we have entered into supply agreements with two multinational manufacturing firms for the production of the API for Ebola and Marburg therapeutics. There is a limited number of companies that can produce PMO in the quantities and with the quality and purity that we require for our development efforts. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

We also have supply arrangements with several preferred manufacturing firms for the production of the custom raw materials required for PMO production. We believe there are several contract manufacturers capable of manufacturing these materials, and as our products advance, more suppliers might become necessary; however, establishing a relationship with alternative suppliers can be a lengthy process and might cause delays in our development efforts and could materially and adversely impact our business.

Manufacturers and suppliers of product candidates are subject to the FDA s current Good Manufacturing Practices, or cGMP, requirements, and other rules and regulations prescribed by foreign regulatory authorities. We depend on our third party suppliers and manufacturers for continued compliance with cGMP requirements and applicable foreign standards.

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Sales and Marketing Strategy

We have not obtained regulatory approval for any of our product candidates. If we obtain approval for any of our products, we may retain all or certain commercialization rights to those products, and / or enter into arrangements with other pharmaceutical or biotechnology companies for the marketing and sale of our products.

Patents and Proprietary Rights

Our success depends in part upon our ability to protect our core technology and intellectual property. To accomplish this, we rely on a combination of intellectual property rights, including patents, trade secrets, copyrights and trademarks, and contractual protections.

We seek appropriate patent protection for our proprietary technologies by filing patent applications in the United States and other countries. As of February 28, 2011, we owned or held exclusive or partially exclusive licenses to approximately 189 U.S. and corresponding foreign patents and 181 U.S. and corresponding foreign patent applications. We intend to protect our proprietary technology with additional filings as appropriate.

Our patents and patent applications are directed to our product candidates as well as to our RNA-based technology platforms. Although we believe our patents and patent applications provide us with a competitive advantage, the patent positions of biotechnology and pharmaceutical companies can be uncertain and involve complex legal and factual questions. We and our corporate collaborators may not be able to develop patentable products or processes or obtain patents from pending patent applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect the technology owned by or licensed to us or our corporate collaborators. For example, we are aware of a European patent to which Prosensa has rights that may provide the basis for Prosensa or other parties that have rights to patent to assert that our drug AVI-4658 infringes on such patent. We are currently opposing this patent in the Opposition Division of the European Patent Office and believe that we may be able to invalidate some or all of the claims covered by this patent and non-U.S. foreign equivalents.

Our clinical product candidates are protected by composition and use patents and patent applications. Patent protection afforded by the patents and patent applications covering our product candidates will expire over various time frames.

Some of our patents on core technologies expired in 2008, including a patent for our basic PMO chemistry. However, as we continue to advance the research supporting our PMO-based technologies, we believe that the patented and likely patentable improvements we are developing will provide the necessary basis for freedom to develop and commercialize our products. We also rely on trade secrets and proprietary know-how, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. These agreements provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of their relationship with us except in limited circumstances. These agreements also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

We are the owner of three registered trademarks in the United States for AVI BioPharma®, Cytoporter® and NeuGene®. We have two pending trademark applications for PMOplus and PMO-X. We are the owner of international trademark registrations for Kepler Pharmaceuticals® in Europe, Australia, Japan, New Zealand, Norway and Switzerland. We have pending international trademark applications for AVI BioPharma in the European Union and Australia.

We have licensed certain technology to supplement and support certain of our core technologies. We have certain obligations and minimum royalties under those agreements, which costs are not material to our business.

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Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of the use, formulation and structure of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to protect our product candidates from unauthorized making, using, selling, offering to sell or importing by third parties is dependent on the extent to which we have rights under valid and enforceable patents that cover these activities.

We do not have patents or patent applications in every jurisdiction where there is a potential commercial market for our product candidates. For each of our programs, our decision to seek patent protection in specific foreign markets, in addition to the United States, is based on many factors, including:

our available resources;

the size of the commercial market;

the presence of a potential competitor in the market;

and whether the legal authorities in the market effectively enforce patent rights.

We continually evaluate our patent portfolio and patent strategy and believe our owned and licensed patents and patent applications provide us with a competitive advantage; however, if markets where we do not have patents or patent applications become commercially important, our business may be adversely affected.

The patent positions of pharmaceutical, biotechnology and other life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date in the United States, and tests used for determining the patentability of patent claims in all technologies are in flux. The pharmaceutical, biotechnology and other life sciences patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents that we own or have licensed or in third-party patents.

Government Regulation

The testing, manufacturing, labeling, advertising, promotion, distribution, export and marketing of our products are subject to extensive regulation by governmental authorities in the United States and in other countries. In the United States, the FDA, under the Federal Food, Drug and Cosmetic Act, or FDCA, and its implementing regulations, regulates pharmaceutical products. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, withdrawal of approval of approved products, warning letters, untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, civil penalties and/or criminal prosecution.

Drug Approval Process

To obtain FDA approval of a product candidate, we must, among other things, submit data providing substantial evidence of safety and efficacy of the product, as well as detailed information on the manufacture and composition of the product candidate and proposed labeling. The testing and collection of data and the preparation of necessary applications are expensive and time-consuming. The FDA may not act quickly or favorably in reviewing these applications, and we may encounter significant difficulties or costs in our efforts to obtain FDA approvals that could delay or preclude us from marketing our products.

The steps required before a drug may be approved for marketing in the United States generally include:

preclinical laboratory tests and animal tests;

submission to the FDA of an Investigational New Drug Application, or IND, for human clinical testing, which must become effective before human clinical trials commence;

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adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug product for each indication;

the submission to the FDA of a New Drug Application, or NDA;

satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMP;

potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA.

Preclinical studies may include laboratory evaluations of the product chemistry, toxicity, and formulation, as well as animal studies to assess the potential safety and efficacy of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the clinical trials as described in the protocol submitted as part of the IND prior to that time. In this case, the trials are placed on clinical hold, and the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed. For example, on March 11, 2011, we received a letter from the FDA indicating that our initial response to a clinical hold letter from the FDA for AVI-7100 was incomplete. The letter requested additional information related to our background technology to clarify information that we provided in our previous response to the clinical hold letter. We are working to respond on an expedited basis to provide the FDA with this information. If the FDA is satisfied with our follow-up response we believe we will be able to initiate our Phase I clinical trial on AVI-7100 in the first half of 2011.

Clinical trials involve the administration of the product candidate to healthy volunteers or participants under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted in accordance with the FDA s good clinical practices requirements and state subject rights laws. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. The IRB will consider, among other things, clinical trial design, participant informed consent, ethical factors, the safety of human subjects, and the possible liability of the institution. The FDA may order the partial, temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. The IRB may also require the clinical trial at that site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials typically are conducted in three sequential phases prior to approval, but the phases may overlap. A fourth, or post-approval, phase may include additional clinical studies. These phases generally include the following:

Phase I. Phase I clinical trials involve the initial introduction of the drug into human subjects, frequently healthy volunteers. These studies are designed to determine the safety of usually single doses of the compound and determine any dose limiting intolerance , as well as evidence of the metabolism and pharmacokinetics of the drug in humans. Phase I studies usually involve less than 100 subjects and are most commonly conducted in healthy adult volunteers.

Phase II. Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, to determine dosage tolerance and optimal dosage, and to identify possible adverse effects and safety risks. Phase II studies usually involve patients with the disease under investigation and numbers may vary from several dozen to several hundred.

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Phase III. If a compound is found to be potentially effective and to have an acceptable safety profile in Phase II (or sometimes Phase I) studies, the clinical trial program will be expanded to further confirm clinical efficacy, optimal dosage and safety within an expanded patient population which may involve geographically dispersed clinical trial sites. Phase III studies usually include several hundred to several thousand patients. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of an NDA.

Phase IV. Phase IV clinical trials are studies required of or agreed to by a sponsor that are conducted after the FDA has approved a product for marketing. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. Failure to promptly conduct Phase IV clinical trials could result in withdrawal of approval for products approved under accelerated approval regulations.

A company seeking marketing approval for a new drug in the United States must submit to the FDA the results of the preclinical and clinical trials, together with, among other things, detailed information on the manufacture and composition of the product candidate and proposed labeling, in the form of an NDA, including payment of a user fee. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months in which to complete its initial review of a standard NDA and respond to the applicant, and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date. If the FDA s evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable, the FDA may issue an approval letter. If the FDA finds deficiencies in the NDA, it may issue a complete response letter, which contains the conditions that must be met in order to secure final approval of the NDA. If and when those conditions have been met to the FDA s satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA s evaluation of the NDA submission and the clinical and manufacturing procedures and facilities is not favorable, the FDA may refuse to approve the NDA. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. Resubmissions by the NDA sponsor in response to a complete response letter trigger new review periods of varying length (typically two to six months) based on the content of the resubmission. The FDA may also refer an application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval (Subpart H), that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. We were granted fast track status for AVI-4658 in 2007. We cannot be sure that any of our other drug candidates will qualify for any of these programs, or that, if a drug does qualify, that the review time will be shorter than a standard review.

Often, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to:

report certain adverse reactions to the FDA;

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submit annual and periodic reports summarizing product information and safety data;

comply with certain requirements concerning advertising and promotional labeling for their products; and

continue to have quality control and manufacturing procedures conform to cGMP after approval.

The FDA periodically inspects the sponsor s records related to safety reporting and/or manufacturing; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Many other countries and jurisdictions have similar drug development and regulatory review processes. We have conducted clinical trials in the United Kingdom and intend to submit for marketing approval in countries other than the United States. Therefore, we will have to comply with the legal and regulatory requirements in the countries where we conduct trials and submit for marketing approval.

Animal Rule

In the case of product candidates that are intended to treat rare life-threatening diseases, such as infection caused by exposure to various hemorrhagic fever viruses, conducting controlled clinical trials to determine efficacy may be unethical or unfeasible. Under regulations issued by the FDA in 2002, often referred to as the animal rule, the approval of certain such products can be based on clinical data from trials in healthy subjects that demonstrate adequate safety, and immunogenicity and efficacy data from adequate and well-controlled animal studies. Human trials demonstrating the safety of the product are generally also required. Among other requirements, the animal studies must establish that the drug or biological product is reasonably likely to produce clinical benefits in humans. Because the FDA must agree that data derived from animal studies may be extrapolated to establish safety and effectiveness in humans, seeking approval under the animal rule adds significant time, complexity and uncertainty to the testing and approval process. No animal model is established as predicting human outcomes in the prevention or treatment of any filovirus disease. We have yet to demonstrate the predictive value of our animal studies to the FDA s satisfaction. In addition, products approved under the animal rule are subject to additional requirements including post-marketing study requirements, restrictions imposed on marketing or distribution or requirements to provide information to patients.

Emergency Use Authorization

The Secretary of the Department of Health and Human Services, or DHHS, may, under certain circumstances, issue an Emergency Use Authorization, or EUA that would permit the use of unapproved drug products. Before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

a determination by the Secretary of Department of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological or nuclear agent or agents;

a determination by the Secretary of the DoD that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent of agents; or

a determination by the Secretary of the DHHS of a public health emergency that effects or has the significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agent.

In order to be the subject of an EUA, the FDA Commissioner must conclude that, based on the totality of scientific evidence available, it is reasonable to relieve that the product may be effective in diagnosing, treating,

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or preventing a disease attributable to the agents described above; that the product s potential benefits outweigh its potential risks; and that there is no adequate, approved alternative to the product.

Although an EUA may not be issued until after an emergency has been declared by the Secretary of the DHHS, the Agency strongly encourages an entity with a possible candidate product, particularly one at an advanced stage of development, to contact the FDA Center responsible for the candidate product even before a determination of actual or potential emergency. Such an entity may submit a request for consideration that includes data to demonstrate that, based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition. We may submit such a request for consideration with respect to our product candidates intended to treat Marburg and Ebola.

Orphan Drug Designation and Exclusivity

Some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. In the United States, orphan drug designation must be requested before submitting an application for marketing approval. An orphan drug designation does not shorten the duration of the regulatory review and approval process. The approval of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. Safety and efficacy of a compound must be established through adequate and well-controlled studies. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity period, which means the FDA may not grant approval to any other application to market a different drug for the same indication for a period of seven years, except in limited circumstances, such as where an alternative product demonstrates clinical superiority to the product with orphan exclusivity. In addition, holders of exclusivity for orphan drugs are expected to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the drug. An additional six months of exclusivity may be granted to a sponsor of an NDA, if the sponsor conducted a pediatric study or studies of such product. This process is initiated by FDA as a written request for pediatric studies that applies to sponsor s product. If the sponsor conducts qualifying studies and the studies are accepted by the FDA, then an additional six months of pediatric exclusivity will attach to any other regulatory exclusivity or patent protection applicable to any drug product containing the same active moiety as the drug studied and for which the party submitting the studies holds the NDA. Competitors may receive approval of different drugs or biologics for the indications for which the orphan product has exclusivity. We have been granted orphan drug designation for AVI-4658 and AVI-5038 in the U.S. and European Union.

The European Orphan Drug Regulation is considered for drugs intended to diagnose, prevent or treat a life-threatening or very serious condition afflicting five or fewer out of 10,000 people in the EU, including compounds that for serious and chronic conditions would likely not be marketed without incentives due to low market return on the sponsor s development investment. The medicinal product considered should be of significant benefit to those affected by the condition. Benefits of being granted orphan drug status are significant, including eight years of data exclusivity, two years of marketing exclusivity and a potential one year extension of both. The EU Community and Member States may not accept or grant for ten years a new marketing authorization or application for another drug for the same therapeutic indication as the orphan drug, although the ten year period can be reduced to six years if, at the end of the fifth year, available evidence establishes that the product is sufficiently profitable not to justify maintenance of market exclusivity. A supplementary protection certificate may extend the protection six months beyond patent expiration if that is later than the orphan drug exclusivity period. To apply for the supplementary protection, a pediatric investigation plan, or PIP, must be included in the market application. In Europe all drugs now seeking a marketing authorization need to have a PIP agreed with the EMA before it can be approved, even if is a drug being developed specifically for a pediatric indication. If a product is developed solely for use in the pediatric population, then a Pediatric Use Marketing

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Authorization, or PUMA, may provide eight years of data exclusivity and ten years of marketing exclusivity. This PUMA applies to our DMD compounds, AVI-4658 and AVI-5038.

Other Regulatory Requirements

In addition to regulation by the FDA and certain state regulatory agencies, we are also subject to a variety of foreign regulations governing clinical trials and the marketing of other products. Outside of the United States, our ability to market a product depends upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. In any country, however, we will only be permitted to commercialize our products if the appropriate regulatory authority is satisfied that we have presented adequate evidence of safety, quality and efficacy. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing of the product in those countries. The time needed to secure approval may be longer or shorter than that required for FDA approval. The regulatory approval and oversight process in other countries includes all of the risks associated with regulation by the FDA and certain state regulatory agencies as described above.

Pharmaceutical Pricing and Reimbursement

In both U.S. and foreign markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, depends in significant part on the availability of adequate financial coverage and reimbursement from third party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Third party payors are increasingly challenging the prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost effectiveness of our products. Even with the availability of such studies, our products may be considered less safe, less effective or less cost-effective than alternative products, and third party payors may not provide coverage and reimbursement for our product candidates, in whole or in part.

Political, economic and regulatory influences are subjecting the healthcare industry in the United States to fundamental changes. There have been, and we expect there will continue to be, legislative and regulatory proposals to change the healthcare system in ways that could significantly affect our business, including the Patient Protection and Affordable Care Act of 2010. We anticipate that the U.S. Congress, state legislatures and the private sector will continue to consider and may adopt healthcare policies intended to curb rising healthcare costs. These cost containment measures include:

- controls on government funded reimbursement for drugs;
- controls on healthcare providers;
- challenges to the pricing of drugs or limits or prohibitions on reimbursement for specific products through other means;
- reform of drug importation laws; and
- expansion of use of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict what additional legislation, regulations or policies, if any, relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation, regulations or policies would have on our business. Any cost containment measures, including those listed above, or other healthcare system reforms that are adopted could have a material adverse effect on our business prospects.

Competition

The pharmaceutical and biotechnology industries are intensely competitive, and any product candidate developed by us would compete with existing drugs and therapies. There are many pharmaceutical companies,

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biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of rare and infectious diseases. Many of these organizations have substantially greater financial, technical, manufacturing and marketing resources than we have. Several of them have developed or are developing therapies that could be used for treatment of the same diseases that we are targeting. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on:

- our ability to complete clinical development and obtain regulatory approvals for our product candidates;
- the efficacy, safety and reliability of our product candidates;
- the timing and scope of regulatory approvals;
- product acceptance by physicians and other health care providers;
- protection of our proprietary rights and the level of generic competition;
- the speed at which we develop product candidates;
- our ability to supply commercial quantities of a product to the market;
- obtaining reimbursement for product use in approved indications;
- our ability to recruit and retain skilled employees; and
- the availability of substantial capital resources to fund development and commercialization activities.

DMD Program Competition. Currently, no product has been approved for the treatment of DMD. Several other companies including, but not limited to, Prosensa in collaboration with GlaxoSmithKline plc, or GSK, Acceleron Pharma Inc., in collaboration with Shire PLC, and PTC Therapeutics, Inc., in collaboration with Genzyme Corporation, have product candidates in development for the treatment of DMD.

The Prosensa / GSK program has commenced treatment in a Phase III clinical study in ambulant individuals with DMD who have a dystrophin gene mutation amenable to treatment by skipping exon 51. Prosensa s candidate for skipping exon 51, PRO-51, utilizes the same exon skipping mechanism of action as AVI-4658, but the compound uses a different chemistry, 2 O-methyl-phosphorothioate, which has the potential for different performance, safety and tolerability characteristics than AVI-4658. This randomised, placebo controlled study will enroll 180 participants who will be dosed for 48 weeks. The primary efficacy endpoint is a measure of muscle function using the six minute walking distance test. The Prosensa / GSK product candidate may, or may not, prove to be safer and more efficacious than, and it could gain marketing approval before, our lead DMD product candidate, AVI-4658.

The Acceleron Pharma / Shire program focuses on ACE-031. ACE-031 is a recombinant fusion protein therapeutic, which, by inhibiting signaling through a cell surface receptor called activin receptor type IIB, is designed to build muscle and increase strength, for the potential treatment of DMD and other neuromuscular disorders. ACE-031 has the potential to benefit all individuals with DMD irrespective of the underlying genetic mutation and may, or may not, prove to be safer and more efficacious than AVI-4658. ACE-031 is not disease-modifying and it may also be complementary to therapy with AVI-4658.

