

AVI BIOPHARMA INC
Form 10-Q
November 09, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

OR

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

For the transition period from to

Commission file number 001-14895

AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Oregon

(State or other jurisdiction of incorporation
or organization)

93-0797222

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

3450 Monte Villa Parkway, Suite 101, Bothell, Washington

(Address of principal executive offices)

98021

(Zip Code)

Issuer's telephone number, including area code: **425-354-5038**

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

Indicate by check mark 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 or a non-accelerated filer. See the definition of accelerated filer, large accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting Company

(Do not check if a smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 110,435,315 outstanding at November 8, 2009.

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AVI BIOPHARMA, INC.

(A Development Stage Company)

BALANCE SHEETS

(unaudited)

(in thousands, except per share data)

| | September 30, 2009 | December 31, 2008 |
|---|-----------------------|----------------------|
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 50,268 | \$ 11,192 |
| Short-term securities - available-for-sale | 169 | 282 |
| Accounts receivable | 5,671 | 4,971 |
| Other current assets | 839 | 599 |
| Total Current Assets | 56,947 | 17,044 |
| Property and Equipment, net of accumulated depreciation and amortization of \$13,735 and \$12,919 | 2,102 | 5,189 |
| Patent Costs, net of accumulated amortization of \$1,959 and \$1,927 | 3,580 | 3,268 |
| Assets held for sale | 2,373 | |
| Other assets | 121 | 35 |
| Total Assets | \$ 65,123 | \$ 25,536 |
| Liabilities and Shareholders' Equity | | |
| Current Liabilities: | | |
| Accounts payable | \$ 4,303 | \$ 2,014 |
| Accrued employee compensation | 1,098 | 1,306 |
| Long-term debt, current portion | 76 | 74 |
| Warrant valuation | 35,400 | 1,254 |
| Deferred revenue | 2,096 | 2,190 |
| Other liabilities | 86 | 450 |
| Total Current Liabilities | 43,059 | 7,288 |
| Commitments and Contingencies | | |
| Long-term debt, non-current portion | 1,950 | 2,001 |
| Other long-term liabilities | 610 | 515 |
| Shareholders' Equity: | | |

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| | | | |
|---|-----------|----|-----------|
| Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding | | | |
| Common stock, \$.0001 par value, 200,000,000 shares authorized; 110,433,113 and 71,161,072 issued and outstanding | | 11 | 7 |
| Additional paid-in capital | 298,487 | | 266,035 |
| Deficit accumulated during the development stage | (278,994) | | (250,310) |
| Total Shareholders' Equity | 19,504 | | 15,732 |
| Total Liabilities and Shareholders' Equity | \$ 65,123 | \$ | 25,536 |

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 September 30, | | Nine months ended September 30, | | July 22, 1980 |
|---|----------------------------------|------------|---------------------------------|-------------|---|
| | 2009 | 2008 | 2009 | 2008 | (Inception) through September 30, 2009 |
| Revenues from license fees, grants and research contracts | \$ 6,349 | \$ 5,171 | \$ 12,444 | \$ 15,778 | \$ 54,668 |
| Operating expenses: | | | | | |
| Research and development | 7,473 | 7,680 | 17,771 | 22,261 | 223,807 |
| General and administrative | 1,800 | 3,429 | 6,226 | 8,165 | 71,550 |
| Acquired in-process research and development | | | | 9,916 | 29,461 |
| Operating loss | (2,924) | (5,938) | (11,553) | (24,564) | (270,150) |
| Other non-operating (loss) income: | | | | | |
| Interest (expense) income and other, net | (127) | 60 | (142) | 308 | 8,635 |
| (Increase) decrease on warrant valuation | (5,039) | (169) | (16,989) | 1,444 | (4,341) |
| Realized gain on sale of short-term securities available-for-sale | | | | | 3,863 |
| Write-down of short-term securities available-for-sale | (5,166) | (109) | (17,131) | 1,752 | (17,001) |
| | | | | | (8,844) |
| Net loss | \$ (8,090) | \$ (6,047) | \$ (28,684) | \$ (22,812) | \$ (278,994) |
| Net loss per share - basic and diluted | \$ (0.08) | \$ (0.08) | \$ (0.33) | \$ (0.33) | |
| Weighted average number of common shares outstanding for computing basic and diluted loss per share (in thousands) | 95,261 | 71,151 | 87,493 | 69,160 | |

See accompanying notes to financial statements.

