AVI BIOPHARMA INC
Form 10-Q
May 10, 2011
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# UNITED STATES

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended March 31, 2011**

**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**

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 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 (Check one):

| | |
|---|---|
| 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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

| **Common Stock with $0.0001 par value** | **135,564,651** |
|---|---|
| (Class) | (Outstanding as of May 1, 2011) |

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**PART I FINANCIAL INFORMATION**

**Item 1. Financial Statements.**

**AVI BIOPHARMA, INC.**

**(A Development Stage Company)**

**BALANCE SHEETS**

**(unaudited)**

**(in thousands, except per share data)**

| | March 31, 2011 | December 31, 2010 |
|---|---|---|
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 23,283 | $ 33,589 |
| Accounts receivable | 13,576 | 3,224 |
| Other current assets | 1,636 | 1,025 |
| Total Current Assets | 38,495 | 37,838 |
| Property held for sale | 1,965 | 1,965 |
| Property and Equipment, net of accumulated depreciation and amortization of $15,150 and $14,963 | 2,111 | 2,070 |
| Patent Costs, net of accumulated amortization of $1,790 and $1,742 | 4,074 | 3,980 |
| Other assets | 386 | 123 |
| Total Assets | $ 47,031 | $ 45,976 |
| **Liabilities and Shareholders Equity** | | |
| Current Liabilities: | | |
| Accounts payable | $ 6,484 | $ 1,311 |
| Accrued employee compensation | 2,088 | 2,015 |
| Long-term debt, current portion | 82 | 81 |
| Warrant valuation | 31,193 | 39,111 |
| Deferred revenue | 3,304 | 3,304 |
| Other liabilities | 69 | 35 |
| Total Current Liabilities | 43,220 | 45,857 |
| Commitments and Contingencies | | |
| Long-term debt, non-current portion | 1,821 | 1,842 |
| Other long-term liabilities | 1,070 | 1,094 |
| 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; 112,561,377 and 112,352,452 issued and outstanding | 11 | 11 |
| Additional paid-in capital | 306,722 | 304,818 |
| Deficit accumulated during the development stage | (305,813) | (307,646) |

| | | |
|---|---|---|
| Total Shareholders Equity (Deficit) | 920 | (2,817) |
| Total Liabilities and Shareholders Equity (Deficit) | $ 47,031 | $ 45,976 |

See accompanying notes to financial statements.

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**AVI BIOPHARMA, INC.**

**(A Development Stage Company)**

**STATEMENTS OF OPERATIONS**

**(unaudited)**

**(in thousands, except per share amounts)**

| | Three months ended March 31, | | July 22, 1980 (Inception) through March 31, |
|---|---|---|---|
| | 2011 | 2010 | 2011 |
| Revenues from license fees, grants and research contracts | $ 14,296 | $ 1,205 | $ 103,525 |
| Operating expenses: | | | |
| Research and development | 14,801 | 6,096 | 281,205 |
| General and administrative | 5,026 | 2,844 | 93,428 |
| Acquired in-process research and development | | | 29,461 |
| Operating loss | (5,531) | (7,735) | (300,569) |
| Other income (loss): | | | |
| Interest income and other, net | 90 | 42 | 8,672 |
| (Increase) decrease on warrant valuation | 7,274 | 7,109 | (778) |
| Realized gain on sale of short-term securities available-for-sale | | | 3,863 |
| Write-down of short-term securities available-for-sale | | | (17,001) |
| | 7,364 | 7,151 | (5,244) |
| Net income (loss) | $ 1,833 | $ (584) | $ (305,813) |
| Net income (loss) per share - basic | $ 0.02 | $ (0.01) | |
| Net income (loss) per share - diluted | $ 0.02 | $ (0.01) | |
| Weighted average number of common shares outstanding for computing basic income (loss) per share (in thousands) | 112,482 | 110,429 | |
| Weighted average number of common shares outstanding for computing diluted income (loss) per share (in thousands) | 121,285 | 110,429 | |

See accompanying notes to financial statements.