The PTC Therapeutics / Genzyme program is focused on the development of PTC124, or Ataluren, an orally active small molecule therapeutic that works by enabling the formation of functioning protein in genetic disorders caused by a nonsense mutation. Ataluren has the potential to treat approximately 15% of individuals with DMD that have point mutations which create premature termination codons and cannot be treated by exon skipping. AVI-4658 does not address these types of point mutations and, thus, Ataluren is not in direct competition with AVI-4658.

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Hemorrhagic Fever Virus Programs. No specific treatment has been proven effective, and no vaccine currently exists for either Ebola or Marburg. Investigational compounds cannot be tested on humans except in outbreak environments so these agents must be tested extensively and meet strict government regulations. Vaccine development is in the early stages in both the biotech industry (e.g., Tekmira Pharmaceuticals Corp.) and by U.S. government agencies (e.g., the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention), although no IND is currently open. We are commencing initial human safety studies during 2011.

Currently, there are no therapeutics or vaccines approved for the treatment or prevention of Dengue fever. Patient care is focused on supportive treatment aimed at limiting the complications of the infection. While the WHO considers the prevention of Dengue to be a priority research area, there has been no successful development of a vaccine. There are several Dengue vaccines in clinical trials, but there are currently no Dengue specific anti-viral therapeutics that have advanced beyond preclinical testing.

Influenza Program. Currently, four therapeutic products for influenza have received market approval from the FDA: (1) oseltamivir (Tamiflu), a Roche Holding and Gilead product; (2) zanamivir (Relenza), a GlaxoSmithKline product; and (3) amantadine and (4) rimantadine, both generic products which are no longer recommended in the United States due to the high levels of resistance to these drugs exhibited by influenza. In addition to these products, Daiichi Sankyo s laninamivir and BioCryst s peramivir were launched in 2010 in Japan. Currently, BioCryst s peramivir is in a Phase III trial supported in part by funds from DHHS. In addition, other companies including, Toyama Chemical (a subsidiary of Fujifilm), have influenza therapeutic compounds in development. Toyama Chemical s favipiravir is in a Phase II clinical trial in the United States and has completed a Phase III trial in Japan.

In addition to therapeutic products, other companies are focusing development efforts on universal influenza vaccines, including BiondVax Pharmaceuticals Ltd., which initiated a Phase IIa trial of its universal influenza vaccine candidate in October 2010. Successful development of a universal influenza vaccine could lead to a reduction in the number of influenza cases and, therefore, the market size.

Platform Technology. We believe that other biotechnology and pharmaceutical companies share a focus on RNA-based drug discovery and development. Competitors with respect to our RNA-based technologies include, but are not limited to, Alnylam Pharmaceuticals, Inc., Isis Pharmaceuticals, Inc., Prosensa, and Santaris Pharma A/S. We are unaware of any other commercial organization that is developing therapeutics based on a PMO chemistry platform.

Research and Development

We devote a substantial portion of our resources to developing new product candidates. During 2010, 2009 and 2008, we expended approximately $36.0 million, $24.4 million and $27.3 million, respectively, on research and development activities.

Employees

As of December 31, 2010, we had 98 employees, 43 of which hold advanced degrees. Of these employees, 66 are engaged directly in research and development activities and 32 are in administration. We anticipate modest growth in staffing in 2011. None of our employees are covered by collective bargaining agreements and we consider relations with our employees to be good.

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Item 1A. Risk Factors.

Factors That Could Affect Future Results

Set forth below and elsewhere in this Annual Report on Form 10-K, and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this Annual Report on Form 10-K. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also affect our results of operations and financial condition.

Risks Relating to Our Business

Our product candidates are at an early stage of development, and it is possible that none of our product candidates will ever become commercial products.

Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, AVI-4658 is in clinical trials, we have open INDs for AVI-6002 in Ebola and AVI-6003 in Marburg, and the rest of our product candidates are in preclinical development. Our IND for AVI-7100 for the treatment of influenza is currently subject to a clinical hold. Providing the evidence required by the FDA to demonstrate that AVI-7100 is safe to use in humans has delayed, and may continue to delay, our clinical development of AVI-7100. Providing the FDA with additional evidence of the safety of the product will require additional time and resources and may not ultimately result in a lifting of the clinical hold, which would materially limit our ability to develop and commercialize this product candidate. We expect that much of our effort and many of our expenditures over the next several years will be devoted to development activities associated with AVI-4658 in Duchenne muscular dystrophy, or DMD, AVI-6002 in Ebola, AVI-6003 in Marburg and AVI-7100 in influenza. With current resources, we may be restricted or delayed in our ability to develop other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including AVI-4658, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates based on an inability to adequately demonstrate the safety and effectiveness of our product candidates, lack of funding, changes in the regulatory landscape or other reasons. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payers and the medical community. Assuming that any of our product candidates receives the required regulatory approvals, commercial success will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety to the medical community;
- cost-effectiveness of the product;
- the availability of adequate reimbursement by third parties, including governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers;
- the product s potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs;
- marketing and distribution support for the product; and

any exclusivities applicable to the product.

Although we have been granted orphan status for two of our product candidates, we are not guaranteed to receive orphan exclusivity based on that status and would not enjoy such exclusivity in the event that another

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entity could get approval of the same product for the same indication before we receive approval. Furthermore, pediatric exclusivity only attaches if another exclusivity exists for the product, so if no other regulatory exclusivity or patent protection exists for the product once it is approved, we would not receive the benefit of any pediatric exclusivity.

If we are unable to develop and commercialize any of our product candidates, if development is delayed or if sales revenue from any product candidate that receives marketing approval is insufficient, we may never reach sustained profitability.

If we are unable to obtain or maintain required regulatory approvals, we will not be able to commercialize our product candidates, our ability to generate revenue will be materially impaired and our business will not be successful.

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States, and other regulatory authorities in other countries, with regulations differing from country to country. Marketing of our product candidates in the United States or foreign countries is not permitted until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we may never receive regulatory approval for the commercial sale of any of our product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured. We have never prepared or filed the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols or other approval strategies to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Changes in our approval strategies may require additional studies that were not originally planned. Due to these and other factors, such as the fact that a product utilizing our RNA-based technologies has never been approved by any regulatory authority, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

If we receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA s policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States, or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in, or failure to, receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability. We will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. We have not filed for

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regulatory approval to market our product candidates in any foreign jurisdiction. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical and clinical studies, that the product candidate is safe and effective in humans. Ongoing and future clinical trials of our product candidates may not show sufficient safety or efficacy to obtain regulatory approvals.

Phase I clinical trials generally are not designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate s side effects at various doses and dosing schedules in healthy volunteers. Delays in establishing the appropriate dosage levels can lead to delays in the overall clinical development of a product candidate. As of the date of this Annual Report on Form 10-K, we do not believe that we have identified a consistently effective dose of AVI-4658 for individuals with DMD. We are expeditiously moving to start a U.S.-based clinical trial for AVI-4658 at higher doses in the first half of 2011 to further explore and identify a more consistently effective dose that may be more appropriate for future clinical trials and that can serve as a basis for approval by governmental regulatory authorities; however, we cannot assure you that these efforts will be successful. If a consistently effective dose is found in the U.S. based clinical trial, we will expect to engage in discussions with regulatory authorities about the design and subsequent execution of any further studies which may be required. Regulatory authorities might require more extensive clinical trials than anticipated and conforming to any guidance regulatory authorities provide does not guarantee receipt of marketing approval, even if we believe our clinical trials are successful. Such additional clinical trials might include an open label extension study for all participants who have previously received AVI-4658, as well as other participants (e.g., non-ambulatory participants) and any additional placebo-controlled pivotal study or studies. If we are not able to establish an optimal dosage in this trial we may need to conduct additional dose-ranging trials before conducting our pivotal trials of the product.

Furthermore, success in preclinical and early clinical trials does not ensure that later larger-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be reproduced in later trials. For example, pivotal trials for AVI-4658 and AVI-7100 will likely involve a larger number of participants to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.

The Animal Rule is a new and seldom-used approach to seeking approval of a new drug and may not be a viable pathway for seeking approval of our infectious disease product candidates.

We plan to develop the therapeutic product candidates to treat Ebola and Marburg viruses in the United States using the Animal Rule mechanism. There is no guarantee that the FDA will agree to this approach to the development of our infectious disease product candidates, and if they do not we will have to take a more traditional approach to the development of these products, which may not be possible given ethical considerations and other limitations associated with these deadly diseases. Pursuant to the Animal Rule, the sponsor of a drug product must demonstrate efficacy in humans through animal models. No animal model is established as predicting human outcomes in the prevention or treatment of any filovirus disease. We have yet to demonstrate the predictive value of our animal studies to the FDA s satisfaction. If we fail to do so, we will have

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to demonstrate efficacy of AVI-6002 and AVI-6003 through adequate well-controlled trials in humans in order to obtain regulatory approval of these products in the United States, which will greatly add to the time and expense required to commercialize these products. Furthermore, the Animal Rule mechanism has become available only relatively recently and has been infrequently used. We do not have any experience successfully navigating this approach to drug approval. The Animal Rule approach has yet to be well tested generally and is currently under evaluation by the FDA. Even if the Animal Rule represents a viable approach to seeking approval of these products, it may present challenges for gaining final regulatory approval for these product candidates, including an extended timeline to approval and less predictable study requirements.

We rely on U.S. government contracts to support several important research and development programs and substantially all of our revenue. If the U.S. government fails to fund such programs on a timely basis or at all, or such contracts are terminated, the results of our operations would be materially and adversely affected.

We rely on U.S. government contracts and awards to fund several of our development programs, including those for the Ebola, Marburg and influenza viruses and for substantially all of our current revenue.

The funding of U.S. government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may extend over several fiscal years. Consequently, programs are often only partially funded initially and additional funds are committed only as Congress makes further appropriations. If appropriations for one of our programs become unavailable or are reduced or delayed, our contracts may be terminated or adjusted by the government, which could have a negative impact on our future revenue under such contract or subcontract. From time to time, when a formal appropriation bill has not been signed into law before the end of the U.S. government s fiscal year, Congress may pass a continuing resolution that authorizes agencies of the U.S. government to continue to operate, generally at the same funding levels from the prior year, but does not authorize new spending initiatives, during a certain period. During such a period, or until the regular appropriation bills are passed, delays can occur in government procurement due to lack of funding and such delays can affect our operations during the period of delay.

In addition, U.S. government contracts generally also permit the government to terminate the contract, in whole or in part, without prior notice, at the government s convenience or for default based on performance. If one of our contracts is terminated for convenience, we would generally be entitled to payments for our allowable costs and would receive some allowance for profit on the work performed. If one of our contracts is terminated for default, we would generally be entitled to payments for our work that has been completed to that point. A termination arising out of our default could expose us to liability and have a negative impact on our ability to obtain future contracts.

The termination of one or more of these government contracts, whether due to lack of funding, for convenience, or otherwise, or the occurrence of delays or product failures in connection with one or more of these contracts, could negatively impact our financial condition. Furthermore, we can give no assurance that we would be able to procure new U.S. government contracts to offset the revenue lost as a result of termination of any of our existing contracts. Even if our contracts are not terminated and are completed, there is no assurance that we will receive future government contracts.

Our U.S. government contracts may be terminated and we may be liable for penalties under a variety of procurement rules and regulations and changes in government regulations or practices could adversely affect our profitability, cash balances or growth prospects.

We must comply with laws and regulations relating to the formation, administration and performance of U.S. government contracts, which affect how we do business with our customers. Such laws and regulations may potentially impose added costs on our business and our failure to comply with them may lead to penalties and the termination of our U.S. government contracts. Some significant regulations that affect us include:

- the Federal Acquisition Regulation and supplements, which regulate the formation, administration and performance of U.S. government contracts;

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the Truth in Negotiations Act, which requires certification and disclosure of cost and pricing data in connection with contract negotiations; and

the Cost Accounting Standards, which impose accounting requirements that govern our right to reimbursement under certain cost-based government contracts.

Our contracts with the U.S. government are subject to periodic review and investigation. If such a review or investigation identifies improper or illegal activities, we may be subject to civil or criminal penalties or administrative sanctions, including the termination of contracts, forfeiture of profits, the triggering of price reduction clauses, suspension of payments, fines and suspension or debarment from doing business with U.S. government agencies. We could also suffer harm to our reputation if allegations of impropriety were made against us, which would impair our ability to win awards of contracts in the future or receive renewals of existing contracts.

In addition, U.S. government agencies routinely audit and review their contractors performance on contracts, cost structure, pricing practices and compliance with applicable laws, regulations and standards. They also review the adequacy of, and a contractor s compliance with, its internal control systems and policies, including the contractor s purchasing, property, estimating, compensation and management information systems. Such audits may result in adjustments to our contract costs, and any costs found to be improperly allocated will not be reimbursed. We have recorded contract revenues for the periods presented in this Annual Report on Form 10-K based upon costs we expect to realize upon final audit; however, we do not know the outcome of any future audits and adjustments and, if future audit adjustments exceed our estimates, our results of operations could be adversely affected. Additionally, we may be required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third party contractors in order to satisfy our contractual obligations pursuant to our agreements with the U.S. government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement also has to be compliant with the terms of our government grants. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our grants, may result in violations of our contracts with the U.S. government.

Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain.

We have completed a Phase Ib/II clinical trial for AVI-4658 in the UK and announced results in October 2010. We expect to commence additional trials of AVI-4658 and other product candidates in the future, including the initiation of a Phase II trial in AVI-4658 in the first half of 2011. Each of our clinical trials requires the investment of substantial planning, expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling participants who meet trial eligibility criteria, failure of participants to complete the clinical trial, delay or failure to obtain IRB or regulatory approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Participant enrollment is a function of many factors, including the size of the relevant population, the proximity of participants to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of

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the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs. In addition, for some programs (e.g., DMD and Ebola and Marburg infections) there are currently no approved drugs to compare against and an agreement about how to measure efficacy has yet to be reached with the FDA and then demonstrated.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under cGMP and other requirements in foreign countries, and may require large numbers of participants. The FDA or other foreign governmental agencies or we ourselves could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the trial design;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- our inability to obtain regulatory approval to conduct a clinical trial;

lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;

our inability to recruit and enroll individuals to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or

our inability to retain participants who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies and drugs or given to larger populations, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups and parents of trial participants may demand additional clinical trials or continued access to drug even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials or continued access are unwarranted. Any disagreement with patient advocacy groups or parents of trial participants may require management s time and attention and may result in

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legal proceedings being instituted against us, which could be expensive, time-consuming and distracting, and may result in delay of the program. Negative or inconclusive results or adverse medical events, including participant fatalities that may be attributable to our product candidates, during a clinical trial may necessitate it to be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board, or DSMB, and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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

We incurred a net loss of $32.2 million for the year ended December 31, 2010 and $25.2 million for the year ended December 31, 2009. As of December 31, 2010, our accumulated deficit was $307.6 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from 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, partner one or more programs, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

We will need additional funds to conduct our planned research and development efforts. If we fail to continue to attract significant capital or fail to enter into strategic relationships, we may be unable to continue to develop our product candidates.

We will require additional capital from time to time in the future in order to continue the development of product candidates in our pipeline and to expand our product portfolio. 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 and competitive and technological developments in the market. An unforeseen change in these factors, or others, might increase our need for additional capital.

We would expect to seek additional financing from the sale and issuance of equity or debt securities, and we cannot predict that financing will be available when and as we need financing or that, if available, the financing terms will be commercially reasonable. If we are unable to obtain additional financing when and if we require, or on commercially reasonable terms, it would have a material adverse effect on our business and results of operations.

If we are able to consummate such financings, the trading price of our common stock could be adversely affected and/or the terms of such financings may adversely affect the interests of our existing shareholders. To the extent we issue additional equity securities, our existing shareholders could experience substantial dilution in their economic and voting rights. For example, in connection with our December 2007, January 2009 and August 2009 financings, we sold an aggregate of 49.2 million shares of our common stock and issued warrants to purchase an additional 29.7 million shares of our common stock.

Further, we may also enter into relationships with pharmaceutical or biotechnology companies to perform research and development with respect to our RNA-based technologies, research programs or to conduct clinical trials and to market our product candidates. We currently do not have a strategic relationship with a third party to perform research or development using our RNA-based technologies or assist us in funding the continued development and commercialization of any of our programs or drug candidates other than that with the U.S. government. If we are unable to enter into partnerships or strategic relationships with respect to our technologies or any of our programs or drug candidates on favorable terms it may impede our ability to discover, develop and commercialize product candidates.

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We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the advancement of our research and development programs and the development of our product candidates.

We do not currently have the internal ability to manufacture the product candidates that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our product candidates. We may also need to rely on manufacturers for the production of our product candidates to support our research and development programs. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling and labeling of vials and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, fill vials and store sufficient quantities of our product candidates for use in our research and development programs and clinical trials. For example, for our Ebola and Marburg hemorrhagic fever virus development programs, we have entered into supply agreements with two multinational manufacturing firms for the production of the API for Ebola and Marburg therapeutics. There is a limited number of companies that can produce PMO in the quantities and with the quality and purity that we require for our development efforts. If we are required to seek alternative supply arrangements, the resulting delays and potential inability to find a suitable replacement could materially and adversely impact our business.

Our product candidates require precise high-quality manufacturing. The failure to achieve and maintain high quality standards, including failure to detect or control anticipated or unanticipated manufacturing errors could result in patient injury or death or product recalls. Contract drug manufacturers often encounter difficulties involving production yields, quality control and quality assurance and shortages of qualified personnel. If our contract manufacturers or other third parties fail to deliver our product candidates for our research and development programs and for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials, research and development programs or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we are unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

We do not yet have all of the agreements necessary for the supply of our product candidates in quantities sufficient for commercial sale and we may not be able to establish or maintain sufficient commercial manufacturing arrangements on commercially reasonable terms. Securing commercial quantities of our product candidates from contract manufacturers will require us to commit significant capital and resources. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers have a limited number of facilities in which our product candidates can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Our contract manufacturers are required to produce our clinical product candidates under current Good Manufacturing Practice, or cGMP, conditions in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer s compliance with these regulations and standards. Any

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difficulties or delays in our contractors manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, make us postpone or cancel clinical trials, prevent or delay regulatory approval by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our product candidates, or cause our products to be recalled or withdrawn.