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AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

| | Nine months ended September 30, | | For the Period |
|--|---------------------------------|-------------|--|
| | 2009 | 2008 | July 22, 1980 (Inception) through September 30, 2009 |
| Cash flows from operating activities: | | | |
| Net loss | \$ (28,684) | \$ (22,812) | \$ (278,994) |
| Adjustments to reconcile net loss to net cash flows used in operating activities: | | | |
| Depreciation and amortization | 1,080 | 1,043 | 17,383 |
| Loss on disposal of assets | 221 | 11 | 1,179 |
| 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 | 128 | | 928 |
| Stock-based compensation | 1,592 | 4,121 | 21,915 |
| Conversion of interest accrued to common stock | | | 8 |
| Acquired in-process research and development | | 9,916 | 29,461 |
| Increase (decrease) on warrant valuation | 16,989 | (1,444) | 4,341 |
| Net (increase) in: | | | |
| Accounts receivable and other current assets | (940) | (1,181) | (6,426) |
| Other assets | (86) | (235) | (121) |
| Net increase in accounts payable, accrued employee compensation, and other liabilities | 1,957 | 716 | 6,919 |
| Net cash used in operating activities | (7,743) | (9,865) | (190,269) |
| Cash flows from investing activities: | | | |
| Purchase of property and equipment | (276) | (364) | (17,214) |
| Patent costs | (751) | (419) | (6,931) |
| Sale (purchase) of marketable securities | 113 | (8) | (112,873) |
| Sale of marketable securities | | | 117,613 |
| Acquisition costs | | (11) | (2,389) |
| Net cash used in investing activities | (914) | (802) | (21,794) |
| 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 | 47,782 | 44 | 262,879 |
| Repayments of long-term debt | (49) | (99) | (162) |
| 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 | 47,733 | (55) | 262,331 |
| Increase (decrease) in cash and cash equivalents | 39,076 | (10,722) | 50,268 |

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| | | | | |
|----------------------------|----|--------|----|------------------|
| Cash and cash equivalents: | | | | |
| Beginning of period | | 11,192 | | 24,803 |
| End of period | \$ | 50,268 | \$ | 14,081 \$ 50,268 |

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

| | | | | |
|--|----|----|----|-----------|
| Cash paid during the year for interest | \$ | 65 | \$ | 33 \$ 273 |
|--|----|----|----|-----------|

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 | \$ | | \$ | | \$ | 545 |
| Issuance of common stock for building purchase | \$ | | \$ | | \$ | 750 |
| Assumption of long-term debt for building purchase | \$ | | \$ | | \$ | 2,200 |
| Issuance of common stock for Ercole assets | \$ | | \$ | 8,075 | \$ | 8,075 |
| Assumption of liabilities for Ercole assets | \$ | | \$ | 2,124 | \$ | 2,124 |
| Issuance of common stock and warrants in satisfaction of employee bonuses | \$ | 239 | \$ | | \$ | 239 |

See accompanying notes to financial statements.

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AVI BIOPHARMA, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Note 1. Basis of Presentation

The financial information included herein for the three and nine-month period ended September 30, 2009 and 2008 and the financial information as of September 30, 2009 is unaudited; however, such information reflects all adjustments consisting of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The financial information as of December 31, 2008 is derived from AVI BioPharma, Inc.'s (the Company's) Form 10-K. The interim financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Form 10-K. 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 Company's net loss, assets, liabilities, shareholders' equity or cash flows.

Estimates and Uncertainties. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 revenues and expenses during the reporting period. Actual results could differ from those estimates.

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

Note 2. Fair Value Measurements

The Company measures at fair value certain financial assets and liabilities. U.S. generally accepted account principles (US GAAP), specifies 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. These two types of inputs have created the following fair-value hierarchy:

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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 invests its cash in money market funds and certificates of deposits. The Company has not experienced credit losses on investments in these instruments. The Company's assets measured at fair value on a recurring basis consisted of the following as of September 30, 2009:

| (in thousands) | Fair Value Measurement as of September 30, 2009 | | | |
|--|---|-----------|---------|---------|
| | Total | Level 1 | Level 2 | Level 3 |
| Short-term securities available-for-sale | \$ 50,608 | \$ 50,156 | 452 | |
| Total | \$ 50,608 | \$ 50,156 | \$ 452 | \$ |

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

| (in thousands) | Fair Value Measurement as of September 30, 2009 | | | |
|-------------------|---|---------|---------|-----------|
| | Total | Level 1 | Level 2 | Level 3 |
| Warrant Liability | \$ 35,400 | | | \$ 35,400 |
| Total | \$ 35,400 | \$ | \$ | \$ 35,400 |