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**AVI BIOPHARMA, INC.**

**(A Development Stage Company)**

**STATEMENTS OF CASH FLOWS**

**(unaudited)**

**(in thousands)**

| | Three months ended March 31, 2011 | 2010 | For the Period July 22, 1980 (Inception) through March 31, 2011 |
|---|---|---|---|
| Cash flows from operating activities: | | | |
| Net income (loss) | $ 1,833 | $ (584) | $ (305,813) |
| Adjustments to reconcile net income (loss) to net cash flows used in operating activities: | | | |
| Depreciation and amortization | 239 | 347 | 19,384 |
| Loss on disposal of assets | 26 | 189 | 2,107 |
| 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 | | | 1,336 |
| Stock-based compensation | 1,145 | 426 | 27,011 |
| Conversion of interest accrued to common stock | | | 8 |
| Acquired in-process research and development | | | 29,461 |
| (Gain) loss on warrant liability | (7,274) | (7,109) | 778 |
| (Increase) decrease in accounts receivable, other current assets and other assets | (11,226) | 334 | (15,337) |
| Net increase in accounts payable, accrued employee compensation, and other liabilities | 5,191 | 85 | 11,326 |
| Net cash used in operating activities | (10,066) | (6,312) | (216,601) |
| Cash flows from investing activities: | | | |
| Purchase of property and equipment | (227) | (207) | (18,928) |
| Patent costs | (109) | (297) | (8,474) |
| Purchase of marketable securities | | (1) | (112,993) |
| Sale of marketable securities | | | 117,724 |
| Acquisition costs | | | (2,389) |
| Net cash used in investing activities | (336) | (505) | (25,060) |
| 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 | 116 | | 265,614 |
| Repayments of long-term debt | (20) | (20) | (284) |
| 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 | 96 | (20) | 264,944 |
| Increase (decrease) in cash and cash equivalents | (10,306) | (6,837) | 23,283 |
| Cash and cash equivalents: | | | |

| | | | |
|---|---|---|---|
| Beginning of period | 33,589 | 48,275 | |
| End of period | $ 23,283 | $ 41,438 | $ 23,283 |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: | | | |
| Cash paid during the year for interest | $ 23 | $ 19 | $ 422 |
| SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES: | | | |
| Short-term securities available-for-sale received in connection with the private offering | $ | $ | $ 17,897 |
| Issuance of common stock and warrants in satisfaction of liabilities | $ 644 | $ | $ 1,188 |
| 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 |
| Assumption of liabilities for Ercole assets | $ | $ | $ 2,124 |

See accompanying notes to financial statements.

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**AVI BIOPHARMA, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**(Unaudited)**

**Note 1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements reflect the accounts of AVI BioPharma, Inc. (the Company ) and its consolidated subsidiaries. The accompanying unaudited condensed consolidated balance sheet data as of December 31, 2010 was derived from audited financial statements not included in this report. The accompanying unaudited condensed consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America ( GAAP ) and the rules and regulations of the U.S. Securities and Exchange Commission ( SEC ) pertaining to interim financial statements. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

Management has determined that the Company operates one segment: the development of pharmaceutical products on its own behalf or in collaboration with others.

The accompanying unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2010. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

***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 income, assets, liabilities, shareholders equity (deficit) or cash flows.

***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.

***Commitments and Contingencies***

As of the date of this report, the Company is 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.

In May 2011, the Company entered into an agreement for the provision of professional services. Pursuant to the terms of the agreement, the Company will make payments totaling $1.2 million over approximately the next 12 months.

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**Note 2. Fair Value Measurements**

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 March 31, 2011 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| | | (in thousands) | | |
| Cash and cash equivalents | $ 23,283 | $ 23,283 | $ | $ |
| Total assets | $ 23,283 | $ 23,283 | $ | $ |

| | Fair Value Measurement as of March 31, 2011 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |
| | | (in thousands) | | |
| Warrants | $ 31,193 | $ | $ | $ 31,193 |
| Total liabilities | $ 31,193 | $ | $ | $ 31,193 |

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

| | 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 |

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A reconciliation of the change in value of the Company s warrants for the three months ended March 31, 2011 is as follows:

| | | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) (in thousands) |
|---|---|---|
| Balance at December 31, 2010 | $ | 39,111 |
| Change in value of warrants | | (7,274) |
| Reclassification upon exercise of warrants | | (644) |
| Balance at March 31, 2011 | $ | 31,193 |

A reconciliation of the change in value of the Company s warrants for the three months ended March 31, 2010 is as follows:

| | | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) (in thousands) |
|---|---|---|
| Balance at December 31, 2009 | $ | 27,609 |
| Change in value of warrants | | (7,109) |
| Balance at March 31, 2010 | $ | 20,500 |

See Note 6 Warrants for additional information related to the determination of fair value of the warrants.

The carrying amounts reported in the balance sheets for cash, 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.

**Note 3. 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 $8.7 million and $0.5 million of receivables that were unbilled at March 31, 2011 and 2010, respectively.

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**Note 4. 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 recognizes revenues from U.S. government research contracts during the period in which the related expenditures are incurred and present these revenues and related expenses gross in the consolidated financial statements. As of March 31, 2011, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of $152.3 million for development of its product candidates, of which $90.4 million had been billed or recognized as revenue and $61.9 million of which relates to development that has not yet been completed and has not been billed. 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. The Company s technology is expected to be used to continue developing RNA-based drugs against Ebola and Marburg viruses. As of March 31, 2011, the Company has recognized revenue of $9.7 million with respect to these contracts and the Company does not expect to receive any additional funds under these contracts.