We may not be able to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing resulting approved drug products, if any.

To date, our product candidates have been manufactured in small quantities for preclinical studies and early stage clinical trials. In order to conduct larger or late-stage scale clinical trials for a product candidate and for commercialization of the resulting drug product if that product candidate is approved for sale, we will need to manufacture it in larger quantities. We may not be able to successfully increase the manufacturing capacity for any of our product candidates, whether in collaboration with third-party manufacturers or on our own, in a timely or cost-effective manner or at all. If a contract manufacturer makes improvements in the manufacturing process for our product candidates, we may not own, or may have to share, the intellectual property rights to those improvements. Significant scale-up of manufacturing may require additional validation studies, which are costly and which the FDA must review and approve. In addition, quality issues may arise during those scale-up activities because of the inherent properties of a product candidate itself or of a product candidate in combination with other components added during the manufacturing and packaging process, or during shipping and storage of the finished product or active pharmaceutical ingredients. If we are unable to successfully scale-up manufacture of any of our product candidates in sufficient quality and quantity, the development of that product candidate and regulatory approval or commercial launch for any resulting drug products may be delayed or there may be a shortage in supply, which could significantly harm our business.

We rely on third parties to provide services in connection with our preclinical and clinical development programs. The inadequate performance by or loss of any of these service providers could affect our product candidate development.

Several third parties provide services in connection with our preclinical and clinical development programs, including in vitro and in vivo studies, assay and reagent development, immunohistochemistry, toxicology, pharmacokinetics, clinical assessments, data monitoring and management and statistical analysis and other outsourced activities. If these service providers do not adequately perform the services for which we have contracted or cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our product candidates, our development programs may be delayed.

Our RNA-based, or antisense, technology has not been incorporated into a commercial product and is still at a relatively early stage of development.

Our RNA-based platforms, utilizing proprietary antisense technology, have not been incorporated into a commercial product and are still at a relatively early stage of development. This antisense technology is used in all of our therapeutic candidates, including AVI-4658. We are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we have initiated clinical trials for AVI-4658, additional preclinical studies may be required for AVI-4658 and before other product candidates enter human clinical trials. For example, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038, our preclinical PPMO drug candidate for DMD that is based on a different chemistry, derived from the PMO chemistry used in AVI-4658. Based on those findings, we conducted additional preclinical work to help clarify the therapeutic index of AVI-5038, but have not yet alleviated the toxicity problem. In addition, preclinical models to study participant toxicity and activity of compounds are not necessarily predictive of toxicity or efficacy of these compounds in the treatment of human disease and there may be substantially different results in clinical trials from the results obtained in preclinical studies. Any failures or setbacks utilizing our antisense technology, including adverse effects resulting from the use of this technology

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in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to maintain and/or enter into new corporate collaborations regarding these technologies, which would negatively affect our business and financial position.

We intend to increase the size of our workforce and if we fail to manage our growth effectively, our growth prospects and operating results could be adversely affected.

Our ability to perform our U.S. government contracts, growth prospects and operating results depend on highly-skilled personnel to conduct research and product development activities and we intend to recruit, hire and retain additional personnel in the near term. Competition for qualified personnel in our industry, particularly those with experience with either rare or infectious diseases that we target, or may target in the future, is intense. In addition, we expect to meet some of our short-term personnel needs by engaging contractors who may be difficult to retain if they are offered permanent positions with other companies. If we are unable to attract, assimilate or retain such personnel or manage our growth effectively, our continued growth, expansion and ability to advance our proprietary programs and perform our U.S. government contracts would be adversely affected.

We rely on highly skilled personnel, and if we are unable to retain or motivate key personnel or hire qualified personnel, our operations may be adversely affected.

Our operations and our ability to execute our business strategy are highly dependent on the efforts of our executive management team. In April 2010, our chief executive officer and president resigned in connection with the settlement with a group of our shareholders. Following his departure, our board of directors appointed J. David Boyle II, our chief financial officer, to serve as interim chief executive officer and president. In December 2010, our board of directors appointed Christopher Garabedian, a member of the board of directors, to serve as the president and chief executive officer beginning in January 2011. In connection with Mr. Garabedian s appointment, Mr. Boyle returned to the chief financial officer position. If the transition in executive leadership is not smooth, the resulting disruption could negatively affect our operations and impede our ability to execute our strategic plan. In addition, although the members of our senior management team have employment agreements with us, these agreements may not provide sufficient incentives for these officers to continue employment with us. The loss of one or more of the members of our senior management team could adversely affect our operations.

Recent changes in our executive leadership and board of directors and any similar changes in the future may serve as a significant distraction for our management.

As previously disclosed on April 20, 2010, we entered into a settlement agreement with a shareholder group that had sought a special meeting of our shareholders to replace certain members of our board of directors. In connection with such settlement agreement, among other things, we experienced the change in our executive leadership described above and our board of directors underwent significant change. Such changes, or any other future changes in the executive leadership of the company, may disrupt our operations as our company adjusts to the reallocation of responsibilities and assimilates new leadership and, potentially, differing perspectives on our strategic direction. The dispute with the shareholder group required the expenditure of significant time and resources by us and if we are involved in a similar dispute in the future, we may incur significant additional expenditures and it may be a significant distraction for our management and employees.

Asserting, defending and maintaining our intellectual property rights could be challenging and costly, and our failure to do so could harm our ability to compete and impair the outcome of our operations. The pharmaceutical, biotechnology and academic environments are highly competitive and competing intellectual property could limit our ability to protect our products.

Our success will depend in significant part on our existing 189 patents (domestic and foreign) issued or licensed to us and 181 (domestic and foreign) pending patent applications and our ability to obtain additional patents and licenses in the future. We license patents from other parties for certain complementary technologies.

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We cannot be certain that 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. Pharmaceutical research and development is highly competitive; others may file patents first that cover our products or technology. We are aware of a European patent to which Prosensa has rights that may provide the basis for Prosensa or other parties that have rights to the patent to assert that our drug AVI-4658 infringes on such patent. We are currently opposing this patent in the Opposition Division of the European Patent Office and believe that we may be able to invalidate some or all of the claims covered by this patent and non-U.S. foreign equivalents. Final resolution of this opposition proceeding may take a number of 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 on 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. If any patent related to our products or technology issues, and if our activities are determined to be covered by such a patent, we cannot assure you that we will be able to obtain or maintain a license, which could have a material adverse effect on our business, financial condition, operating results and ability to obtain and/or maintain our strategic business relationships.

Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of pharmaceutical and biotechnology firms, as well as academia, is generally highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the U.S. Patent and Trademark Office, or 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 pharmaceutical and biotechnology patent applications at the USPTO and the approval or rejection of patents may take several years.

To help protect our proprietary rights in unpatented trade secrets, we require our employees, consultants and advisors to execute confidentiality agreements and invention assignment 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.

Our research collaborators may publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antisense technology and other RNA technologies or that are developing alternative approaches to or therapeutics for the disease indications on which we are focused. Some of these competitors are developing or testing product candidates that now, or may in the future, compete directly with our product candidates. For example, we believe that companies including Alnylam Pharmaceuticals, Isis Pharmaceuticals, and Santaris share a focus on RNA-based drug discovery and development. Competitors with respect to our exon skipping DMD program, or AVI-4658, include Prosensa and GlaxoSmithKline, or GSK, and other companies such as Acceleron have also been working on DMD programs.

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A European based clinical trial evaluating the systemic administration of the Prosensa/GSK lead DMD drug candidate started several months before the start of our similar clinical trial, although the full biological results from this trial have yet to be made publically available. The Prosensa/GSK drug candidate may, or may not, prove to be safer or more efficacious than our product candidate and it could gain marketing approval before our product candidate. This might affect our ability to successfully complete a clinical development program or market AVI-4658 once approved. This competition may also extend to other exon skipping drugs for DMD limiting our ability to gain market share. We also face significant competition with respect to our influenza program from many different companies, including large biopharmaceutical companies that have both marketed products like Tamiflu® and other products in various stages of development.

Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that have significantly greater resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than our product candidates or that would render our technology obsolete or noncompetitive. Our competitors may, among other things:

develop safer or more effective products;

implement more effective approaches to sales and marketing;

develop less costly products;

obtain quicker regulatory approval;

have access to more manufacturing capacity;

develop products that are more convenient and easier to administer;

form more advantageous strategic alliances; or

establish superior proprietary positions.

We may be subject to clinical trial claims and our insurance may not be adequate to cover damages.

We currently have no products that have been approved for commercial sale; however, the current and future use of our product candidates by us and our corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Our operations involve the use of hazardous materials, and we must comply with environmental laws, which can be expensive, and may affect our business and operating results.

Our research and development activities involve the use of hazardous materials, including organic and inorganic solvents and reagents. Accordingly, we are subject to federal, state, and local laws and regulations governing the use, storage, handling, manufacturing, exposure to, and disposal of these hazardous materials. In addition, we are subject to environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Although we believe that our activities conform in all material respects with such environmental laws, there can be no assurance that violations of these laws will not occur in the future as a result of human error,

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accident, equipment failure, or other causes. Liability under environmental, health and safety laws can be joint and several and without regard to fault or negligence. The failure to comply with past, present, or future laws could result in the imposition of substantial fines and penalties, remediation costs, property damage and personal injury claims, loss of permits or a cessation of operations, and any of these events could harm our business and financial conditions. We expect that our operations will be affected by other new environmental and health and workplace safety laws on an ongoing basis, and although we cannot predict the ultimate impact of any such new laws, they may impose greater compliance costs or result in increased risks or penalties, which could harm our business.

Risks Related to Our Common Stock

Provisions of our articles of incorporation, bylaws and Oregon corporate law might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then current management and board of directors.

Certain provisions of our articles of incorporation and bylaws may make it more difficult for a third party to acquire control of us or effect a change in our board of directors and management. These provisions include:

- classification of our board of directors into two classes, with one class elected each year;
- prohibit cumulative voting of shares in the election of directors;
- prohibit shareholder actions by less than unanimous written consent;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by shareholders at shareholder meetings; and
- the ability of our board of directors to authorize the issuance of undesignated preferred stock, the terms and rights of which may be established and shares of which may be issued without shareholder approval, including rights superior to the rights of the holders of common stock.

In addition, 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 provisions could discourage, delay or prevent a transaction involving a change of control, even if doing so would benefit our shareholders. These provisions also could discourage proxy contests and make it more difficult for shareholders to elect directors of their choosing or cause us to take other corporate actions, such as replacing or removing management or members of our board of directors.

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

The market prices for, and trading volumes of, securities of biotechnology companies, including our securities, have been historically volatile. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a variety of factors, including:

- positive or negative results of testing and clinical trials by ourselves, strategic partners, or competitors;

delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to our company;

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;

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comments by securities analysts;

the perception that shares of our common stock may be delisted from The NASDAQ Stock Market; or

general market conditions in our industry or in the economy as a whole.

In addition, the stock market has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may seriously affect the market price of companies stock, including ours, regardless of actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company s securities, securities class action litigation has often been instigated against these companies. Such litigation, if instigated against us, could result in substantial costs and a diversion of our management s attention and resources.

Our common stock is listed on The NASDAQ Global Market and we may not be able to maintain that listing, which may make it more difficult for investors to sell shares of our common stock.

Our common stock is listed on The NASDAQ Global Market. The NASDAQ Global Market has several quantitative and qualitative requirements with which companies must comply in order to maintain this listing, including a $1.00 minimum bid price per share and $50 million minimum value of listed securities. In the past our stock price has traded near, and at times below, the $1.00 minimum bid price required for continued listing on NASDAQ. For example, the trading price for our common stock was $0.99 as recently as May 11, 2009. Although NASDAQ in the past has provided relief from the $1.00 minimum bid price requirement as a result of the weakness in the stock market, it may not do so in the future. If we fail to maintain compliance with NASDAQ s listing standards, and our common stock becomes ineligible for listing on The NASDAQ Stock Market the liquidity and price of our common stock would be adversely affected.

If our common stock was delisted, the price of our stock and the ability of our shareholders to trade in our stock would be adversely affected. In addition, we would be subject to a number of restrictions regarding the registration of our stock under U.S. federal securities laws, and we would not be able to allow our employees to exercise their outstanding options, which could adversely affect our business and results of operations. If we are delisted in the future from The NASDAQ Global Market, there may be other negative implications, including the potential loss of confidence by actual or potential collaboration partners, suppliers and employees and the loss of institutional investor interest in our company.

We expect our quarterly operating results to fluctuate in future periods, which may cause our stock price to fluctuate or decline.

Our quarterly operating results have fluctuated in the past, and we believe they will continue to do so in the future. Some of these fluctuations may be more pronounced than they were in the past as a result of the issuance of warrants to purchase 29.7 million shares of our common stock by us in December 2007 and January and August 2009. Each of these warrants is classified as a derivative liability. Accordingly, the fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting date with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option valuation model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. Due to the classification of such warrants and other factors, quarterly results of operations are difficult to forecast, and period-to-period comparisons of our operating results may not be predictive of future performance. In one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

Item 1B. Unresolved Staff Comments.

None.

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Item 2. Properties.

A description of the facilities we own and/or occupy is included in the following table. We believe that our current facilities are suitable and have sufficient capacity to meet the projected needs of our business for the next 12 months or that additional space is readily available. Except as noted below, all of our properties are currently being used in the operation of our business.

Location of Property	Square Footage	Lease Expiration Date	Purpose	Other Information
3450 Monte Villa Parkway, Suite 101, Bothell, WA 98021	19,108	November 2014	Laboratory and office space	Corporate headquarters
19909 120th Avenue NE, Suite 101, Bothell, WA 98011	8,398	December 2012	Office space	Administrative office
4575 SW Research Way, Suite 200, Corvallis, OR 97333	53,000	December 2020	Laboratory and office space	Primary laboratory
1749 SW Airport Avenue, Corvallis, OR 97330	34,000	N/A facility is owned	Currently unoccupied; acquired with intention of providing future expansion space for the manufacture of potential products and components	Property listed for sale in September 2009

Item 3. Legal Proceedings.

As of the date hereof, we are not a party to any material legal proceedings with respect to us, our subsidiaries, or any of our material properties. In the normal course of business, we may from time to time be named as a party to various legal claims, actions and complaints, including matters involving employment, intellectual property, effects from the use of therapeutics utilizing our technology, or others. It is impossible to predict with certainty whether any resulting liability would have a material adverse effect on our financial position, results of operations or cash flows.

Item 4. (Removed and Reserved).

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock is quoted on The NASDAQ Global Market under the symbol AVII. The following table sets forth the high and low sales prices as reported by The NASDAQ Global Market for each quarterly period in the two most recent years:

	High	Low
Year Ended December 31, 2009		
First Quarter	$ 1.55	$ 0.52
Second Quarter	1.98	0.66
Third Quarter	2.73	1.20
Fourth Quarter	2.08	1.33
Year Ended December 31, 2010		
First Quarter	$ 1.80	$ 1.16
Second Quarter	1.88	1.11
Third Quarter	2.24	1.44
Fourth Quarter	2.20	1.72

Holders

As of February 28, 2011, we had 592 shareholders of record of our common stock.

Dividends

We have neither declared nor paid cash dividends on our common stock in 2010 or 2009. We currently expect to retain future earnings, if any, to finance the operation and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors.

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Performance Graph

The following graph compares the performance of our Common Stock for the periods indicated with the performance of the NASDAQ Composite Index and the Amex Biotech Index. This graph assumes an investment of $100 on December 31, 2005 in each of the our common stock, the NASDAQ Composite Index and the Amex Biotech Index, and assumes reinvestment of dividends, if any. The stock price performance shown on the graph below is not necessarily indicative of future stock price performance.

	AVII	NASDAQ Composite Index	Amex Biotech Index
End of Fiscal 2005	$ 100.00	$ 100.00	$ 100.00
End of Fiscal 2006	92.71	109.52	110.77
End of Fiscal 2007	40.87	118.33	115.51
End of Fiscal 2008	19.13	74.01	95.04
End of Fiscal 2009	42.32	102.89	138.36
End of Fiscal 2010	61.45	120.29	190.57

Recent Sales of Unregistered Securities.

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers.

None.

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Item 6. Selected Financial Data.

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

	Year Ended December 31,				
	2010	2009	2008	2007	2006
			(in thousands)		
Operations data:					
Revenues	$ 29,420	$ 17,585	$ 21,258	$ 10,985	$ 115
Research and development	35,972	24,396	27,331	31,058	25,346
General and administrative	14,382	8,696	11,469	13,035	7,753
Acquired in-process research and development			9,916		
Operating loss	(20,934)	(15,507)	(27,458)	(33,108)	(32,984)
Interest (expense) income, and other net	259	(454)	344	984	1,910
Decrease (increase) on warrant valuation	(11,502)	(9,198)	3,161	4,956	2,386
Net loss	(32,177)	(25,159)	(23,953)	(27,168)	(28,688)
Net loss per share basic and diluted	$ (0.29)	$ (0.27)	$ (0.34)	$ (0.50)	$ (0.54)
Balance sheet data:					
Cash and investments	$ 33,767	$ 48,446	$ 11,474	$ 25,074	$ 33,152
Working capital	(8,019)	17,803	9,756	18,959	25,596
Total assets	45,976	60,027	25,536	38,638	40,863
Shareholders equity (deficit)	(2,817)	23,630	15,732	26,382	32,519

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below, and those discussed in the section titled Risk Factors included elsewhere in this Annual Report on Form 10-K. Throughout this discussion, unless the context specifies or implies otherwise, the terms AVI , we , us and our refer to AVI BioPharma, Inc. and its subsidiaries.

Overview

We are a biopharmaceutical company focused on the discovery and development of unique RNA-based therapeutics for the treatment of both rare and infectious diseases. Applying our proprietary, highly-differentiated and innovative platform technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. We are primarily focused on rapidly advancing the development of our Duchenne muscular dystrophy drug candidates. We are also focused on developing therapeutics for the treatment of infectious diseases and leveraging our RNA-based technology platforms to identify additional product candidates and explore various strategic opportunities.

Our lead program focuses on the development of disease modifying therapeutic candidates for Duchenne muscular dystrophy, or DMD, a rare genetic muscle wasting disease caused by the absence of dystrophin, a protein necessary for muscle function. AVI-4658 is our lead therapeutic candidate for DMD and is intended to target a substantial group of individuals with DMD. We are also leveraging the capabilities of our RNA-based technology platforms to develop therapeutics for the treatment of infectious diseases. The U.S. Department of Defense, or DoD, has provided significant financial support for the development of therapeutics for Ebola, Marburg, Dengue and influenza, as described in greater detail below.