A reconciliation of the change in value of the Company's warrant liability valuation for the three months ended September 30, 2009 is as follows:

| (in thousands) | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) | |
|---|---|--------|
| Balance at July 1, 2009 | \$ | 21,387 |
| Total increase in liability included in earnings | | 5,039 |
| Issuances | | 8,974 |
| Balance at September 30, 2009 | \$ | 35,400 |
| The increase in the third quarter liability relating to warrants still held at September 30, 2009 | \$ | 5,039 |

A reconciliation of the change in value of the Company's warrant liability valuation for the nine months ended September 30, 2009 is as follows:

| (in thousands) | Fair Value Measurements Using Significant Unobservable Inputs (Level 3) | |
|--|---|--------|
| Balance at January 1, 2009 | \$ | 1,254 |
| Total increase in liability included in earnings | | 16,989 |
| Issuances | | 17,157 |
| Balance at September 30, 2009 | \$ | 35,400 |
| The increase in the year to date liability relating to warrants still held at September 30, 2009 | \$ | 16,989 |

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

Note 3. Revenue Recognition

Government Research Contract Revenue. The Company recognizes revenues from federal research contracts during the period in which the related expenditures are incurred. The Company presents these revenues and related expenses gross in the financial statements in accordance with ASC 605 45 *Reporting Revenue Gross as a Principal versus Net as an Agent*.

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

The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of Company performance under the other elements of the arrangement. In addition, if the Company has continuing involvement through research and development services that are required because its know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement. At September 30, 2009, the Company had deferred revenue of \$2.1 million, which represents up-front fees received from third parties pursuant to certain contractual arrangements. The Company will recognize the revenue from these contracts upon the achievement of certain performance milestones, as specified in the agreements.

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

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Patent costs consist primarily of legal and filing fees incurred to file patents on proprietary technology developed by the Company. Patent costs are amortized on a straight-line basis over the shorter of the estimated economic lives or the legal lives of the patents, generally 17 years.

Note 5. Acquisition of Ercole

On March 20, 2008, the Company acquired all of the stock of Ercole Biotech, Inc. (Ercole) in exchange for 5,811,721 shares of AVI common stock. The transaction included the assumption of approximately \$1.8 million in liabilities of Ercole. As a result of the transfer, Ercole became and remains a wholly owned subsidiary of the Company. The AVI common stock was valued at approximately \$8.4 million. AVI also issued warrants to purchase AVI stock to settle certain outstanding warrants held in Ercole, which were valued at \$436,535. These warrants are classified in equity. The acquisition was aimed at consolidating AVI's position in directed alternative RNA splicing therapeutics. Ercole and the Company had been collaborating since 2006 to develop drug candidates, including AVI-4658, currently in clinical testing in the United Kingdom for the treatment of Duchenne muscular dystrophy. Ercole has other ongoing discovery research programs.

The total estimated purchase price of \$10.3 million has been allocated as follows:

| | | |
|--|----|-----------|
| Cash | \$ | 54,000 |
| A/R | \$ | 76,000 |
| Prepaid Expenses | \$ | 7,000 |
| Fixed Assets | \$ | 10,000 |
| Patents | \$ | 190,000 |
| Acquired In-Process Research and Development | \$ | 9,916,000 |

The pending patents acquired as part of the Ercole acquisition have an expected expiration date of 2026. Acquired in-process research and development consists of other discovery research programs in areas including beta thalassemia and soluble tumor necrosis factor receptor. As these programs were in development at the time of acquisition, there were significant risks associated with completing these projects, and there were no alternative future uses for these projects, the associated value has been considered acquired in-process research and development.

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

Note 6. Other Current Assets

Amounts included in other current assets are as follows:

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| (in thousands) | September 30, 2009 | December 31, 2008 |
|----------------------|-----------------------|-------------------|
| Prepaid expenses | \$ 438 | \$ 316 |
| Other receivables | 118 | |
| Restricted cash | 283 | 283 |
| Other current assets | \$ 839 | \$ 599 |

The Company has pledged \$150,000 as collateral for company credit cards issued to certain employees and \$125,000 as collateral for payments on long-term debt. The Company classifies these amounts as restricted cash. As of September 30, 2009, restricted cash, including accrued interest, was \$283,000. The remaining components of other current assets include normally occurring prepaid expenses and other receivables.