***November 2006 Agreement (Ebola, Marburg and Junín Viruses)***

In November 2006, the Company entered into a two-year research contract with the U.S. Defense Threat Reduction Agency ( DTRA ) pursuant to which the Company was entitled to $28.0 million to fund development of the Company s antisense therapeutic candidates for 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, 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 March 31, 2011, the Company had recognized revenue of $38.4 million with respect to this contract and the Company does not expect further significant 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 that 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 March 31, 2011, the Company has recognized revenue of $7.0 million with respect to this contract and does not expect to receive additional significant revenue in 2011.

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***June 2010 Agreement (H1N1/Influenza)***

On June 4, 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 U.S. Department of Defense ( DoD ). The contract originally provided for funding of up to $18.0 million (which was reduced to $17.7 million in March 2011 when the contract was definitized) 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 development 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. In April 2011, the contract was amended to remove clinical studies from the scope of work and to add *in vitro* broad spectrum strain investigation, additional formulation work related to intranasal delivery and an intravenous compatibility study. As a result of this amendment, the amount of funding under the contract decreased to an aggregate of $13.1 million. As of March 31, 2011, the Company has recognized revenue of $11.1 million with respect to this contract and expects to receive the remaining funding under this contract in 2011.

***July 2010 Agreement (Ebola and Marburg)***

On July 14, 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 instigated 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 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 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 March 31, 2011, the Company has recognized revenue of $21.7 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 three months ended March 31, 2011 and 2010.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in thousands) | |
| January 2006 Agreements *(Ebola and Marburg host factor, Dengue, Anthrax and Ricin)* | $ | $ 322 |
| November 2006 Agreement *(Ebola, Marburg and Junín Viruses)* | | 545 |
| May 2009 Agreement *(H1N1)* | 67 | 258 |
| June 2010 Agreement *(H1N1)* | 2,324 | |
| July 2010 Agreement *(Ebola and Marburg)* | 11,905 | |
| Other Agreements | | 80 |
| Total | $ 14,296 | $ 1,205 |

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**Note 5. 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 March 31, 2011, 2,069,183 shares of common stock remain available for future grant under the Plan.

A summary of the Company s stock option activity with respect to the three months ended March 31, 2011 follows:

| Stock Options | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding at December 31, 2010 | 8,490,055 | $ 2.14 | | |
| Granted | 2,655,000 | 2.27 | | |
| Exercised | | | | |
| Canceled or expired | (55,708) | 7.15 | | |
| Outstanding at March 31, 2011 | 11,089,347 | $ 2.15 | 7.53 | $ 2,924,000 |
| Vested at March 31, 2011 and expected to vest | 10,752,743 | $ 2.15 | 7.47 | $ 2,885,000 |
| Exercisable at March 31, 2011 | 4,944,515 | $ 2.53 | 5.49 | $ 1,539,000 |

The weighted-average fair value per share of stock-based awards, including stock options and restricted stock grants, granted to employees during the three months ended March 31, 2011 and 2010 was $1.54 and $1.06, respectively. During the same periods, no stock options were exercised and the total grant date fair value of stock options that vested was $1,089,000 and $838,000, respectively.

***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.

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:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| Risk-free interest rate | 2.38% | 2.83% |
| Expected dividend yield | 0% | 0% |
| Expected lives | 5.4 years | 5.76 years |
| Expected volatility | 81.6% | 87.87% |

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The risk-free interest rate is estimated using an average of treasury bill interest rates at the time of grant that correlate to the prevailing interest rates for a period commensurate with the expected life. 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 life. 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.

***Stock-based Compensation Expense***

The amount of stock-based compensation expense recognized in the three months ended March 31, 2011 and 2010 related to stock options was $1,145,000 and $426,000, respectively. A summary of the stock based compensation expense recognized in the statement of operations is as follows:

| | Three Months Ended | |
|---|---|---|
| | March 31, 2011 | March 31, 2010 |
| | (in thousands) | |
| Research and development | $ 373 | $ 199 |
| General and administrative | 772 | 227 |
| Total | $ 1,145 | $ 426 |

As of March 31, 2011, there was $6,836,000 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 2.6 years.

On January 10, 2011, in connection with her appointment as the Company s senior vice president and general counsel, the Company granted Effie Toshav an option to purchase 650,000 shares of the Company s common stock at an exercise price of $2.58 per share. These shares were granted outside the Plan. This option is exercisable at the rate of 25% of the shares on January 10, 2012 and 1/48th of the total granted shares on each monthly anniversary thereafter such that the option will be fully vested on January 10, 2015. The shares granted are included in the summary stock compensation table noted above in this Note 5.