The basis for our novel RNA-based therapeutics is our phosphorodiamidate-linked morpholino oligomer, or PMO, chemistries. By applying our technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based therapeutics, our technologies can be used to selectively up-regulate or down-regulate the production of a target protein, or direct the expression of novel proteins involved in human diseases and disorders. We believe that these broad capabilities represent highly competitive RNA-based technology platforms and a strong intellectual property position, which we are leveraging to identify additional product candidates and explore various strategic opportunities. As of February 28, 2011, we owned or held exclusive or partially exclusive licenses to approximately 189 U.S. and corresponding foreign patents and 181 U.S. and corresponding foreign patent applications.

On June 4, 2010, we were awarded a new contract with the U.S. Defense Threat Reduction Agency, or DTRA, an agency of the U.S. Department of Defense, or DoD, to advance the development of AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program, or TMT, of the DoD. The contract provides for funding of up to $18.0 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, the study of an intranasal delivery formulation and the funding of the entry into a Phase I clinical program to obtain human safety data to support potential use under an Emergency Use Authorization.

On July 14, 2010, we were awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of our hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately $291 million. Activity under the first segment began in July 2010 and

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provides us funding of up to approximately $80 million. Activities under the first segment include Phase I studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period. After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to us of up to approximately $291 million. Under an earlier contract, we completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003.

In October 2010, we were awarded five cash grants totaling approximately $1.2 million under the U.S. government s Qualifying Therapeutic Discovery Project, or QTDP, program. We were awarded grants for all five of the project applications submitted for our DMD program and infectious disease programs. The QTDP was part of the March 2010 Patient Protection and Affordable Care Act and provides a tax credit or grant equal to 50 percent of eligible costs and expenses for tax years 2009 and 2010. Under the program, a total of $1 billion in grant or tax credits was made available to companies with 250 or fewer employees. The grant we received for each application was approximately $244,000.

On April 20, 2010, our chief executive officer and president, Leslie Hudson, Ph.D., tendered his resignation at the request of our board of directors. Pursuant to his separation agreement, Dr. Hudson will receive total cash severance payments of $1,412,170 (comprised of two times the sum of (1) his annual base salary in effect as of the separation date ($494,000), (2) the average of his last two annual bonuses ($188,669), and (3) the annual cost of Pfizer retiree healthcare coverage for him and his spouse ($23,000). The cash severance payments are paid to Dr. Hudson in 24 equal monthly installments, less required deductions and withholdings following the effective date of the separation agreement. In addition, as of the effective date of the separation agreement, unvested options to purchase 1,166,833 shares of our common stock and 116,500 shares of restricted stock previously granted to Dr. Hudson became fully vested and exercisable, which resulted in a charge to stock compensation expense of $1,181,000 in the second quarter of 2010.

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. As the result of new Influenza, Ebola and Marburg U.S. government research contracts, we expect future revenues and research and development cost to increase. We have been unprofitable since inception and, other than limited interest, license fees, grants and research contracts, we have had no material revenue from the sale of products or other sources, other than from government grants and research contracts, and we do not expect material revenue for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development efforts and seek to enter additional collaborative efforts. As of December 31, 2010, our accumulated deficit was $307.6 million.

In March 2008, we acquired all of the stock of Ercole Biotechnology, Inc. (Ercole) in exchange for 5,811,721 shares of our common stock, which was valued at approximately $8.4 million, and the assumption of approximately $1.8 million in liabilities of Ercole. We also issued warrants to purchase our common stock (also classified as equity), which were valued at $437,000, in exchange for certain outstanding warrants issued by Ercole. From 2006 to the time of the acquisition, we and Ercole had collaborated with respect to the development drug candidates, including AVI-4658.

U.S. Government Contracts

In the periods presented, substantially all of the revenue generated by our company was derived from research contracts with the U.S. government. As of December 31, 2010, we had contracts with the U.S. government pursuant to which we are entitled to receive up to an aggregate of $157.1 million for development of our product candidates, of which $76.1 million had been billed or recognized as revenue and $81.0 million of which relates to development that has not yet been completed and has not been billed or recognized as revenue. The following is a description of such contracts.

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January 2006 Agreement (Ebola and Marburg Host Factors, Dengue, Anthrax and Ricin)

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of $11.0 million to fund our ongoing defense-related programs under four different contracts, all of which were executed in 2007, and the last of which expired in October 2010. Net of government administrative costs, it was anticipated that we would receive up to $9.8 million under this allocation. As of December 31, 2010, we have recognized revenue of $9.7 million with respect to these contracts and do not expect to receive any additional funds under these contracts. Our technology is expected to be used to continue developing RNA-based drugs against Ebola and Marburg viruses.

November 2006 Agreement (Ebola, Marburg and Junín Viruses)

In November 2006, we entered into a two-year research contract with the DTRA pursuant to which we were entitled to $28.0 million to fund development of our antisense therapeutic candidates Ebola, Marburg and Junín hemorrhagic viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by $5.9 million to an aggregate of $33.9 million. In September 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional $11.5 million to an aggregate of $45.4 million. In November 2010, we and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and this contract would be deemed concluded. As of December 31, 2010, we had recognized revenue of $38.4 million with respect to this contract and do not expect further significant revenue.

May 2009 Agreement (H1N1/Influenza)

In May 2009, we entered into a contract with the DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to $4.1 million to our company for the work involving the application of our proprietary PMO and PMOplus antisense chemistry and we plan to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu® resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by $4.0 million to an aggregate of $8.1 million. As of December 31, 2010, we have recognized revenue of $6.9 million with respect to this contract and do not expect to receive additional significant revenue under these contracts in 2011.

June 2010 Agreement (H1N1/Influenza)

On June 4, 2010, we entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by us, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the TMT. The contract provides for funding of up to $18.0 million to advance the development of AVI-7100, including studies enabling an IND application with the FDA, the study of an intranasal delivery formulation, and the funding of the entry into a Phase I clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization. As of December 31, 2010, we have recognized revenue of $8.8 million with respect to this contract and expect to receive the remaining funding under this contract in 2011.

July 2010 Agreement (Ebola and Marburg)

On July 14, 2010, we were awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the our hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments for each therapeutic candidate with potential funding of up to approximately $291 million. Activity under the first segment began in July 2010 and provides for funding to us of up to approximately $80 million. Activities under the first segment include Phase I studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.

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After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to us of up to approximately $291 million over a period of approximately six years. Under an earlier contract, we completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of December 31, 2010, we have recognized revenue of $9.8 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government and other revenue on our results of operations for the years ended December 31, 2010, 2009 and 2008.

	Year Ended December 31,		
	2010	2009	2008
		(in thousands)	
January 2006 Agreements (*Ebola and Marburg host factor, Dengue, Anthrax and Ricin*)	$ 519	$ 2,288	$ 4,251
November 2006 Agreement (*Ebola, Marburg and Junín Viruses*)	3,204	10,421	16,760
May 2009 Agreement (*H1N1*)	5,171	1,716	
June 2010 Agreement (*H1N1*)	8,809		
July 2010 Agreement (*Ebola and Marburg*)	9,822		
Grants	1,622	725	53
Other Agreements	273	2,435	194
Total	$ 29,420	$ 17,585	$ 21,258

Key Financial Metrics

Revenue

Government Research Contract Revenue. Substantially all of our revenue was generated from U.S. government research contracts. See Note 7 U.S. Government Contracts of the financial statements included elsewhere in this Annual Report on Form 10-K. We recognize revenue from U.S. government research contracts during the period in which the related expenses are incurred and present such revenues and related expenses gross in the consolidated financial statements.

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

We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of our performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement. As of December 31, 2010, we had deferred revenue of $3.3 million, which represents up-front fees received from third parties pursuant to certain contractual arrangements and will be recognized as performance obligations are satisfied.

As the result of recent new government research contracts for H1N1/Influenza, Ebola and Marburg, we expect future revenues to increase in the near term.

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Expenses

Research and Development. Research and development expense consists of costs associated with research activities as well as costs associated with our product development efforts, conducting preclinical studies, and clinical trial and manufacturing costs.

Direct research and development expenses associated with our programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants and other outside services, such as data management and statistical analysis support, and materials and supplies used in support of the clinical programs. Indirect costs of our clinical program include salaries, stock based compensation, and an allocation of our facility costs. As the result of recent new government research contracts for H1N1 Influenza, Ebola and Marburg, we expect future research and development costs to increase.

The amount and timing of future research and development expense will depend on our ability to obtain U.S. government awards to fund the advanced development of our antiviral therapeutic candidates. Without such funding, we would likely drastically reduce our spending in these areas. Future research and development expenses may also increase if our internal projects, such as DMD, enter later stage clinical development. Our research and development programs are at an early stage and may not result in any approved products. Product candidates that appear promising at early stages of development may not reach the market for a variety of reasons. Similarly, any of our product candidates may be found to be ineffective during clinical trials, may take longer to complete clinical trials than we have anticipated, may fail to receive necessary regulatory approvals, and may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality.

As a result of these uncertainties and the other risks inherent in the drug development process, we cannot determine the duration and completion costs of current or future clinical stages of any of our product candidates. Similarly, we cannot determine when, if, or to what extent we may generate revenue from the commercialization and sale of any product candidate. The timeframe for development of any product candidate, associated development costs, and the probability of regulatory and commercial success vary widely.

General and Administrative. General and administrative expense consists principally of salaries, benefits, stock-based compensation expense, and related costs for personnel in our executive, finance, information technology, business development and human resource functions. Other general and administrative expenses include an allocation of our facility costs and professional fees for legal, consulting and accounting services.

Interest Income (Expense) and Other, Net. Interest income and other income or expense, net, consists of interest on our cash, cash equivalents and short-term investments and rental income and other income. Our cash equivalents consist of money market investments and our short term investments consist of certificates of deposit which are included in other current assets. Interest expense includes interest paid on our mortgage loan related to the Corvallis property held for sale. Other income includes rental income on sublease facilities.

Change in Fair Value of Warrants. Warrants issued in connection with our December 2007 and January and August 2009 financings are classified as liabilities as opposed to equity due to their settlement terms. These warrants are non-cash liabilities; we are not required to expend any cash to settle these liabilities. The fair market value of these warrants was recorded on the balance sheet at issuance and the warrants are marked to market each financial reporting period, with changes in the fair value recorded as a gain or loss in our statement of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. For more information, see Note 9 Warrants of the financial statements included elsewhere in this Annual Report on Form 10-K.

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Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements included elsewhere in this Annual Report on Form 10-K. The preparation of our financial statements in accordance with accounting principles generally accepted in the United States, or GAAP, 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 for the periods presented. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

The policies that we believe are the most critical to aid the understanding of our financial results include:

- revenue recognition;
- impairment of long-lived assets;
- stock-based compensation; and
- accounting for and valuation of warrants classified as liabilities.

Revenue Recognition

We have historically generated revenue from our U.S. government research contracts and other license arrangements. For a more detailed description of our revenue recognition policies, see Key Financial Metrics above and Note 2 Summary of Significant Accounting Policies of the financial statements included elsewhere in this Annual Report on Form 10-K.

Long-Lived Asset Impairment

Long-lived assets held and used by us and intangible assets with determinable lives are reviewed for impairment whenever events or circumstances indicate that the carrying amount of assets may not be recoverable in accordance with GAAP pronouncements. For more information, see Note 2 Summary of Significant Accounting Policies of the financial statements included elsewhere in this Annual Report on Form 10-K.

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Stock Compensation Expense

To determine stock-based compensation costs, we apply the provisions of Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718, Share-Based Payments. We use the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards on the date of grant, which requires the use of subjective and complex assumptions to determine the fair value of stock-based awards, including the option s expected term and the price volatility of the underlying stock. We recognize the value of the portion of the awards that is ultimately expected to vest as expense over the requisite vesting periods on a straight-line basis for the entire award. Stock options granted to employees are service-based and prior to December 31, 2010 typically vest over a three year period, with one-third of the underlying shares vesting on each anniversary of grant, and have a ten year term. Beginning in January 2011, stock options will typically vest over a four year period, with one fourth of the underlying shares vesting on the first anniversary of the grant and 1/48th of the underlying shares vesting monthly thereafter, such that the underlying shares will be fully vested on the fourth anniversary of the grant. Compensation expense of $3.2 million is shown in the operating activities section of the statements of cash flows. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The following table summarizes the weighted average assumptions used in determining the fair value of stock options granted:

	Year Ended December 31,		
	2010	**2009**	**2008**
Risk-free interest rate	1.4% -3.8%	1.2% -1.8%	1.1% -3.4%
Expected dividend yield	%	%	%
Expected lives	5.3 -8.0 years	3.6 -9.1 years	3.6 -9.1 years
Expected volatility	82.5% - 90.3%	92.0% - 94.4%	81.0% - 90.7%

The risk free interest rate is estimated using an average of treasury bill interest rates over a historical period commensurate with the expected life of the option that correlates to the prevailing interest rates at the time of grant. The expected dividend yield is zero as we have not paid any dividends to date and do 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 calculated volatility of our common stock over a historical period commensurate with the expected life of the option. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

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 we use different assumptions, our stock-based compensation expense could be materially different in the future. See Note 3 Stock Compensation of the audited financial statements included elsewhere in this Annual Report on Form 10-K for a further discussion of stock-based compensation.

Warrant Liability

In December 2007 and January and August of 2009, we issued warrants to purchase an aggregate of 29.7 million shares of our common stock in connection with a registered direct offering of our common stock and warrants. These warrants are classified as a liability due to their settlement terms. These warrants are non-cash liabilities; we are not required to expend any cash to settle these liabilities.

The fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option pricing model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. If, for

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example, the market value of our common stock or its volatility at December 31, 2010 were 10% higher or lower than used in the valuation of such warrants, our valuation of the warrants would have increased by up to $5.2 million or decreased up to $5.1 million, respectively, with such difference reflected in our statement of operations.

Results of Operations for the years ended December 31, 2010, 2009 and 2008

The following table sets forth selected consolidated statements of operations data for each of the periods indicated:

Summary of Results for Fiscal Years 2010, 2009 and 2008

	Year Ended December 31,		
	2010	2009	2008
	(in thousands, except per share amounts)		
Operations data:			
Revenues	$ 29,420	$ 17,585	$ 21,258
Research and development	35,972	24,396	27,331
General and administrative	14,382	8,696	11,469
Acquired in-process research and development			9,916
Operating loss	(20,934)	(15,507)	(27,458)
Interest (expense) income, and other net	259	(454)	344
Decrease (increase) on warrant valuation	(11,502)	(9,198)	3,161
Net loss	(32,177)	(25,159)	(23,953)
Net loss per share - basic and diluted	$ (0.29)	$ (0.27)	$ (0.34)

Revenue

Revenue for 2010 increased by $11.8 million, or 67%, compared to 2009 due to the increase from the new Ebola and Marburg contract of $9.8 million, increases in revenue from the H1N1 contracts of $12.3 million, and an increase of $1.2 million from the U.S. government s Qualifying Therapeutic Discovery Project, partially offset by a $11.5 million decrease in revenue from the 2006 Ebola, Marburg and Junín contract and decreases in Children s National Medical Center contract related to DMD.

Revenue for 2009 decreased by $3.7 million, or 17%, compared to 2008 due to a decline in revenues from the 2006 Ebola, Marburg and Junín research contract.

Research and Development Expenses

Research and development expenses for 2010 increased by $11.6 million, or 47%, compared to 2009 due primarily to $5.6 million in costs related to the July 2010 Ebola and Marburg government contract and $4.2 million in costs related to the June 2010 H1N1 government contract. Both of these contracts were new in 2010. Additionally, $5.5 million is related to the increased production of therapeutic drug substance, a $1.5 million increase in costs for the 2009 H1N1 government contract offset by a $4.3 million decline in spending related to the 2006 Ebola, Marburg and Junín government contracts and a $0.9 million decline in all other R&D accounts for the total increase in research and development costs for 2010.

Research and development expenses for 2009 decreased by $2.9 million, or 11%, compared to 2008 due primarily to lower activity with respect to U.S. government research projects.

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General and Administrative Expenses

General and administrative expenses for 2010 increased by $5.7 million, or 65%, compared to 2009. This significant increase in 2010 was due to $2.6 million in severance costs and stock compensation expense related to the departure in April 2010 of our former chief executive officer and an increase of $2.0 million of higher employee costs related to the increase in new staff hired to execute the new Ebola, Marburg and H1N1 government contracts. Other increases included legal costs of $0.9 million, facilities expense of $0.4 million for the addition of our new Bothell, Washington facilities, and a $0.4 million loss on the write down of the property held for sale, partially offset by a $0.6 million decrease in professional consulting costs.

General and administrative expenses for 2009 decreased by $2.8 million, or 24%, compared to 2008. The decrease was due primarily to non-cash costs related to common stock issued to Ercole executives in connection with the 2008 acquisition of Ercole, 2008 severance and stock compensation expenses related to the resignation of former executive officers, and relocation costs for new executive officers.

Interest Income (Expense) and Other, Net

The increase in interest income (expense) and other, net for 2010 compared to 2009 was attributable to increased interest income on invested cash of $0.1 million and $0.1 million from increased rental income from the sublease of excess space in our Corvallis, Oregon facility, compared to $0.5 million in patents abandonments and impairment of property held for sale that occurred in 2009.

Interest income (expense) and other, net for 2009 declined $0.8 million, compared to 2008 primarily due to declines in market rates of interest on our interest earning investments and the write off of patents and property held for sale.

Change in Fair Value of Warrant Liability

The increase in fair value of warrant liability of $11.5 million in 2010 compared to the increase in fair value of warrant liability of $9.2 million in 2009 was primarily attributable to the changes in our stock price. The increase in fair value of warrant liability of $9.2 million in 2009 compared to the decrease in fair value of warrant liability of $3.2 million in 2008 was attributable to the issuance of new warrants in 2009 and changes in our stock price.

Net Loss

The increase in net loss of $7.0 million, or 28% for 2010 compared to 2009 was primarily attributable to an increase in general and administrative costs and the increase in the warrant liability, partially offset by an increase in interest and rent income.

The increase in net loss of $1.2 million for 2009 compared to 2008 was attributable primarily to the increase in the fair value of warrant liability, partially off-set by a combined reduction of research and development costs and general and administration costs, and a reduction of one-time costs for acquired in process research and development of $9.9 million related to the acquisition of Ercole Biotech.

Liquidity and Capital Resources

At December 31, 2010, cash and cash equivalents were $33.6 million, compared to $48.3 million at December 31, 2009. Our principal sources of liquidity are revenue from our U.S. government research contracts and equity financings. Our principal uses of cash are research and development expenses, general and administrative expenses and other working capital requirements. Based on the factors described below, we believe that our currently available cash, cash equivalents and short-term investments, exclusive of receipt of future proceeds pursuant to our contracts with the U.S. government, are sufficient to finance our operations for at least the next 12 months.

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Sources of Funds

Our primary source of revenue is from development of product candidates pursuant to our contracts with the U.S. government. Government funding is subject to the U.S. government s appropriations process and the U.S. government has the right under our contracts with them to terminate such contracts for convenience. If U.S. government funding is not received or is delayed, our results of operations could be materially and adversely affected and we may need to seek additional sources of capital. We do not generate any revenue from non-government, commercial sale of our pharmaceutical product candidates.

In January 2009, we sold approximately 14.2 million shares of our common stock and also issued warrants to purchase approximately 14.2 million shares of our common stock in an offering registered under the Securities Act of 1933, or the Securities Act. The offering generated net proceeds of approximately $15.5 million. The warrants issued to the investors in the offering have an exercise price of $1.16 per share and are exercisable at any time on or before July 30, 2014. In connection with the offering, we also issued to the placement agent a warrant to purchase approximately 427,000 shares of our common stock at an exercise price of $1.45 per share. The warrant issued to the placement agent is exercisable on or before January 30, 2014.

In August 2009, we sold approximately 24.3 million shares of our common stock and also issued warrants to purchase approximately 9.7 million shares of our common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $32.3 million. The warrants issued to the investors in the offering have an exercise price of $1.78 per share and are exercisable at any time on or before August 25, 2014.

We will require additional capital from time to time in the future in order to continue the development of products and to expand our product portfolio. We expect to seek additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities. We cannot assure you that financing will be available when and as needed or that, if available, the financings will be on favorable or acceptable terms. If we are unable to obtain additional financing when and if we require, it would have a material adverse effect on our business and results of operations. To the extent we issue additional equity securities, our existing shareholders could experience substantial dilution.

We have never generated material commercial revenue from the sale of our non-governmental products and cannot offer any assurances that we will be able to do so in the future.

Uses of Funds

From inception in 1980 through the date of this Annual Report on Form 10-K, our accumulated deficit is $307.6 million. Our principal uses of cash have been research and development expenses, general and administrative expenses, costs associated with the acquisition of in-process research and development and other working capital requirements.

Historical Trends

	Year Ended December 31,		
	2010	2009	2008
		(in thousands)	
Cash provided by (used in):			
Operating activities	$ (15,209)	$ (8,800)	$ (12,340)
Investing activities	(1,961)	(1,883)	(1,239)
Financing activities	2,484	47,766	(32)
Increase (decrease) in cash and equivalents	$ (14,686)	$ 37,083	$ (13,611)

Operating Activities. We used $15.2 million of cash in operating activities for the year ended December 31, 2010, an increase of $6.4 million, or 73%, compared to $8.8 million of cash used in operating activities for the year ended December 31, 2009. The increase in net cash used in operating activities during the comparative

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periods was primarily attributable to increased research and development costs and higher general and administrative expenses, partially offset by higher revenue. We used $8.8 million of cash in operating activities for the year ended December 31, 2009, a decrease of $3.5 million, or 29%, compared to $12.3 million of cash used in operating activities for the year ended December 31, 2008. The decrease in net cash used in operating activities during the comparative periods was primarily attributable to the reduction in accounts receivable.

Investing Activities. We used $2.0 million of cash in investing activities for the year ended December 31, 2010, an increase of $0.1 million, or 4%, compared to $1.9 million of cash used in investing activities for the year ended December 31, 2009. The majority of the increase in cash used for investing activities was attributable to increased spending on fixed assets with no liquidation of a certificate of deposit in 2010 as occurred in 2009.

We used $1.9 million of cash in investing activities for the year ended December 31, 2009, an increase of $0.6 million, or 52%, compared to $1.2 million of cash used in investing activities for the year ended December 31, 2008. The increase in cash used for investing activities was attributable to increased spending on patents and fixed assets, partially offset by the liquidation of a certificate of deposit.

Financing Activities. We had financing activities of $2.5 million that consisted of stock option and warrant exercises and debt repayment for the year ended December 31, 2010. The $47.8 million of cash generated by financing activities for the year ended December 31, 2009 was attributable to our January and August 2009 equity financings, slightly offset by loan payments for the property held for sale.

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term. These requirements include our ability to meet the requirements of our U.S. government research projects, 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 as we advance our research, development and commercialization programs.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

Contractual Payment Obligations

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and acquisition of technology access rights, among others. The following table presents contractual obligations arising from these arrangements as of December 31, 2010:

		Payments Due By Period			
Contractual Obligations	**Total**	**2011**	**2012 and 2013**	**2014 and 2015**	**2016 and beyond**
			(in thousands)		
Operating leases	$ 18,189	$ 2,403	$ 4,441	$ 3,446	$ 7,899
Royalty payments	1,270	100	160	235	775
	$ 19,459	$ 2,503	$ 4,601	$ 3,681	$ 8,674

Recent Accounting Pronouncements

See Note 2 Summary of Significant Accounting Policies Recent Accounting Pronouncements of the financial statements included elsewhere in this Annual Report on Form 10-K.

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

We had cash, cash equivalents, and short-term investments of $33.8 million and $48.4 million at December 31, 2010 and 2009, respectively. We do not enter into investments for trading or speculative purposes; our cash equivalents are invested in money market accounts and our short-term investments consisted of short-term certificates of deposit. We believe that we do not have any material exposure to changes in the fair value of these assets in the near term due to extremely low rates of investment interest and to the short term nature of our cash, cash equivalents, and short-term investments. Future declines in interest rates, however, would reduce investment income, but are not likely to be a material source of revenue to our company in the foreseeable future. A 0.001% decline in interest rates, occurring January 1, 2010 and sustained throughout the period ended December 31, 2010, would result in a decline in investment income of approximately $41,000 for that same period.

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Disclosure Controls and Procedures

We carried out an evaluation as of the end of the period covered by this Annual Report on Form 10-K, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to paragraph (b) of Rule 13a-15 and 15d-15 under the Exchange Act. 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 us in the reports we file or submit under the Exchange Act (1) is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission s rules and forms, and (2) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

We do not expect that our 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 our 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. We considered these limitations during the development of our disclosure controls and procedures, and will continually reevaluate them to ensure they provide reasonable assurance that such controls and procedures are effective.

Internal Control over Financial Reporting

Management s Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for our company, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

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Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

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

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

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2010. In making this assessment, management used the criteria in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded that, as of December 31, 2010, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2010 has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which appears in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act during the quarter ended December 31, 2010 that our certifying officers concluded materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders

AVI BioPharma, Inc:

We have audited AVI BioPharma, Inc. s (a development stage company) internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). AVI BioPharma, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Managements Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on AVI BioPharma, Inc. s internal control over financial reporting based on our audit.

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

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

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

In our opinion, AVI BioPharma, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of AVI BioPharma, Inc. (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, shareholders equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2010 and the information included in the cumulative from inception presentations for the period January 1, 2002 to December 31, 2010 (not separately presented herein), and our report dated March 14, 2011 expressed an unqualified opinion on those financial statements. The financial statements of AVI BioPharma, Inc. for the period July 22, 1980 (inception) to 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.

/s/ KPMG LLP

Seattle, Washington

March 14, 2011

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Item 9B. Other Information.

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information regarding our directors and executive officers required by this item is included in our definitive proxy statement for our 2011 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 on Form 10-K and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item is included in our definitive proxy statement for our 2011 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 on Form 10-K and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item is included in our definitive proxy statement for our 2011 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 on Form 10-K and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item is included in our definitive proxy statement for our 2011 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 on Form 10-K 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 2011 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 on Form 10-K and is incorporated herein by reference.

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PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The following financial statements of the Company and the Report of KPMG LLP, Independent Auditors, are included in Part IV of this Annual Report on Form 10-K on the pages indicated:

(2) 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.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits.

The following exhibits are filed herewith or are incorporated by reference to exhibits previously filed with the SEC:

		Incorporated by Reference to Filings Indicated				
Exhibit Number	**Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
2.1	Agreement and Plan of Merger dated March 12, 2008 by and among AVI BioPharma, Inc., EB Acquisition Corp., Ercole Biotech, Inc. and the Stockholder Representative.	8-K	001-14895	2.1	3/13/08	
3.1	Third Restated and Amended Articles of Incorporation of Antivirals, Inc.	SB-2	333-20513	3.1	1/28/97	
3.2	First Amendment to Third Restated and Amended Articles of Incorporation of Antivirals, Inc.	8-K	000-22613	3.3	9/30/98	
3.3	Articles of Amendment to Article 2 of the Third Restated and Amended Articles of Incorporation of AVI BioPharma, Inc., as amended.	Schedule 14A	001-14895	Appendix B	4/11/02	
3.4	Amended and Restated Bylaws of AVI BioPharma, Inc.					X

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Exhibit Number	Description	Incorporated by Reference to Filings Indicated Form	File No.	Exhibit	Filing Date	Filed Herewith
4.1	Form of Specimen Certificate for Common Stock.					X
4.2	Form of Warrant to Purchase Common Stock, issued on December 19, 2007.	8-K	001-14895	4.5	12/13/07	
4.3	Form of Common Stock Purchase Warrant, issued on January 30, 2009.	8-K	001-14895	4.4	1/30/09	
4.4	Form of Common Stock Purchase Warrant, issued on August 25, 2009.	8-K	001-14895	4.1	8/24/09	
10.1	Employment Agreement with Dwight Weller, Ph.D., dated November 4, 1996.	SB-2	333-20513	10.5	5/29/97	
10.2	Amendment to Employment Agreement with Dwight Weller, Ph.D., dated December 28, 2008.					X
10.3	Amendment No. 2 to Employment Agreement with Dwight Weller, Ph.D., dated January 19, 2010.					X
10.4	Employment Agreement with Patrick Iversen, Ph.D., dated July 14, 1997.	10KSB	000-22613	10.12	3/30/98	
10.5	Amendment to Employment Agreement with Patrick Iversen, Ph.D., dated December 28, 2008.					X
10.6	Amendment No. 2 to Employment Agreement with Patrick Iversen, Ph.D., dated January 18, 2010.					X
10.7	Employment Agreement dated February 8, 2008 by and between AVI BioPharma, Inc. and Leslie Hudson, Ph.D.	10-Q	001-14895	10.63	5/12/08	
10.8	Employment Agreement dated April 10, 2008 by and between AVI BioPharma, Inc. and Dr. Ryszard Kole.	10-Q	001-14895	10.64	8/11/08	
10.9	Amendment to Employment Agreement with Dr. Ryszard Kole, dated October 16, 2009.					X
10.10	Employment Agreement dated July 24, 2008 by and between AVI BioPharma, Inc. and J. David Boyle II.					X
10.11	Amendment No. 1 to Employment Agreement dated August 1, 2008 by and between AVI BioPharma, Inc. and J. David Boyle II.					X
10.12	Amendment No. 2 to Employment Agreement with J. David Boyle II, dated November 3, 2009.					X

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Exhibit Number	Description	Incorporated by Reference to Filings Indicated Form	File No.	Exhibit	Filing Date	Filed Herewith
10.13	Employment Agreement dated January 26, 2009 between AVI BioPharma, Inc. and Stephen Bevan Shrewsbury, M.D.	10-Q	001-14895	10.71	5/11/09	
10.14	Amendment to Employment Agreement with Stephen Bevan Shrewsbury, M.D., dated October 16, 2009.					X
10.15	Employment Agreement dated May 15, 2009 between AVI BioPharma, Inc. and Paul Medeiros.					X
10.16	Amendment to Employment Agreement with Paul Medeiros, dated October 16, 2009.					X
10.17	Executive Employment Agreement dated December 17, 2010 by and between AVI BioPharma, Inc. and Christopher Garabedian.					X
10.18	Offer Letter between AVI BioPharma, Inc. and Graham Johnson, B.Sc., Ph.D., dated July 9, 2010					X
10.19	Separation and Release Agreement dated April 20, 2010 between Leslie Hudson and AVI BioPharma, Inc.	8-K	001-14895	10.2	4/22/10	
10.20	Professional Services Agreement between James B. Hicks Ph.D., LLC and AVI BioPharma, Inc., dated October 26, 2007.	10-K	001-14895	10.61	3/17/08	
10.21	Engagement Letter dated January 28, 2009 between AVI BioPharma, Inc. and Rodman & Renshaw, LLC.	8-K	001-14895	1.3	1/30/09	
10.22	2002 Equity Incentive Plan.	Schedule 14A	001-14895	Appendix A	4/11/02	
10.23	AVI BioPharma, Inc. Non-Employee Director Compensation Policy.	8-K	001-14895	10.85	10/1/10	
10.24	Form of Indemnification Agreement.	8-K	001-14895	10.86	10/8/10	
10.25	Technology Transfer Agreement between Anti-Gene Development Group and Antivirals, Inc., dated February 9, 1992.	SB-2	333-20513	10.6	5/29/97	
10.26	License and Option Agreement between Anti-Gene Development Group and Antivirals, Inc., dated February 9, 1993.	SB-2	333-20513	10.8	1/28/97	
10.27	Amendment to Technology Transfer Agreement between Anti-Gene Development Group and Antivirals, Inc. dated January 20, 1997.	SB-2	333-20513	10.7	1/28/97	

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Exhibit Number	Description	Incorporated by Reference to Filings Indicated Form	File No.	Exhibit	Filing Date	Filed Herewith
10.28	2000 Amendment to Technology Transfer Agreement between Anti-Gene Development Group and AVI BioPharma, Inc., dated March 9, 2000.	S-1	333-39542	10.23	6/16/00	
10.29	License Agreement between ImmunoTherapy Corporation, The Ohio State University and The Ohio State University Research Foundation, dated March 12, 1996.	S-4	333-60849	10.17	8/7/98	
10.30	License Agreement between ImmunoTherapy Corporation, The Ohio State University and The Ohio State University Research Foundation, dated December 26, 1996.	S-4	333-60849	10.18	8/7/98	
10.31	Amendment to License Agreement between ImmunoTherapy Corporation and The Ohio State University Research Foundation, dated September 23, 1997.	S-4	333-60849	10.19	8/7/98	
10.32*	Collaboration and License Agreement between Isis Pharmaceuticals and Ercole Biotech, Inc. dated May 16, 2003.	10-K	001-14895	10.78	3/16/10	
10.33*	License Agreement dated January 26, 2006 by and between Chiron Corporation and AVI BioPharma, Inc.	10-Q	001-14895	10.53	5/10/06	
10.34*	License and Development Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc.	S-3	333-133211	10.51	4/11/06	
10.35*	Cross License Agreement dated January 8, 2007 by and between Eleos, Inc. and AVI BioPharma, Inc.	10-Q	001-14895	10.58	5/10/07	
10.36	Exclusive License Agreement by and between The University of Western Australia and AVI BioPharma, Inc., dated November 24, 2008.					X
10.37	United States of America Sales, Distribution, and Development Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.	10-K	001-14895	10.29	3/27/01	
10.38*	Supply Agreement, dated March 10, 2006, by and between Cook Group Incorporated and AVI BioPharma, Inc.	S-3	333-133211	10.50	4/11/06	
10.39	Agreement between AVI BioPharma, Inc. and the U.S. Defense Threat Reduction Agency dated May 5, 2009.	10-Q	001-14895	10.72	8/10/09	
10.40	Amendment of Contract between AVI BioPharma, Inc. and the U.S. Defense Threat Reduction Agency (contract no. HDTRA1-07-C-0010), effective May 29, 2009.	10-Q	001-14895	10.74	8/10/09	

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Exhibit Number	Description	Incorporated by Reference to Filings Indicated Form	File No.	Exhibit	Filing Date	Filed Herewith
10.41	Amendment of Contract between AVI BioPharma, Inc. and the U.S. Defense Threat Reduction Agency (contract no. HDTRA 1-07-C0010), effective September 30, 2009.	10-Q	001-14895	10.77	11/9/09	
10.42*	Amendment of Contract between AVI BioPharma, Inc. and the U.S. Defense Threat Reduction Agency (contract no HDTRA 1-09-C-0046), effective March 25, 2010.	10-Q	001-14895	10.81	5/10/10	
10.43*	Contract Number HDTRA1-10-C-0079 between Defense Threat Reduction Agency and AVI BioPharma, Inc. dated June 4, 2010.	10-Q	001-14895	10.84	8/9/10	
10.44*	Contract Number W9113M-10-C-0056 between U.S. Army Space and Missile Defense Command and AVI BioPharma, Inc. dated July 14, 2010.	10-Q	001-14895	10.86	11/9/10	
10.45*	Sponsored Research Agreement between AVI BioPharma, Inc. and Charley s Fund, Inc., effective October 12, 2007.	10-K	001-14895	10.58	3/17/08	
10.46*	First Amendment to Sponsored Research Agreement between AVI BioPharma, Inc. and Charley s Fund, Inc. dated June 2, 2009.	10-Q	001-14895	10.75	8/10/09	
10.47	Common Stock and Warrant Purchase Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.	S-3	333-45888	4.1	9/15/00	
10.48	Registration Rights Agreement, dated April 4, 2000, between SuperGen, Inc. and AVI BioPharma, Inc.	S-3	333-45888	4.2	9/15/00	
10.49	Shareholder s Trust Agreement between and among AVI BioPharma, Inc., AVI Shareholder Advocacy Trust, The Shareholder Advocate LLC, and Richard Macary, dated October 29, 2007.	10-K	001-14895	10.59	3/17/08	
10.50	Securities Purchase Agreement dated January 29, 2009 between AVI BioPharma, Inc. and the Purchasers identified on the signature pages thereto.	8-K	001-14895	10.67	1/30/09	
10.51	Letter Agreement Regarding Board of Director Representation dated January 29, 2009 between AVI BioPharma, Inc. and Eastbourne Capital Management, LLC.	8-K	001-14895	10.68	1/30/09	
10.52	Commercial Lease between Research Way Investments, Landlord, and Antivirals, Inc., Tenant, effective June 15, 1992.	SB-2	333-20513	10.9	1/28/97	
10.53	Lease Extension and Modification Agreement dated September 1, 1996, by and between Research Way Investments and Antivirals, Inc.					X

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Exhibit Number	Description	Incorporated by Reference to Filings Indicated Form	File No.	Exhibit	Filing Date	Filed Herewith
10.54	Second Lease Extension and Modification Agreement dated January 24, 2006 by and between Research Way Investments and AVI BioPharma, Inc.	10-Q	001-14895	10.55	8/9/06	
10.55	Real Property Purchase Agreement by and between WKL Investments Airport, LLC and AVI BioPharma, Inc., dated March 1, 2007, as amended.	10-Q	001-14895	10.61	8/9/07	
10.56	Lease dated July 24, 2009 by and between BMR-3450 Monte Villa Parkway, LLC and AVI BioPharma, Inc.	10-Q	001-14895	10.76	11/9/09	
10.57	Lease dated October 20, 2010, by and between S/I North Creek VII LLC and AVI BioPharma, Inc.					X
10.58	Settlement Agreement dated April 20, 2010 among AVI BioPharma, Inc. and the Shareholder Group (as defined therein).	8-K	001-14895	10.1	4/22/10	
21.1	Subsidiaries of the Registrant.	10-K	001-14895	21.1	3/16/10	
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (contained on signature page).					X
31.1	Certification of Christopher Garabedian, President and Chief Executive Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of J. David Boyle II, Chief Financial Officer, pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1	Certification of Christopher Garabedian, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
32.2	Certification of J. David Boyle II, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X

* Confidential treatment has been granted for portions of this exhibit.
Indicates management contract or compensatory plan, contract or arrangement.