Paul Medeiros, the Company s Senior Vice President of Business Development and Chief Business Officer, will cease to be an employee of the Company effective June 1, 2011. Pursuant to the terms of a separation and release agreement that the Company expects to enter into with Mr. Medeiros in connection with the termination of his employment, Mr. Medeiros will receive 12 months of his base compensation in a lump sum (an amount equal to $321,300) and all of his unvested stock options will vest on June 1, 2011 and be exercisable for a period of 180 days following June 1, 2011. As of March 31, 2011, the Company has

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recorded a deferred liability for the salary and has recorded a charge of $288,000 for the stock compensation expense for the three months ending March 31, 2011.

**Note 6. Warrants**

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

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:

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| Risk-free interest rate | 0.8%-1.3% | 0.1%-2.6% |
| Expected dividend yield | 0% | 0% |
| Expected lives | 1.7-3.4 years | 0.1-4.4 years |
| Expected volatility | 71.4%-88.5% | 62.3%-93.0% |
| Shares underlying warrants classified as liabilities | 28,948,962 | 30,203,466 |
| Shares underlying warrants classified as equity | 255,895 | 2,129,530 |
| Market value of stock at beginning of period | $ 2.12 | $ 1.58 |
| Market value of stock at end of period | $ 1.86 | $ 1.18 |

The risk-free interest rate is estimated using an average of treasury bill interest rates at the valuation date that correlate to the prevailing interest rates over a period commensurate with the expected lives. 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, taking into account factors such as future events or circumstances that could impact volatility, over a period commensurate with the expected lives. 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.

The Company also has warrants that are classified as permanent equity; the fair value of the warrants was recorded as additional paid-in capital at the time of issuance and no further adjustments are made. For the three months ended March 31, 2011 and 2010, 255,895 and 2,129,530 shares, respectively, were underlying such warrants.

A summary of the Company s warrant activity with respect to the three months ended March 31, 2011 is as follows:

| Warrants | Shares | Weighted Average Exercisable Price | Weighted Average Remaining Contractual Term |
|---|---|---|---|
| Outstanding at December 31, 2010 | 29,665,441 | $ 1.58 | |
| Granted | | | |
| Exercised | (460,584) | $ 1.39 | |
| Canceled or expired | | | |
| Outstanding at March 31, 2011 | 29,204,857 | $ 1.59 | 3.1 |

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**Note 7. Earnings Per Share**

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares and dilutive common stock equivalent shares outstanding.

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in thousands, except per share data) | |
| Net income (loss) | $ 1,833 | $ (584) |
| 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 | 112,482 | 110,429 |
| Dilutive effect of warrants and stock options after application of the treasury stock method* | 8,803 | |
| Weighted-average number of common shares outstanding for computing diluted earnings per share | 121,285 | 110,429 |
| Net income (loss) per share basic | $ 0.02 | $ (0.01) |
| Net income (loss) per share diluted | $ 0.02 | $ (0.01) |

* Warrants and stock options to purchase 12,572,964 and 41,504,386 shares of common stock as of March 31, 2011 and 2010, respectively, were excluded from the net income (loss) per share calculation as their effect would have been anti-dilutive.

**Note 8. Liquidity**

Since its inception in 1980 through March 31, 2011 the Company has incurred losses of approximately $305.8 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 revenue from product sales will be achieved. The Company expects to incur operating losses over the next several years.

At March 31, 2011, cash and cash equivalents were $23.3 million, compared to $33.6 million at December 31, 2010. 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 March 31, 2011, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of $152.3 million for

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development of its product candidates, of which $90.4 million had been recognized as revenue and $61.9 million of which relates to development that has not yet been completed and has not been billed. See Note 4 U.S. Government Contracts for additional information.

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 9 Equity Financings for more information.

In April 2011, the Company sold 23.0 million shares of its common stock at the price of $1.50 per share in an offering registered under the Securities Act. The offering generated gross proceeds of $34.5 million.

**Note 9. Equity Financings**

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 6 Warrants. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

In April 2011, the Company sold 23.0 million shares of its common stock. See Note 12 Subsequent Events for more information.

**Note 10. Income Taxes**

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.

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 March 31, 2011 or December 31, 2010, and has not recognized interest and/or penalties in the statement of operations for the three months ended March 31, 2011 or March 31, 2010.