(c) 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.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 14, 2011

AVI BIOPHARMA, INC.

By: /s/ Christopher Garabedian
Christopher Garabedian

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher Garabedian, J. David Boyle II and Effie Toshav, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated on March 14, 2011:

Signature	Title
/s/ Christopher Garabedian Christopher Garabedian	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ J. David Boyle II J. David Boyle II	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)
/s/ William Goolsbee William Goolsbee	Chairman of the Board
/s/ M. Kathleen Behrens M. Kathleen Behrens, Ph.D.	Director
/s/ Anthony Chase Anthony Chase	Director
/s/ John C. Hodgman John C. Hodgman	Director

/s/ Gil Price	Director
Gil Price, M.D.	
/s/ Hans Wigzell	Director
Hans Wigzell, M.D., Ph.D.	

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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. (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, shareholders equity (deficit) and comprehensive income (loss), and cash flows for each of the years in the three-year period ended December 31, 2010 and the information included in the cumulative from inception presentations for the period January 1, 2002 to December 31, 2010 (not separately presented herein). 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 July 22, 1980 (inception) to 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.

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, the financial statements referred to above present fairly, in all material respects, the financial position of AVI BioPharma, Inc. (a development stage company) as of December 31, 2010 and 2009, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2010 and the information included in the cumulative from inception presentations for the period January 1, 2002 to December 31, 2010 (not separately presented herein), in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of AVI BioPharma, Inc. s internal control over financial reporting as of December 31, 2010, 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 14, 2011 expressed an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ KPMG LLP

Seattle, Washington

March 14, 2011

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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

(in thousands)	December 31, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 33,589	$ 48,275
Accounts receivable	3,224	2,085
Other current assets	1,025	950
Total Current Assets	37,838	51,310
Property held for sale	1,965	2,372
Property and Equipment, net of accumulated depreciation and amortization of $14,963 and $14,026	2,070	2,466
Patent Costs, net of accumulated amortization of $1,742 and $1,762	3,980	3,759
Other assets	123	120
Total Assets	$ 45,976	$ 60,027
Liabilities and Shareholders Equity (Deficit)		
Current Liabilities:		
Accounts payable	$ 1,311	$ 1,381
Accrued employee compensation	2,015	922
Long-term debt, current portion	81	77
Warrant valuation	39,111	27,609
Deferred revenue	3,304	3,428
Other liabilities	35	90
Total Current Liabilities	45,857	33,507
Commitments and Contingencies		
Long-term debt, non-current portion	1,842	1,924
Other long-term liabilities	1,094	966
Shareholders Equity (Deficit):		
Preferred stock, $.0001 par value, 20,000,000 shares authorized; none issued and outstanding		
Common stock, $.0001 par value, 200,000,000 shares authorized; 112,352,452 and 110,495,587 issued and outstanding	11	11
Additional paid-in capital	304,818	299,088
Deficit accumulated during the development stage	(307,646)	(275,469)
Total Shareholders Equity (Deficit)	(2,817)	23,630
Total Liabilities and Shareholders Equity (Deficit)	$ 45,976	$ 60,027

See accompanying notes to financial statements.

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AVI BioPharma, Inc.

(A Development Stage Company)

Statements of Operations

(in thousands)	Year ended December 31, 2010	2009	2008	July 22, 1980 (Inception) through December 31, 2010
Revenues from license fees, grants and research contracts	$ 29,420	$ 17,585	$ 21,258	$ 89,229
Operating expenses:				
Research and development	35,972	24,396	27,331	266,404
General and administrative	14,382	8,696	11,469	88,402
Acquired in-process research and development			9,916	29,461
Operating loss	(20,934)	(15,507)	(27,458)	(295,038)
Other non-operating (loss) income:				
Interest (expense) income and other, net	259	(454)	344	8,582
(Increase) decrease on warrant valuation	(11,502)	(9,198)	3,161	(8,052)
Realized gain on sale of short-term securities available-for-sale				3,863
Write-down of short-term securities available-for-sale				(17,001)
	(11,243)	(9,652)	3,505	(12,608)
Net loss	$ (32,177)	$ (25,159)	$ (23,953)	$ (307,646)
Net loss per share basic and diluted	$ (0.29)	$ (0.27)	$ (0.34)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share	111,233	93,090	69,491	

See accompanying notes to financial statements.

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AVI BioPharma, Inc.

(A Development Stage Company)

Statements of Shareholders Equity (Deficit) and Comprehensive Income (Loss)

(in thousands)	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 (Deficit)
BALANCE AT JULY 22, 1980 (Inception)			$	$	$	$	$
Issuance of partnership units, warrants and common stock	3,615	8,273	1	33,733			33,734
Compensation expense related to issuance of warrants for common stock and partnership Units				537			537
Exercise of warrants for partnership units and common stock	42	2,248		4,152			4,152
Exercise of options for common stock		1,029		4,124			4,124
Issuance of common stock for ESPP		770		2,260			2,260
Issuance of common stock and warrants for cash and securities, net of offering costs		47,882	5	176,795			176,800
Issuance of common stock and warrants for the acquisition of ImmunoTherapy Corporation		2,132		17,167			17,167
Issuance of common stock and warrants for services		536		2,469			2,469
Compensation expense related to issuance of options for common stock				7,155			7,155
Stock-based compensation				4,719			4,719
Conversion of debt into common stock and partnership units	9	10		88			88
Issuance of common stock in exchange for partnership units	(1,810)	1,633					
Withdrawal of partnership net assets upon conveyance of technology	(1,856)			(177)			(177)
Common stock subject to rescission, net		(64)		(289)			(289)
Comprehensive income (loss):							
Write-down of short-term securities available-for-sale					17,001		17,001
Realized gain on sale of short-term securities available-for-sale					(3,766)		(3,766)
Unrealized loss on short-term securities available-for-sale					(13,235)		(13,235)
Net loss						(226,357)	(226,357)
Comprehensive loss							(226,357)
BALANCE AT DECEMBER 31, 2007		64,449	$ 6	$ 252,733	$	$ (226,357)	$ 26,382
Exercise of options for common stock		7		9			9
Issuance of common stock for ESPP		84		72			72
Issuance of common stock and warrants to vendors		324		828			828
Compensation expense to non-employees on issuance of options and warrants to purchase common stock				180			180
Compensation expense on issuance of restricted stock		100		166			166
Stock-based compensation		326		3,656			3,656
Issuance of common stock for acquisition of Ercole		5,812	1	8,391			8,392
Comprehensive income (loss):							
Unrealized gain on short-term securities available-for-sale, net							
Net loss						(23,953)	(23,953)
Comprehensive loss							(23,953)

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(in thousands)	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 (Deficit)
BALANCE AT DECEMBER 31, 2008		71,102	$ 7	$ 266,035	$	$ (250,310)	$ 15,732
Exercise of options for common stock		62		76			76
Issuance of common stock for ESPP		124		85			85
Issuance of common stock for cash and securities, net of offering costs		38,520	4	30,518			30,522
Compensation expense on issuance of restricted stock		427		203			203
Stock-based compensation		261		2,171			2,171
Comprehensive income (loss):							
Unrealized gain on short-term securities available-for-sale, net							
Net loss						(25,159)	(25,159)
Comprehensive loss							(25,159)
BALANCE AT DECEMBER 31, 2009		110,496	$ 11	$ 299,088	$	$ (275,469)	$ 23,630
Exercise of options for common stock		1,702		2,012			2,012
Exercise of warrants for common stock		308		549			549
Issuance of common stock for cash and securities, net of offering costs							
Compensation expense on issuance or cancelation of restricted stock		(154)		64			64
Stock-based compensation				3,105			3,105
Comprehensive income (loss):							
Unrealized gain on short-term securities available-for-sale, net							
Net loss						(32,177)	(32,177)
Comprehensive loss							(32,177)
BALANCE AT DECEMBER 31, 2010		112,352	$ 11	$ 304,818	$	$ (307,646)	$ (2,817)

See accompanying notes to financial statements.

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AVI BioPharma, Inc.

(A Development Stage Company)

Statements of Cash Flows

(in thousands)	Year ended December 31, 2010	2009	2008	For the Period July 22, 1980 (Inception) through December 31, 2010
Cash flows from operating activities:				
Net loss	$ (32,177)	$ (25,159)	$ (23,953)	$ (307,646)
Adjustments to reconcile net loss to net cash flows used in operating activities:				
Depreciation and amortization	1,463	1,379	1,469	19,145
Loss on disposal of assets	776	347	584	2,081
Realized gain on sale of short-term securities available-for-sale				(3,863)
Write-down of short-term securities available-for-sale				17,001
Impairment charge on real estate owned	408	128	800	1,336
Stock-based compensation	3,169	2,374	4,830	25,866
Conversion of interest accrued to common stock				8
Acquired in-process research and development			9,916	29,461
Increase (decrease) on warrant valuation	11,502	9,198	(3,161)	8,052
(Increase) decrease in:				
Accounts receivable and other current assets	(1,211)	2,621	(1,850)	(4,111)
Net increase in accounts payable, accrued employee compensation, and other liabilities	861	312	(975)	6,135
Net cash used in operating activities	(15,209)	(8,800)	(12,340)	(206,535)
Cash flows from investing activities:				
Purchase of property and equipment	(832)	(931)	(369)	(18,701)
Patent costs	(1,122)	(1,063)	(848)	(8,365)
Purchase of marketable securities	(7)		(11)	(112,993)
Sale of marketable securities		111		117,724
Acquisition costs			(11)	(2,389)
Net cash (used in) provided by investing activities	(1,961)	(1,883)	(1,239)	(24,724)
Cash flows from financing activities:				
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	2,561	47,840	81	265,498
Repayments of long-term debt	(77)	(74)	(113)	(264)
Buyback of common stock pursuant to rescission offering				(289)
Withdrawal of partnership net assets				(177)
Issuance of convertible debt				80
Net cash provided by (used in) financing activities	2,484	47,766	(32)	264,848
Increase (decrease) in cash and cash equivalents	(14,686)	37,083	(13,611)	33,589
Cash and cash equivalents:				
Beginning of period	48,275	11,192	24,803	
End of period	$ 33,589	$ 48,275	$ 11,192	$ 33,589
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid during the year for interest	$ 94	$ 97	$ 104	$ 399

SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:				
Short-term securities available-for-sale received in connection with the private offering	$	$	$	17,897
Change in unrealized gain (loss) on short-term securities available-for-sale				
Issuance of common stock and warrants in satisfaction of liabilities				545
Issuance of common stock for building purchase				750
Assumption of long-term debt for building purchase				2,200
Issuance of common stock for Ercole assets			8,075	8,075
Assumption of liabilities for Ercole assets			2,124	2,124

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) is a biopharmaceutical company incorporated in the State of Oregon on July 22, 1980. The mission of the Company is to discover and develop unique RNA-based therapeutics for the treatment of both rare and infectious diseases.

AGDG

Through May 19, 1993, the financial statements included the combined accounts of the Company and Anti-Gene Development Group, a limited partnership founded in 1981 and registered in the State of Oregon (AGDG). Substantially all income generated and proceeds from the sale of AGDG partnership units through that date were paid to the Company under the terms of research and development contracts between AGDG and the Company. Significant transactions between the Company and AGDG through that date have been eliminated.

Pursuant to an exchange offer by the Company, each AGDG partner could elect to exchange each AGDG partnership unit held and warrant unit held by such partner for 1,100 shares of Company common stock and warrants to purchase 1,100 shares of Company common stock. As a result of such exchange offer, which was completed in May 1993, the Company issued 1,632,950 shares of its common stock and warrants to purchase 381,700 shares of its common stock. Effective May 19, 1993, the Company and AGDG entered into a technology transfer agreement pursuant to which AGDG conveyed all intellectual property then within its control to the Company. In connection with such conveyance, the Company tendered to AGDG for liquidation all partnership units received pursuant to the exchange offer described above and received a 49.4% undivided interest in the intellectual property. The Company then purchased the remaining undivided interest in the intellectual property in return for giving AGDG the right to receive 4.05% 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 AGDG 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 LLC paid the Company $1.0 million and the royalty rate that the Company is required to pay to AGDG under the technology transfer agreement on future sales of therapeutic products was reduced from 4.05% to 3.00%.

In May 1993, the remaining net assets of AGDG, consisting of $177,000 in cash, ceased to be combined with those of the Company. Pursuant to the technology transfer agreement, AGDG agreed to not sell any additional partnership units, ceased all income generating activities and will not enter into any other research and development contracts with the Company. AGDG 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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Acquisition of Ercole

In March 2008, the Company acquired all of the stock of Ercole Biotechnology, Inc. (Ercole) in exchange for 5,811,721 shares of Company common stock, which was valued at approximately $8.4 million, and the assumption of approximately $1.8 million in liabilities of Ercole. The Company also issued warrants to purchase Company common stock, which were valued at $437,000, in exchange for certain outstanding warrants issued by Ercole. These warrants are classified as equity. From 2006 to the time of the acquisition, the Company and Ercole had collaborated with respect to the development drug candidates, including AVI-4658. The total estimated purchase price of $10.2 million has been allocated as follows:

Accounts receivable	$ 76,000
Prepaid expenses	7,000
Fixed assets	10,000
Patents	190,000
Acquired in-process research and development	9,916,000

The pending patents acquired as part of the Ercole acquisition have an expected expiration date of 2028. Acquired in-process research and development consists of other discovery research programs in areas including beta thalassemia and soluble tumor necrosis factor receptor. As these programs were in development at the time of acquisition, there were significant risks associated with completing these projects, and there were no alternative future uses for these projects, the associated value has been considered acquired in-process research and development.

Ercole has been a development stage company since inception and does not have a product for sale. The Company has retained a limited number of Ercole employees and has incorporated in-process technology of Ercole into the Company s processes. The acquisition of Ercole did not meet the definition of a business and it was therefore accounted for as an asset acquisition.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) and reflect the following significant accounting policies. Management has determined that the Company operates one segment: the development of pharmaceutical products on its own behalf or in collaboration with others.

Estimates and Uncertainties

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue 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 liability classified warrants and stock-based awards, long lived asset impairment, and revenue recognition.

Reclassifications

Certain prior year amounts have been reclassified to conform to current year presentation. These changes did not have a significant impact on the Company s net loss, assets, liabilities, shareholders equity (deficit) or cash flows.

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Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents.

Accounts Receivable

Accounts receivable are stated at invoiced amount and do not bear interest as they are due within 12 months. Because a majority of accounts receivable are from the U.S. government and historically no amounts have been written off, an allowance for doubtful accounts receivable is not considered necessary. The accounts receivable balance included $3.2 million and $0.4 million of receivables that were unbilled at December 31, 2010 and 2009, respectively.

Amounts included in accounts receivable are as follows:

	As of December 31,	
	2010	2009
	(in thousands)	
Research contract	$ 3,224	$ 2,085
Total accounts receivable	$ 3,224	$ 2,085

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 and 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. Expenditures made for equipment specifically utilized and paid for by government research projects are expensed.

Amounts included in property held for sale are as follows:

	As of December 31,	
	2010	2009
	(in thousands)	
Property held for sale	$ 1,965	$ 2,372

In 2009, the Company decided to outsource its large scale manufacturing activities and listed for sale the industrial property located in Corvallis, Oregon and recorded a $0.1 million impairment charge to reduce carrying value to fair value less estimated costs to sell. The Company recorded an additional impairment charge of $0.4 million in 2010 to reduce its carrying value to the current appraised value. The Company has used a Level 3 fair value measure with the use of an independent appraisal to estimate the value of this property.

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Amounts included in property and equipment are as follows:

	As of December 31,	
	2010	2009
	(in thousands)	
Lab equipment	$ 6,207	$ 5,933
Office equipment	1,188	970
Leasehold improvements	9,638	9,589
	17,033	16,492
Less accumulated depreciation	(14,963)	(14,026)
Property and equipment, net	$ 2,070	$ 2,466

Depreciation expense of $1.2 million was expensed each year in 2010, 2009 and 2008.

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 and the legal lives of the patents, generally 20 years. Patent amortization was $246,000, $225,000 and $257,000 for the years ended December 31, 2010, 2009 and 2008, respectively. The Company also expensed the remaining net book value of previously capitalized patents that were later abandoned of $766,000, $347,000 and $580,000, in 2010, 2009 and 2008, respectively. The Company expects to incur amortization expense of approximately $168,000 per year over the following five fiscal years.

Revenue Recognition

Government Research Contract Revenue. Substantially all of the Company s revenue was generated from U.S. government research contracts. See Note 7 U.S. Government Contracts. The Company s contracts with the U. S. government are cost plus contracts providing for reimbursed costs and a target fee. The Company recognizes revenue from U.S. government research contracts during the period in which the related expenses are incurred and present such revenues and related expenses gross in the consolidated financial statements.