At December 31, 2010, the Company had net deferred tax assets of approximately $109 million. The deferred tax assets are primarily composed of U.S. federal and state tax net operating loss carryforwards, U.S. federal and state research and development credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these

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assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules could limit the future use of its net operating loss and research and development credit carryforwards to offset future taxable income based on ownership changes and the value of the Company s stock.

**Note 11. 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. 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 guidance is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning January 1, 2011. The adoption of this new guidance did not have a material impact on the Company s financial statements.

**Note 12. Subsequent Events**

In April 2011, the Company sold 23.0 million shares of its common stock at the price of $1.50 per share in an offering registered under the Securities Act. The offering generated gross proceeds of $34.5 million.

**Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations.**

*This section should be read in conjunction with our condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and the section contained in our Annual Report on Form 10-K for the year ended December 31, 2010 under the caption Part II-Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations. This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. All statements other than historical or current facts, including, without limitation, statements about our business strategy, plans and objectives of management, and our future prospects, are forward-looking statements and are sometimes identified by such words as believe, expect, anticipate, may, will, should, could, would, plan, estimate, project, predict, and potential, and words of similar import. These forward-looking statements include, but are not limited to, statements regarding:*

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

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*the efficacy, potency and utility of our product candidates in the treatment of rare and infectious diseases, and their potential to treat a broad number of human diseases;*

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

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

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

*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;*

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

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

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

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

*our estimates regarding how long our existing cash and cash equivalents, exclusive of receipt of future proceeds pursuant to our contracts with the U.S. government, will be sufficient to finance our operations and statements about our future capital needs.*

*These forward-looking statements 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 this Quarterly Report in Part II, Item 1A Risk Factors, and elsewhere in this Quarterly Report. These statements, like all statements in this Quarterly Report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. In this report, we, our, us, AVI, and Company refers to AVI BioPharma, Inc.*

**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

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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. Eteplirsen (the non-proprietary name assigned to 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, eteplirsen 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 eteplirsen 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 eteplirsen 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 against Ebola, Marburg, Dengue and influenza viruses, as described in greater detail 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 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 March 31, 2011, we owned or held exclusive or partially exclusive licenses to approximately 190 U.S. and corresponding foreign patents and 180 U.S. and corresponding foreign patent applications.

In April 2011, we sold 23.0 million shares of our common stock at $1.50 per share in an offering registered under the Securities Act of 1933, or the Securities Act. The offering generated gross proceeds of $34.5 million.

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 costs to increase. We have been unprofitable since inception and, other than government research contracts, limited interest, license fees, and grants, we have had no material revenue. We expect to continue to incur losses for the foreseeable future as we continue our

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research and development efforts and seek to enter additional collaborative efforts. As of March 31, 2011, our accumulated deficit was $305.8 million.

**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 March 31, 2011, we had contracts with the U.S. government pursuant to which we are entitled to receive up to an aggregate of $152.3 million for development of our product candidates, of which $90.4 million had been billed or recognized as revenue and $61.9 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 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. Our technology is expected to be used to continue developing RNA-based drugs against Ebola and Marburg viruses. As of March 31, 2011, 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.

***November 2006 Agreement (Ebola, Marburg and Junín Viruses)***

In November 2006, we entered into a two-year research contract with the U.S. Defense Threat Reduction Agency, or DTRA, pursuant to which we were entitled to $28.0 million to fund development of our antisense therapeutic candidates for 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 March 31, 2011, 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 DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to $4.1 million to us for the work involving the application of our proprietary PMO and PMO*plus*s antisense chemistry and we plan to conduct preclinical development of at least one drug candidate and demonstrate that 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 March 31, 2011, we have recognized revenue of $7.0 million with respect to this contract and do not expect to receive additional significant revenue 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

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countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program, or TMT, of the U.S. Department of Defense, or DoD. The contract originally provided for funding of up to $18.0 million (which was reduced to $17.7 million in March 2011 when the contract was definitized) 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 development 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. In April 2011, the contract was amended to remove clinical studies from the scope of work and to add *in vitro* broad spectrum strain investigation, additional formulation work related to intranasal delivery and an intravenous compatibility study. As a result of this amendment, the amount of funding under the contract decreased to an aggregate of $13.1 million. As of March 31, 2011, we have recognized revenue of $11.1 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 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.

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 March 31, 2011, we have recognized revenue of $21.7 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 our results of operations for the three months ended March 31, 2011 and 2010

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in thousands) | |
| January 2006 Agreements *(Ebola and Marburg host factor, Dengue, Anthrax and Ricin)* | $ | $ 322 |
| November 2006 Agreement *(Ebola, Marburg and Junín Viruses)* | | 545 |
| May 2009 Agreement *(H1N1)* | 67 | 258 |
| June 2010 Agreement *(H1N1)* | 2,324 | |
| July 2010 Agreement *(Ebola and Marburg)* | 11,905 | |
| Other Agreements | | 80 |
| Total | $ 14,296 | $ 1,205 |

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**Key Financial Metrics**

***Revenue***

*Government Research Contract Revenue.* In the periods presented, we have generated substantially all of our revenue from U.S. government research contracts. We recognize revenue from U.S. government research contracts during the period in which the related expenditures are incurred and present such revenue and related expense gross in the consolidated financial statements.

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 March 31, 2011, 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.

***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

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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, legal, 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 and Other, Net*. Interest income and other, 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. 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 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 6 Warrants of the unaudited condensed consolidated financial statements included elsewhere in this report.

**Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements included elsewhere in this report. 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, revenue 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 consolidated 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.

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Our critical accounting policies and significant estimates are detailed in our annual report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 15, 2011.

**Results of Operations for the Three Months Ended March 31, 2011 and 2010**

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

| | Three Months Ended March 31, | | |
|---|---|---|---|
| | 2011 | 2010 | % Change |
| | (In thousands, except per share amounts) | | |
| Revenue: | $ 14,296 | $ 1,205 | 1,086% |
| Expenses: | | | |
| Research and development | 14,801 | 6,096 | 143% |
| General and administrative | 5,026 | 2,844 | 77% |
| Operating loss | (5,531) | (7,735) | (28%) |
| Other income (loss): | | | |
| Interest income and other, net | 90 | 42 | 114% |
| Decrease on warrant valuation | 7,274 | 7,109 | 2% |
| Net income (loss) | $ 1,833 | $ (584) | 414% |
| Basic income (loss) per share | $ 0.02 | $ (0.01) | |
| Diluted income (loss) per share | $ 0.02 | $ (0.01) | |

***Revenue***

Revenue for the three months ended March 31, 2011 increased by $13.1 million, or 1,086%, compared to the three months ended March 31, 2010 due to a $11.9 million increase in revenue from the July 2010 Ebola and Marburg and a $2.1 million total increase in the May 2009 and June 2010 H1N1 U.S. government research contracts offset, in part, by a $0.9 million lower revenue associated with the 2006 U.S. government research contracts.

***Research and Development Expenses***

Research and development expenses for the three months ended March 31, 2011 increased by $8.7 million, or 143%, compared to the three months ended March 31, 2010 due primarily to an $8.0 million increase in spending related to the July 2010 Ebola and Marburg agreements and a $1.2 million increase in spending related to the May 2009 and June 2010 H1N1 agreements, partially offset by $0.5 million decrease in spending on DMD and other research and development programs.

***General and Administrative Expenses***

General and administrative expenses for the three months ended March 31, 2011 increased by $2.2 million, or 77%, compared to the three months ended March 31, 2010. The significant increase in the three months ended March 31, 2011 is primarily due to $1.2 million in salaries and employee related costs from increased staff, $0.6 million in accrued severance and stock compensation expense related to the planned departure of a senior officer, $0.3 million increase in legal costs and $0.1 million in consulting costs.

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***Interest Income and Other, Net***

Interest income and other, net, for the three months ended March 31, 2011 increased by 114% to $0.1 million compared to the three months ended March 31, 2010. The increase in interest income and other, net, for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 was attributable to increased interest earnings on our invested cash.

***Change in Fair Value of Warrant Liability***

The changes in fair value of warrant liability for the three months ended March 31, 2011 compared to the three months ended March 31, 2010 was attributable to changes in our stock price. See Key Financial Metrics Change in Fair Value of Warrants, Critical Accounting Policies Warrant Liability, and Note 6 to the unaudited condensed consolidated financial statements included elsewhere in this report.

***Net income (loss)***

Net income for the three months ended March 31, 2011 increased by $2.4 million, compared to the net loss of $0.6 million for the three months ended March 31, 2010 due primarily due to the higher revenues attributed to the revenue from our agreements with the U.S. government and the change in warrant liability, offset in part by higher research and development costs and general and administration costs.

**Liquidity and Capital Resources**

At March 31, 2011, cash and cash equivalents were $23.3 million, compared to $33.6 million at December 31, 2010. Our principal sources of liquidity are equity financings and revenue from our U.S. government research contracts. 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 and cash equivalents, 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.

***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 April 2011, we sold 23.0 million shares of our common stock at $1.50 per share in an offering registered under the Securities Act of 1933, or the Securities Act. The offering generated net proceeds of approximately $32.0 million.