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

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

Research and Development

Research and development expense consists of costs associated with research activities as well as costs associated with the Company s product development efforts, preclinical studies, and clinical trial and manufacturing costs.

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Direct research and development expenses associated with the Company s programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants and other outside services, such as data management and statistical analysis support, and materials and supplies used in support of the clinical programs. Indirect costs of the Company s clinical program include salaries, stock based compensation, and an allocation of the Company s facility costs.

Research and development expenses are expensed as incurred.

Stock Compensation

The Company issues stock-based compensation to certain employees, officers and directors. GAAP requires companies to account for stock options using the fair value method, which results in the recognition of compensation expense over the vesting period of the awards. See Note 3 Stock Compensation for additional information.

Income Taxes

The Company follows the asset and liability method of accounting for income taxes. 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 that the net deferred tax asset will not be realized. The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination.

Fair Value of Financial Instruments

The Company measures at fair value certain financial assets and liabilities in accordance with a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company s market assumptions. There are three levels of inputs that may be used to measure fair-value:

Level 1 quoted prices for identical instruments in active markets;

Level 2 quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and

Level 3 valuations derived from valuation techniques in which one or more significant value drivers are unobservable.

The Company s assets and liabilities measured at fair value on a recurring basis consisted of the following as of the date indicated:

	Fair Value Measurement as of December 31, 2010			
	Total	Level 1	Level 2	Level 3
		(in thousands)		
Cash equivalents	$ 33,589	$ 33,589	$	$
Total assets	$ 33,589	$ 33,589	$	$

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	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Cash equivalents	$ 48,275	$ 48,275	$	$
Total assets	$ 48,275	$ 48,275	$	$

	Fair Value Measurement as of December 31, 2010			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Warrants	$ 39,111	$	$	$ 39,111
Total liabilities	$ 39,111	$	$	$ 39,111

	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Warrants	$ 27,609	$	$	$ 27,609
Total	$ 27,609	$	$	$ 27,609

A reconciliation of the change in value of the Company s warrants for the years ended December 31, 2010, 2009 and 2008 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)		
	2010	2009	2008
		(in thousands)	
Balance at January 1	$ 27,609	$ 1,254	$ 4,415
Total increase (decrease) in liability included in earnings	11,502	9,198	(3,161)
Issuances		17,157	
Balance at December 31	$ 39,111	$ 27,609	$ 1,254

See Note 9 Warrants for additional information related to the determination of fair value of the warrants. The carrying amounts reported in the balance sheets for accounts receivable, accounts payable, and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Rent Expense

The Company s operating leases for its Corvallis, Oregon and Bothell, Washington facilities provide for scheduled annual rent increases throughout each lease s term. In accordance with GAAP, the Company recognizes the effects of the scheduled rent increases on a straight-line basis over the full term of the leases, which expire in 2020 for the Corvallis, Oregon facility and in 2014 and 2012 for the Company s Bothell, Washington facilities.

During 2010, 2009 and 2008, the Company recognized $33,000, $230,000 and $133,000, respectively, in additional rent expense from the amortization of future scheduled rent increases.

Commitments and Contingencies

As of December 31, 2010, the Company was not a party to any material legal proceedings with respect to itself, its subsidiaries, or any of its material properties. In the normal course of business, the Company may from

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

Long-Lived Asset Impairment

Long-lived assets held and used by the Company and intangible assets with determinable lives are reviewed for impairment whenever events or circumstances indicate that the carrying amount of assets may not be recoverable in accordance with GAAP pronouncements. The Company evaluates recoverability of assets to be held and used by comparing the carrying amount of an asset to future net undiscounted cash flows to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the assets exceeds the fair value of the assets. Such reviews assess the fair value of the assets based upon estimates of future cash flows that the assets are expected to generate.

At December 31, 2008, the Company determined that the ongoing decline in the real estate market had adversely impacted the fair value of an industrial property in Corvallis, Oregon, and an impairment charge of $0.8 million was recorded. The fair value estimate of $2.5 million was based on an independent third party appraisal. In November 2009, the Company decided to outsource its large scale manufacturing activities and listed for sale the industrial property in Corvallis and recorded a $0.1 million impairment charge to reduce carrying value to fair value less costs to sell. The Company recorded an additional impairment charge of $0.4 million in 2010 to reduce its carrying value to the current appraised value. The Company currently has this property listed for sale. The Company used a Level 3 fair value measure with the use of an independent appraisal to estimate the value of this property.

In addition, the Company conducts an evaluation of the status of its patents. Pursuant to these evaluations, the Company recorded charges of $766,000, $347,000 and $580,000 in 2010, 2009 and 2008, respectively, for previously capitalized costs related to patents that have expired or were abandoned.

Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board (FASB), issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical assets or liabilities) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. The guidance became effective for the Company with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for the Company with the reporting period beginning July 1, 2011. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on the Company s financial statements.

In April 2010, the FASB issued guidance on applying the milestone method of revenue recognition for milestone payments for achieving specific performance measures when those payments are related to uncertain future events. The scope of this guidance is limited to transactions involving research or development. Under the guidance, the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestone will be achieved. The guidance is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning January 1, 2011. The Company does not expect that this guidance will have a material impact on the Company s financial statements.

In January 2010, the FASB issued guidance to amend the disclosure requirements related to fair value measurements. The guidance requires the disclosure of roll forward activities on purchases, sales, issuance, and

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settlements of the assets and liabilities measured using significant unobservable inputs (Level 3 fair value measurements). The guidance will become effective for the Company with the reporting period beginning July 1, 2011. Other than requiring additional disclosures, the Company does not believe the adoption of this new guidance will have a material impact on its financial statements.

3. STOCK COMPENSATION

Stock Options

The Company sponsors a 2002 Equity Incentive Plan (the Plan) pursuant to which it may issue options to purchase its common stock to the Company s employees, directors and service providers. In general, stock options granted under the Plan prior to December 31, 2010 vest over a three year period, with one-third of the underlying shares vesting on each anniversary of grant, and have a ten year term. Beginning in January 2011, stock options granted under the Plan will vest over a four year period, with one-fourth of the underlying shares vesting on the first anniversary of the grant and 1/48th of the underlying shares vesting monthly thereafter, such that the underlying shares will be fully vested on the fourth anniversary of the grant. As of December 31, 2010, 1,771,426 shares of common stock remained available for future grant under the Plan. Additionally, on January 3, 2011, pursuant to the terms of the Plan, 2,247,049 additional shares of common stock were added to the Plan and became available for future grant.

A summary of the Company s stock option activity with respect to 2010, 2009 and 2008 follows:

	For the year ended December 31,					
	2010		2009		2008	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of year	8,932,811	$ 2.79	7,540,873	$ 3.34	6,304,453	$ 4.60
Granted	3,607,365	1.58	2,727,000	1.10	2,743,607	1.27
Exercised	(1,701,630)	1.18	(62,711)	1.68	(6,761)	1.31
Canceled or expired	(2,348,491)	4.42	(1,272,351)	2.72	(1,500,426)	4.82
Options outstanding at end of year	8,490,055	$ 2.14	8,932,811	$ 2.79	7,540,873	$ 3.34
Exercisable at end of year	3,919,519	$ 2.93	5,119,227	$ 3.94	4,779,603	$ 4.18
Vested at December 31, 2010 and expected to vest	8,302,857	$ 2.15				

	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life (Years)
Options outstanding at end of year	$ 4,352,864	7.03
Exercisable at end of year	$ 1,332,760	4.94
Vested at December 31, 2010 and expected to vest	$ 4,251,721	6.98

The weighted-average fair value per share of stock-based awards, including stock options and restricted stock grants, granted during the 2010, 2009 and 2008 was $1.11, $1.09 and $1.04, respectively. During the same periods, the total intrinsic value of stock options exercised was $976,000, $105,000 and $2,000, respectively. The total grant date fair value of stock options vested for 2010, 2009 and 2008 was $2,666,000, $1,740,000 and $3,040,000, respectively.

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During 2010, 2009 and 2008, $2,011,000, $76,000 and $9,000, respectively, was received upon the exercise of stock options. The Company is obligated to issue shares from the 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.

Valuation Assumptions

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

The fair values of stock options granted during the periods presented were measured on the date of grant using the Black-Scholes option-pricing model, with the following assumptions:

	Year Ended December 31,		
	2010	**2009**	**2008**
Risk-free interest rate	1.4% -3.8%	1.2% - 1.8%	1.1% - 3.4%
Expected dividend yield	%	%	%
Expected lives	5.3 - 8.0 years	3.6 - 9.1 years	3.6 - 9.1 years
Expected volatility	82.5% - 90.3%	92.0% - 94.4%	81.0% - 90.7%

The risk-free interest rate is estimated using an average of treasury bill interest rates over a period commensurate with the expected term of the option that correlates to the prevailing interest rates at the time of grant. 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 of the Company s common stock over a period commensurate with the expected term of the option. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

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

Restricted Stock Awards

In June 2010 and 2009, the Company granted a total of 20,000 and 25,000 shares of restricted stock, respectively to members of its board of directors. These shares vest on the first anniversary of the date of grant. During 2010 and 2009, the Company recognized compensation expense related to these shares of $26,000 and $17,000, respectively.

In May 2009, the Company granted 100,000 shares of restricted stock to its Chief Business Officer. These shares would have vested upon the achievement of certain performance milestones. No compensation expense related to these shares has been recognized in 2010 or 2009 as the achievement of the performance milestones was not accomplished and the restricted stock was cancelled.

In January 2009, the Company granted 60,000 shares of restricted stock to its Chief Medical Officer. These shares became fully vested 181 days after the date of grant. During 2010 and 2009, the Company recognized compensation expense related to these shares of $0 and $82,000, respectively.

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In February 2008, the Company granted 333,000 shares of restricted stock to its former Chief Executive Officer, Leslie Hudson, Ph.D. Of these shares, 100,000 vested immediately and the remaining 233,000 were scheduled to vest over a period of four years. In April 2010, Dr. Hudson tendered his resignation at the request of the board of directors and pursuant to the terms of the related separation agreement, 116,500 shares of previously granted restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. During 2010, 2009 and 2008, the Company recognized compensation expense related to these shares of $134,000, $64,000 and $166,000, respectively.

	For the year ended December 31,					
	2010		2009		2008	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
	(share data in thousands)					
Restricted stock awards at beginning of year	300	$ 1.09	233	$ 1.09		$
Granted	20	1.30	446	1.03	333	1.09
Vested	(200)	1.09	(379)	1.02	(100)	1.09
Forfeited or canceled	(100)	1.10				
Restricted stock awards at end of year	20	$ 1.30	300	$ 1.09	233	$ 1.09

The weighted-average grant-date fair value of restricted stock awards is based on the market price of the Company s common stock on the date of grant. The grant-date fair value of the restricted stock awards made during 2010, 2009 and 2008 was $1.30, $1.03 and $1.09, respectively. The total grant-date fair values of restricted stock awards that vested during 2010, 2009 and 2008 were approximately $219,000, $385,000 and $109,000, respectively.

Stock-based Compensation Expense

The amount of stock-based compensation expense recognized in 2010, 2009 and 2008 related to stock-based compensation was $3,169,000, $2,374,000 and $4,830,000, respectively. A summary of the stock based compensation expense recognized in the statement of operations is as follows:

	Year Ended December 31,		
	2010	2009	2008
	(in thousands)		
Research and development	$ 970	$ 1,192	$ 1,689
General and administrative	2,199	1,182	3,141
Total	$ 3,169	$ 2,374	$ 4,830

As of December 31, 2010, there was $3,266,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements, including stock options and restricted stock, granted under the Plan. These costs are expected to be recognized over a weighted-average period of 1.8 years.

Pursuant to the terms of the separation agreement between the Company s former Chief Executive Officer and the Company, unvested options previously granted to Dr. Hudson to purchase 1,166,833 shares of common stock and 116,500 shares of restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. The Company recorded a charge of stock compensation expense of $1,181,000 as a result of the accelerated vesting of these shares in the second quarter of 2010.

In September 2008, the Company s President and Chief Operating Officer departed the Company. In accordance with his employment agreement, the vesting of all of the shares underlying options subject to time-based vesting was accelerated. This acceleration of the vesting of these stock options resulted in additional compensation costs of $382,000 for 2008. In March 2010, such options expired without being exercised.

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4. EARNINGS PER SHARE

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and dilutive common stock equivalent shares outstanding. Given that the Company was in a loss position for each of the periods presented, there is no difference between basic and diluted net loss per share since the effect of common stock equivalents would be anti-dilutive and are therefore excluded from the diluted net loss per share calculation.

	Year Ended December 31,		
	2010	2009	2008
		(in thousands)	
Net loss	$ (32,177)	$ (25,159)	$ (23,953)
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	111,233	93,090	69,491
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	111,233	93,090	69,491
Net loss per share basic and diluted	$ (0.29)	$ (0.27)	$ (0.34)

* Warrants and stock options to purchase approximately 38,155,000, 41,266,000 and 17,665,000 shares of common stock as of December 31, 2010, 2009 and 2008, respectively, were excluded from the net loss per share calculation as their effect would have been anti-dilutive.

5. LIQUIDITY

Since its inception in 1980 through December 31, 2010, the Company has incurred losses of approximately $307.6 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. 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 revenue from product sales, the Company expects to incur operating losses over the next several years.

The Company believes it has sufficient cash to fund operations at least through the next 12 months. The Company believes it will continue to receive funding from government to pursue the development of its product candidates, and has assumed certain revenues from these awards in providing this guidance. Should the Company not continue to receive funding from its current contracts or receive additional funding, or should the timing be delayed, it may have a significant negative impact on the Company s guidance.

At December 31, 2010, cash and cash equivalents were $33.6 million, compared to $48.3 million at December 31, 2009. The Company s principal sources of liquidity have been equity financings and revenue from its U.S. government research contracts. The Company s principal uses of cash have been research and development expenses, general and administrative expenses and other working capital requirements.

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. As of December 31, 2010, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of $157.1 million for development of its product candidates, of which $76.1 million had been billed or recognized as revenue and $81 million of which relates to development that has not yet been completed and has not been billed or recognized as revenue. See Note 7 U.S. Government Contracts for additional information.

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In January and August 2009, the Company sold shares of its common stock and also issued warrants to purchase shares of its common stock in offerings registered under the Securities Act of 1933 (the Securities Act). See Note 6 Equity Financing for more information.

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

6. EQUITY FINANCING

In January 2009, the Company sold approximately 14.2 million shares of its common stock and also issued warrants to purchase approximately 14.2 million shares of its common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $15.5 million. The warrants issued to the investors in the offering have an exercise price of $1.16 per share and are exercisable at any time on or before July 30, 2014. In connection with the offering, the Company also issued to the placement agent a warrant to purchase approximately 427,000 shares of the Company s common stock at an exercise price of $1.45 per share. The warrant issued to the placement agent is exercisable on or before January 30, 2014.

In August 2009, the Company sold approximately 24.3 million shares of its common stock and also issued warrants to purchase approximately 9.7 million shares of its common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $32.3 million. The warrants issued to the investors in the offering have an exercise price of $1.78 per share and are exercisable at any time on or before August 25, 2014.

The warrants issued in connection with the January and August 2009 offerings are classified as a liability due to their settlement terms. Accordingly, the fair value of the warrants is recorded on the consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in the consolidated statement of operations as described in greater detail in Note 9 Warrants. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

7. U.S. GOVERNMENT CONTRACTS

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. The Company s contracts with the U. S. government are cost plus contracts providing for reimbursed costs and a target fee. The Company recognizes revenues from U.S. government research contracts during the period in which the related expenditures are incurred and presents these revenues and related expenses gross in the consolidated financial statements. As of December 31, 2010, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of $157.1 million for development of its product candidates, of which $76.1 million had been billed or recognized as revenue and $81.0 million of which relates to development that has not yet been completed and has not been billed or recognized as revenue. The following is a description of such contracts.

January 2006 Agreements (Ebola and Marburg Host Factors, Dengue, Anthrax and Ricin)

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of $11.0 million to fund the Company s ongoing defense-related programs under four different contracts, all of which were executed in 2007, and the last of which expired in October 2010. Net of government administrative costs, it was anticipated that the Company would receive up to $9.8 million under this allocation. As of December 31, 2010, the Company had recognized revenue of $9.7 million with respect to these contracts. The Company s technology is expected to be used to continue developing RNA-based drugs against Ebola and Marburg viruses.

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November 2006 Agreement (Ebola, Marburg and Junín Viruses)

In November 2006, the Company entered into a two-year research contract with Defense Threat Reduction Agency (DTRA), an agency of the U.S. Department of Defense (the DoD), pursuant to which the Company was entitled to $28.0 million to fund its development of antisense therapeutics to treat the effects of Ebola, Marburg and Junín hemorrhagic fever viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by $5.9 million to an aggregate of $33.9 million. In September 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional $11.5 million to an aggregate of $45.4 million. In November 2010, the Company and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and this contract would be deemed concluded. As of December 31, 2010, the Company had recognized revenue of $38.4 million with respect to this contract and does not expect significant further revenue.

May 2009 Agreement (H1N1/Influenza)

In May 2009, the Company entered into a contract with DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to $4.1 million to the Company for the work involving the application of the Company s proprietary PMO and PMO*plus* antisense chemistry and the Company plans to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu®-resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by $4.0 million to an aggregate of $8.1 million. As of December 31, 2010, the Company had recognized revenue of $6.9 million with respect to this contract.

June 2010 Agreement (H1N1/Influenza)

In June 2010, the Company entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by the Company, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program (TMT) of the DoD. The contract provides for funding of up to $18.0 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA), the study of an intranasal delivery formulation, and the funding of the entry into a Phase I clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization. As of December 31, 2010, the Company had recognized revenue of $8.8 million with respect to this contract.

July 2010 Agreement (Ebola and Marburg)

In July 2010, the Company was awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the Company s hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments for each therapeutic candidate with potential funding of up to approximately $291 million. Activity under the first segment, which began in July 2010, provides for funding to the Company of up to approximately $80 million. Activities under the first segment include Phase I studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.

After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval

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of each therapeutic candidate and would provide for a total funding award to the Company of up to approximately $291 million over a period of approximately six years. Under an earlier contract, the Company completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of December 31, 2010, the Company had recognized revenue of $9.8 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government on the Company s results of operations for the periods indicated.