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

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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 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 report, our accumulated deficit is $305.8 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***

| | Three Months Ended March 31, | |
|---|---|---|
| | 2011 | 2010 |
| | (in thousands) | |
| Cash provided by (used in): | | |
| Operating activities | $ (10,066) | $ (6,312) |
| Investing activities | (336) | (505) |
| Financing activities | 96 | (20) |
| Decrease in cash and equivalents | $ (10,306) | $ (6,837) |

*Operating Activities*. We used $10.1 million of cash in operating activities for the three months ended March 31, 2011, an increase of $3.8 million compared to $6.3 million of cash used in operating activities for the three months ended March 31, 2010. The increase in net cash used in operating activities during the comparative periods was primarily attributable to an $11.6 million increase in accounts receivable and other current assets partially offset by a $5.1 million increase in accounts payable and other liabilities and $2.7 million of cash generated by higher revenues from government contracts as compared to the quarter ended March 31, 2010.

*Investing Activities*. We used $0.3 million of cash in investing activities for the three months ended March 31, 2011, a decrease of $0.2 million compared to $0.5 million of cash used in investing activities for the three months ended March 31, 2010. The fluctuation was attributable to decreased spending on patents.

*Financing Activities*. Financing activities provided $0.1 million of cash primarily due to warrant exercises offset by a debt repayment for the three months ended March 31, 2011. Cash used by financing activities for the three months ended March 31, 2010 was attributable to debt repayments.

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.

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**Contractual Obligations and Contingencies**

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 March 31, 2011:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| | | | (in thousands) | | |
| Operating leases premises | $ 17,589 | $ 2,429 | $ 4,323 | $ 3,301 | $ 7,536 |
| Royalty payments | $ 1,256 | $ 100 | $ 160 | $ 390 | $ 606 |

In May 2011, we entered into an agreement for the provision of professional services. Pursuant to the terms of the agreement, we will make payments totaling $1.2 million over approximately the next 12 months. The table above excludes these amounts.

**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.

**Recent Accounting Pronouncements**

See Note 11 to the unaudited condensed consolidated financial statements contained in Part I, Item 1 of this report.

## Item 3. Quantitative and Qualitative Disclosures about Market Risk.

**Interest Rate Sensitivity**

We had cash and cash equivalents of $23.3 million and $33.6 million at March 31, 2011 and December 31, 2010, respectively. We do not enter into investments for trading or speculative purposes; our cash equivalents are invested in money market accounts. 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 and cash equivalents. 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 0.01% decline in interest rates, occurring January 1, 2011 and sustained throughout the period ended March 31, 2011, would result in a decline in investment income of approximately $2,000 for that same period.

## Item 4. Controls and Procedures.

**Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation as of the end of period covered by this report, under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer, of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the

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time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and our chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of March 31, 2011, our disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II OTHER INFORMATION

**Item 1. Legal Proceedings.**

As of the date of this report, 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 drugs 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 1A. Risk Factors.**

*Set forth below and elsewhere in this report 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 report. 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, eteplirsen in DMD, AVI-6002 in Ebola and AVI-6003 in Marburg are in clinical trials, we have an open IND for AVI-7100 in influenza, and the rest of our product candidates are in preclinical development. 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 eteplirsen in Duchenne muscular dystrophy, or DMD, AVI-6002 in Ebola, AVI-6003 in Marburg and AVI-7100 in influenza. With

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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 eteplirsen, 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 to date, we are not guaranteed to receive orphan exclusivity based on that status and would not enjoy such exclusivity in the event that another entity could get approval of the same product for the same indication before we receive approval. Furthermore, pediatric exclusivity only applies if another product with exclusivity has not received regulatory approval, so if another 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

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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, potentially, 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 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 report, we do not believe that we have identified a consistently effective dose of eteplirsen for individuals with DMD. We are expeditiously moving to start a U.S.-based clinical trial for eteplirsen at

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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 eteplirsen, 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 eteplirsen 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 animal models and safety in humans. 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 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.

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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. Furthermore, if we fail to satisfy certain performance or deliverable requirements or to adhere to development timelines, revenues associated with the satisfaction of such requirements or timelines may not be realized.

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;
- 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

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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 report 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 eteplirsen in the UK and announced results in October 2010. We expect to commence additional trials of eteplirsen and other product candidates in the future, including the initiation of a Phase II trial in eteplirsen 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 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.

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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.

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

We had net income of $1.8 million for the three months ended March 31, 2011, but incurred a net loss of $32.2 million for the year ended December 31, 2010. As of March 31, 2011, our accumulated deficit was $305.8 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

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substantial dilution in their economic and voting rights. For example, in connection with our December 2007, January 2009, August 2009 and April 2011 financings, we sold an aggregate of 72.2 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.

***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

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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 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

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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 eteplirsen. We are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we have initiated clinical trials for eteplirsen, additional preclinical studies may be required for eteplirsen 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 eteplirsen. 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 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.