	Year Ended December 31,		
	2010	2009	2008
		(in thousands)	
January 2006 Agreements (*Ebola and Marburg host factor, Dengue, Anthrax and Ricin*)	$ 519	$ 2,288	$ 4,251
November 2006 Agreement (*Ebola, Marburg and Junín Viruses*)	3,204	10,421	16,760
May 2009 Agreement (*H1N1*)	5,171	1,716	
June 2010 Agreement (*H1N1*)	8,809		
July 2010 Agreement (*Ebola and Marburg*)	9,822		
Grants	1,622	725	53
Other Agreements	273	2,435	194
Total	$ 29,420	$ 17,585	$ 21,258

8. LONG-TERM DEBT

The Company has two loans outstanding which bear interest at 4.75%, mature in February 2027 and are collateralized by the facility the Company owns in Corvallis, Oregon. At December 31, 2010, these loans had unpaid principal balances of $1,225,000 and $699,000, for a total indebtedness of $1,923,000. The Company incurred interest expense on these loans of $94,000, $97,000 and $104,000, respectively, for 2010, 2009 and 2008.

The following table sets forth the expected future principal payments on these loans for the years shown (in thousands):

2011	$ 81
2012	85
2013	90
2014	92
2015	98
Thereafter	1,477
Total scheduled loan principal payments	1,923

9. WARRANTS

Warrants issued in connection with the Company s December 2007, January 2009, and August 2009 financings are classified as liabilities as opposed to equity due to their settlement terms. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

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The fair value of these warrants was recorded on the balance sheet at issuance and the warrants are marked to market at each financial reporting period, with changes in the fair value recorded as a gain or loss in the statement of operations. The fair value of the warrants is determined using the Black-Scholes option pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. The following reflects the weighted-average assumptions for each of the periods indicated:

	Year Ended December 31,		
	2010	2009	2008
Risk-free interest rate	0.6% -1.02%	0.2% - 2.69%	0.3% - 3.0%
Expected dividend yield	0%	0%	0%
Expected lives	2.0 - 3.7 years	0.4 - 4.7 years	0.2 - 4.2 years
Expected volatility	84.69% - 90.1%	86.0% - 102.1%	63.6% - 104.8%
Warrants classified as liabilities	29,409,546	30,203,466	7,994,229
Warrants classified as equity	255,895	2,129,530	2,129,530
Market value of stock at beginning of year	$ 1.46	$ 0.66	$ 1.41
Market value of stock at end of year	$ 2.12	$ 1.46	$ 0.66

The risk-free interest rate is estimated using an average of Treasury bill interest rates that correlate to the prevailing interest rates at the time of valuation date. The expected dividend yield is zero as the Company has not paid any dividends to date and does not expect to pay dividends in the future. The expected lives are based on the remaining contractual lives of the related warrants at the valuation date. The expected volatility is estimated using historical volatility of the Company s common stock, over a period commensurate with the remaining contractual lives, taking into account factors such as future events or circumstances that could impact volatility. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these warrants by the holders.

All other warrants issued by the Company other than the warrants issued in connection with its December 2007, January 2009 and August 2009 financings are classified as permanent equity; the fair value of the warrants was recorded as additional paid-in capital and no further adjustments are made. For 2010, 2009 and 2008, 255,895 shares, 2,129,530 shares and 2,129,530 shares, respectively, were underlying such warrants.

A summary of the Company s warrant activity with respect to 2010, 2009 and 2008 is as follows:

	For the year ended December 31,					
	2010		2009		2008	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Warrants outstanding at beginning of year	32,332,996	$ 3.40	10,123,759	$ 8.54	13,856,411	$ 8.12
Granted			24,369,238	1.41	445,985	1.77
Exercised	(308,000)	1.78				
Expired	(2,359,555)	26.50	(2,160,001)	5.00	(4,178,637)	6.42
Warrants outstanding at end of year	29,665,441	$ 1.58	32,332,996	$ 3.40	10,123,759	$ 8.54
Exercisable at end of year	29,665,441	$ 1.58	20,948,808	$ 1.60	8,457,881	$ 3.21

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The following table summarizes information about warrants outstanding at December 31, 2010.

Exercise Price	Outstanding Warrants at December 31, 2010	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
$0.0003	16,667	No expiration date	16,667
0.1679	238,228	1.87	238,228
1.14	1,000	No expiration date	1,000
1.16	14,224,202	3.58	14,224,202
1.45	426,726	3.08	426,726
1.78	9,410,310	3.67	9,410,310
2.45	5,348,308	1.97	5,348,308
	29,665,441		29,665,441

10. SIGNIFICANT AGREEMENTS:

Eleos Agreement

In January 2007, the Company entered into a cross-license agreement with Eleos Inc. (Eleos) for the development of antisense drugs targeting p53, a well-studied human protein that controls cellular response to genetic damage. Under the terms of the agreement, the Company granted Eleos an exclusive license to certain of the Company s intellectual property related to treatment of cancer with p53-related drugs. In return, Eleos granted an exclusive license to its intellectual property to the Company for treatment of most viral diseases with drugs that target p53. The companies are sharing rights under their respective intellectual property rights licensed under the agreement 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 made an upfront payment of $500,000 to the Company. The Company recognized $125,000 in license fees for each of 2010, 2009 and 2008.

Charley s Fund Agreement

In October 2007, Charley s Fund, Inc. (Charley s Fund), a nonprofit organization that funds drug development and discovery initiatives specific to DMD, awarded the Company a $2.45 million research grant. Pursuant to the related sponsored research agreement, the grant would support the development of product candidates using the Company s proprietary exon skipping technologies to overcome the effects of certain genetic errors in the dystrophin gene. The sponsored research agreement was amended in May 2009. Under the terms of the May 2009 amendment, subject to the satisfaction of certain milestones, Charley s Fund agreed that it would pay up to an additional $3.0 million over and above the $2.0 million it had already paid to the Company at the time of the execution of the amendment. As of December 31, 2010, Charley s Fund has made an aggregate of $3.3 million in payments to the Company. Revenue associated with this research and development arrangement is recognized based on proportional performance method, using the payment received method. The Company recognized $0, $0 and $23,000 in revenue from Charley s Fund for the years ended December 31, 2010, 2009 and 2008, respectively.

Agreements with Former Employees

In September 2008, the Company s President and Chief Operating Officer resigned. In accordance with his employment agreement, he was entitled to receive severance payments totaling $630,000, of which, one-third ($210,000) was paid on the effective date of his termination, and the remaining $420,000 was paid in monthly installments of $35,000 over the following 12 months. The Company recognized compensation expense of $630,000 in 2008 pursuant to his resignation, of which $280,000 was classified as a deferred liability as of December 31, 2008. In 2009 the Company recognized $315,000 of compensation expense. In addition, in accordance with such employment agreement, the vesting of all of the shares underlying options subject to time-

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based vesting was accelerated. This acceleration of the vesting of these stock options resulted in additional compensation costs of approximately $382,000 for 2008. In March 2010, such options expired without being exercised.

In April 2010, Dr. Hudson tendered his resignation at the request of the board of directors. Pursuant to the terms of his separation agreement, Dr. Hudson was entitled to receive severance payments totaling $1,412,170 (comprised of two times the sum of (1) his annual base salary in effect as of the separation date ($494,400), (2) the average of his last two annual bonuses ($188,669), and (3) the annual cost of Pfizer retiree healthcare coverage for him and his spouse ($23,000). The cash severance payments are paid to Dr. Hudson in 24 equal monthly installments, less required deductions and withholdings following the effective date of the separation agreement. The Company paid severance payments totaling $473,226 in 2010 pursuant to his resignation, and $910,759 was classified as accrued employee compensation as of December 31, 2010. In addition, 116,500 shares of previously granted restricted stock immediately became fully vested at the effective date of the separation agreement. Finally, unvested options previously granted to Dr. Hudson to purchase 1,166,833 shares of common stock immediately became fully vested and exercisable at the effective date of the separation agreement. The Company recorded a charge of stock compensation expense of $1,181,000 as a result of the accelerated vesting of these shares in the second quarter of 2010.

Real Property Leases

The Company s corporate headquarters are located in Bothell, Washington. The Bothell facility consists of office and laboratory space. The Company also leases additional laboratory and office space in Corvallis, Oregon as set forth below. The Company previously acquired 34,000 square feet of space in Corvallis, Oregon with the intention of providing future expansion space for the manufacture of potential products and components. This property was listed for sale in September 2009. The Company believes that its current facilities are suitable and have sufficient capacity to meet the projected needs of its business for the next 12 months or that additional space is readily available. The following table lists the locations, expiration dates and the square footage of the Company s principal leased properties as of December 31, 2010:

Location of Property	Square Footage	Lease Expiration Date
Bothell, Washington	19,108	November 2014
Bothell, Washington	8,398	December 2012
Corvallis, Oregon	53,000	December 2020

Although the term of the lease for the Bothell, Washington facility ends in November 2014, the Company has a one-time option to terminate the lease at the third anniversary upon payment of a termination fee of $266,000. The Company commenced paying base rent of approximately $43,000 per month in December 2009 and will begin paying base rent of approximately $11,000 per month in May 2011 on its second Bothell facility. The amount of base rent is subject to an annual increase of approximately 3% at each Bothell facility. Monthly rent at the Corvallis, Oregon facility is approximately $71,000 per month and is subject to an annual increase of 3%.

11. INCOME TAXES

As of December 31, 2010, the Company had federal and state net operating loss carryforwards of approximately $202,404,000 and $219,843,000, respectively, available to reduce future taxable income, which expire 2011 through 2028. Of these amounts, approximately $2,007,000 and $2,046,000, respectively, relate to federal and state net operating losses assumed as part of the Ercole acquisition. Utilization of the Ercole net operating losses is limited to approximately $425,000 per year. In addition, Section 382 of the Internal Revenue Code and similar state laws could limit the future use of the remaining net operating losses based on ownership changes and the value of the Company s stock. Approximately $4,934,000 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 affected, will be accounted for as a direct increase to contributed capital rather

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than as a reduction of the year s provision for income taxes. The principal differences between net operating loss carryforwards for tax purposes and the accumulated deficit result from timing differences related to depreciation, amortization, 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 difference between the expected benefit computed using the statutory tax rate and the recorded benefit of zero is primarily due to the change in the valuation allowance.

The Company had net deferred tax assets of $108,702,000 and $103,308,000 at December 31, 2010 and 2009, respectively, primarily from U.S. federal and state net operating loss carryforwards, U.S. federal and state research and development credit carryforwards, share based compensation expense and intangibles. A valuation allowance was recorded to reduce the net deferred tax asset to zero because it is more likely than not that the deferred tax asset will not be realized. The estimate for the 2009 net operating loss carryforward was modified to align the estimated 2009 net operating loss carryforward with the actual information filed on the 2009 federal tax return. The net change in the valuation allowance for deferred tax assets was an increase of approximately $5,394,000 for the year ended December 31, 2010 and an increase of approximately $427,000, for the year ended December 31, 2009, mainly due to the increase in the net operating loss carryforwards and research and development tax credits.

Disclosures of the components of deferred tax assets and liabilities, and valuation allowance necessary to reduce deferred tax assets to an amount that is more likely than not to be realized in the future, differ from those presented in the financial statements and related footnotes contained in the Company s 2009 Annual Report on Form 10-K. Such changes reflect a decrease to the tax-effected net operating loss carryforward and valuation allowance of $7.2 million, from the previously reported amounts of $83,057,000 and $110,539,000, respectively. Such changes did not impact the Company s previously reported net deferred tax assets of $0 as of December 31, 2009.

Deferred tax assets assumed as part of the Ercole acquisition total approximately $1,407,000 and primarily relate to accrual to cash adjustment, net operating losses, and research and development credits. A valuation allowance was recorded to reduce the net deferred tax assets to zero because it is more likely than not that the deferred tax asset will not be realized.

The Company s policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on its balance sheet at December 31, 2010 or December 31, 2009, and has not recognized interest and/or penalties in the statement of operations for 2010, 2009 or 2008. The Company has not recognized any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

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

	December 31,	
	2010	2009
	(in thousands)	
Net operating loss carryforwards	$ 79,813	$ 75,826
Difference in depreciation and amortization	2,882	2,544
Capital loss carryforward	8	8
Research and development tax credits	19,739	18,436
Stock compensation	3,038	4,197
Stock options for consulting services	1,126	1,012
Deferred Rent	430	378
Deferred Revenue	1,288	805
Other	378	102
	108,702	103,308
Valuation allowance	(108,702)	(103,308)
	$	$

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12. COMMITMENTS AND CONTINGENCIES

Lease Obligations

The Company leases office and laboratory facilities under various noncancelable operating leases through December 2020. Rent expense under these leases was $1,821,000, $1,467,000 and $1,429,000 for 2010, 2009 and 2008, respectively, and $14,658,000 for the period from July 22, 1980 (inception) through December 31, 2010. See Note 10 Significant Agreements Real Property Leases for more information.

At December 31, 2010, the aggregate non-cancelable future minimum payments under leases were as follows:

	Year ending December 31, (in thousands)
2011	$ 2,403
2012	2,405
2013	2,036
2014	2,033
2015	1,413
Thereafter	7,899
Total minimum lease payments	$ 18,189

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 $100,000, $75,000 and $75,000 for 2010, 2009 and 2008, respectively, and $1,359,000 for the period from July 22, 1980 (inception) through December 31, 2010.

At December 31, 2010, the aggregate future minimum royalty payments under these agreements were as follows:

	Year ending December 31, (in thousands)
2011	$ 100
2012	80
2013	80
2014	80
2015	155
Thereafter	775
Total minimum royalty payments	$ 1,270

Litigation

As of December 31, 2010, the Company was not a party to any material legal proceedings with respect to itself, its subsidiaries, or any of its material properties. In the normal course of business, the Company may from time to time be named as a party to various legal claims, actions and complaints, including matters involving employment, intellectual property, effects from the use of therapeutics utilizing its technology, or others. It is impossible to predict with certainty whether any resulting liability would have a material adverse effect on the Company s financial position, results of operations or cash flows.

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13. FINANCIAL INFORMATION BY QUARTER (UNAUDITED)

	2010 for Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands)			
Revenues from license fees, grants and research contracts	$ 15,516	$ 8,702	$ 3,997	$ 1,205
Operating expenses:				
Research and development	13,886	9,059	6,931	6,096
General and administrative	3,365	3,440	4,733	2,844
Operating loss	(1,735)	(3,797)	(7,667)	(7,735)
Other income (loss):				
Interest (expense) income, and other, net	84	82	51	42
(Increase) decrease on warrant liability	(5,993)	(3,578)	(9,040)	7,109
Net income (loss)	$ (7,644)	$ (7,293)	$ (16,656)	$ (584)
Net income (loss) per share basic	$ (0.07)	$ (0.07)	$ (0.15)	$ (0.01)
Net income (loss) per share diluted	$ (0.07)	$ (0.07)	$ (0.15)	$ (0.01)
Shares used in per share calculations basic	112,328	111,767	110,383	110,429
Shares used in per share calculations diluted	112,328	111,767	110,383	110,429

	2009 for Quarter Ended			
	December 31	September 30	June 30	March 31
	(in thousands)			
Revenues from license fees, grants and research contracts	$ 5,141	$ 6,349	$ 2,945	$ 3,150
Operating expenses:				
Research and development	6,624	7,473	5,804	4,495
General and administrative	2,470	1,800	2,206	2,220
Operating loss	(3,953)	(2,924)	(5,065)	(3,565)
Other income (loss):				
Interest (expense) income, and other, net	(312)	(127)	(31)	16
(Increase) decrease on warrant liability	7,791	(5,039)	(14,572)	2,622
Net income (loss)	$ 3,526	$ (8,090)	$ (19,668)	$ (927)
Net income (loss) per share basic	$ 0.03	$ (0.08)	$ (0.23)	$ (0.01)
Net income (loss) per share diluted	$ 0.03	$ (0.08)	$ (0.23)	$ (0.01)
Shares used in per share calculations basic	110,266	95,261	85,664	80,759
Shares used in per share calculations diluted	125,647	95,261	85,664	80,759

14. SUBSEQUENT EVENTS:

On December 13, 2010, the Company s board of directors appointed Christopher Garabedian, member of the board of directors, as the president and chief executive officer of the Company, effective January 1, 2011. Mr. Garabedian succeeded J. David Boyle II, the Company s senior vice

president and chief financial officer, who served as the interim president and chief executive officer of the Company from April 20, 2010.

Pursuant to the offer letter, dated as of December 12, 2010, by and between the Company and Mr. Garabedian, he is entitled to a base annual salary of $490,000 and is eligible to receive an annual bonus of up to 50% of his annual base salary, or $245,000, upon achievement of performance objectives determined by the

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board of directors or its delegate. The maximum annual bonus Mr. Garabedian will be eligible to receive is up to 75% of his annual base salary, or $367,500. Mr. Garabedian also received an initial sign-on bonus of $130,000, which must be repaid if he terminates his employment with the Company for any reason on or before January 1, 2012.

In accordance with the offer letter and the terms of the Company s 2002 Equity Incentive Plan, Mr. Garabedian was granted an option to purchase 1,900,000 shares of the Company s common stock. One-fourth of the shares underlying Mr. Garabedian s option will vest on January 1, 2012 and 1/48th of the shares underlying Mr. Garabedian s option will vest on each monthly anniversary of the commencement of his employment thereafter.

Mr. Garabedian will be reimbursed for documented relocation expenses (not to exceed $120,000) and corporate housing expenses (up to $4,500 per month for six months), all of which must be repaid if Mr. Garabedian terminates his employment with the Company for any reason on or before January 1, 2012.

The offer letter also specifies that if Mr. Garabedian s employment is terminated for reasons other than cause, death or disability, then, subject to execution of a release of claims in the form provided by the Company, he will be entitled to continued payments of his base salary for 12 months from the date of termination, accelerated vesting on 50% of his unvested equity awards and an extension of the post-termination exercise period on his outstanding options to 180 days following the date of termination.

Effective January 10, 2011, Effie Toshav was appointed senior vice president and general counsel of the Company. Ms. Toshav was granted an option to purchase 650,000 shares of the Company s common stock at a strike price of $2.58 per share. One-fourth of the shares underlying Ms. Toshav s option will vest on January 10, 2012, and 1/48 of the shares underlying Ms. Toshav s option will vest on each monthly anniversary of the commencement of her employment thereafter.