***If we lose our key personnel or are unable to attract and retain additional qualified personnel, our future growth and ability to compete would suffer.***

We are highly dependent on the efforts and abilities of the principal members of our senior management. Additionally, we have scientific personnel with significant and unique expertise in RNA-based therapeutics and related technologies. The loss of the services of any one of the principal members of our managerial or scientific staff may prevent us from achieving our business objectives.

In addition, the competition for qualified personnel in the biotechnology field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. In order to develop and commercialize our products successfully, we will be required to expand our workforce and our management ranks. We face intense competition for qualified individuals

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from numerous pharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are not able to attract and retain these individuals on favorable terms, our business may be harmed.

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

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 changes in our executive leadership, including the resignation in April 2010 of our former president and chief executive officer, Dr. Leslie Hudson. Following Dr. Hudson s 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 our 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. Additionally, in January 2011, Effie Toshav was hired as our Senior Vice President and General Counsel and effective May 2011 we hired Peter Linsley, Ph.D. as our Senior Vice President and Chief Scientific Officer. Such changes, or any other future changes in our executive leadership, including the recently announced departures of Mr. Paul Medeiros, our Senior Vice President of Business Development and Chief Business Officer, and Dr. Graham Johnson, our Senior Vice President of Preclinical Development and Research, may disrupt our operations as we adjust to the reallocation of responsibilities and assimilate new leadership and, potentially, differing perspectives on our strategic direction. 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.

***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 190 patents (domestic and foreign) issued or licensed to us and 180 (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.

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 eteplirsen 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 in this patent. Final resolution of this opposition proceeding may take a number of years. Because this proceeding is ongoing, the outcome cannot be predicted or determined as of the date of this report.

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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 eteplirsen, include Prosensa and GlaxoSmithKline, or GSK, and other companies such as Acceleron have also been working on DMD programs.

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. Prosensa/GSK also

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recently announced that the FDA lifted the partial clinical hold on the IND for its lead DMD drug candidate allowing Prosensa/GSK to proceed with longer term clinical studies of its lead DMD drug candidate, including a randomized placebo controlled study in patients in the U.S. 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 eteplirsen 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.

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***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, 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;

prohibition of cumulative voting of shares in the election of directors;

prohibition of shareholder actions by less than unanimous written consent;

express authorization of the board of directors to make, alter or repeal our bylaws;

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

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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;

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

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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 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

On January 10, 2011, in connection with her appointment as our senior vice president and general counsel, we granted Effie Toshav an option to purchase 650,000 shares of our common stock at a strike price of $2.58 per share. These shares were granted outside of our 2002 Equity Incentive Plan. This option is exercisable at the rate of 25% of the shares on January 10, 2012 and 1/48th of the total granted shares on each monthly anniversary thereafter such that the option will be fully vested on January 10, 2015. The shares

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granted are included in the summary stock option activity table in Note 5 to the accompanying unaudited condensed consolidated financial statements. The option was granted to Ms. Toshav in reliance on the exemption from the registration requirements of the Securities Act provided by Section 4(2) thereof.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. (Removed and Reserved).**

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

| | | Incorporated by Reference to Filings Indicated | | | | |
|---|---|---|---|---|---|---|
| **Exhibit No** | **Exhibit Description** | **Form** | **File No.** | **Exhibit** | **Filing Date** | **Filed Herewith** |
| 10.1 | Executive Employment Agreement dated January 10, 2011 by and between AVI BioPharma, Inc. and Effie Toshav. | | | | | X |
| 10.2 | Stand Alone Stock Option Grant between AVI BioPharma, Inc. and Effie Toshav dated January 10, 2011. | | | | | X |
| 10.3 | Modification No. PZ0001 to Contract Number HDTRA1-10-C-0079 between Defense Threat Reduction Agency and AVI BioPharma, Inc. effective March 3, 2011. | | | | | X |
| 10.4 | Executive Employment Agreement dated March 29, 2011 by and between AVI BioPharma, Inc. and Peter S. Linsley, Ph.D. | | | | | X |
| 31.1 | Certification of the Company s President and Chief Executive Officer, Christopher Garabedian, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 31.2 | Certification of the Company s Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 32.1 | Certification of the Company s President and Chief Executive Officer, Christopher Garabedian, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | | X |
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Portions of this exhibit are omitted and were filed separately with the Securities and Exchange Commission pursuant to an application requesting confidential treatment.

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**SIGNATURES**

Pursuant to the requirements 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.

Date: May 10, 2011

**AVI BIOPHARMA, INC.**

By: /s/ CHRISTOPHER GARABEDIAN
Christopher Garabedian
President and Chief Executive Officer

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