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Note 7. Liquidity

The Company is in the development stage. Since its inception in 1980 through September 30, 2009, the Company has incurred losses of approximately \$279 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company expects to incur operating losses over the next several years.

The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on completing product development of its RNA-based products, obtaining regulatory approvals for such products, and bringing these products to market. During the period required to develop these products, the Company may require substantial additional financing. There can be no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. The Company believes it has sufficient cash to fund operations at least through the following twelve months, exclusive of future receipts from billings on existing government contracts. For 2009, the Company expects expenditures for operations, net of government funding, including collaborative efforts and research and development activities to be approximately \$10 to \$12 million. This could increase if the Company undertakes additional collaborative efforts. However, if necessary in 2009, the Company believes it can reduce its expenditures because a significant amount of its costs are variable. Those estimated expenditures include amounts necessary to fulfill the Company's obligations under its various collaborative, research and licensing agreements during 2009. The Company believes it will continue to receive funding from government and other sources to pursue the development of its product candidates, and has assumed certain revenues from these awards in providing this guidance. Should the Company not continue to receive funding from its current contracts or receive additional funding, or should the timing be delayed, it may have a significant negative impact on the Company's guidance.

The Company currently has a total of \$61.7 million of contracted development studies. As of September 30, 2009, \$44 million has been billed, of which \$38.3 million has been received in cash and \$5.7 million is in accounts receivable. The Company has \$17.7 in development contracts remaining that have not yet been completed and have not been billed. The Company expects to complete the remaining contract activity and receive the contracted revenue in 2010 and early 2011.

In December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. In May 2009, the Company received an amendment from DTRA to extend the contract performance period to November 29, 2009 and a cost modification of an additional \$5.9 million, increasing the total contract amount to \$33.9 million. In September 2009, the Company received a second amendment from DTRA to extend the contract performance period to February 28, 2011 and a cost modification of an additional \$11.5 million, increasing the total contract amount to \$45.4 million.

During the three month periods ended September 30, 2009 and 2008, the Company recognized \$4.4 million and \$4.9 million, respectively, in research contract revenue from this contract. During the nine month periods ended September 30, 2009 and 2008, the Company recognized \$7.5 million and \$13.6 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenues of \$32.3 million from this contract. Funding of the remainder of the contract is anticipated in 2010 and 2011.

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In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company's technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company has received signed contracts for all of these projects. The Company expects that funding under these signed contracts will be completed over the next 12 months. During the three month periods ended September 30, 2009 and 2008, the Company recognized \$0.3 million and \$0.2 million, respectively, in research contract revenue from these contracts. During the nine month periods ended September 30, 2009 and 2008, the Company recognized \$1.9 million and \$2.1 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenues of \$8.8 million on these contracts. Funding of the remainder of these contracts is anticipated in 2010.

In May 2009, the Company entered into a contract with the U.S. Defense Threat Reduction Agency (DTRA) to develop swine flu drugs. Under this contract, DTRA will pay up to \$4.1 million to the Company for the work to be performed by the Company. The work will involve the application of the Company's proprietary PMO and PMO*plus* antisense chemistry and the Company plans to

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conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. During the three month period ended September 30, 2009, the Company recognized \$0.7 million in revenue under this contract. During the nine month period ended September 30, 2009, the Company recognized \$1.1 million in revenue under this contract.

Also in May 2009, the Company entered into a \$2.5 million contract with Children's National Medical Center in Washington, D.C. to support preclinical studies in the development of AVI-4658 for treatment of Duchenne Muscular Dystrophy. The work will be conducted with Children's National collaborators Eric Hoffman, Ph.D., an authority on DMD and Professor of Pediatrics, and Edward Connor, M.D., Director, Office of Investigational Therapeutics and Professor of Pediatrics. AVI will serve as a subcontractor to a grant awarded to Children's National by the U.S. Department of Defense. During the three month period ended September 30, 2009, the Company recognized \$0.8 million in revenue under this contract. During the nine month period ended September 30, 2009, the Company recognized \$1.8 million in revenue under this contract.

In September 2009, the Company and Charley's Fund, Inc. (Charley's Fund), a nonprofit organization that funds drug discovery and development initiatives specific to DMD, entered into the First Amendment to an existing Sponsored Research Agreement (the Amendment). The Amendment pertains to certain provisions of the Sponsored Research Agreement by and between the Company and Charley's Fund entered into effective October 12, 2007 (the Agreement). Under the terms of the Amendment, the Company was awarded an additional \$3 million in sponsored research funds, for a total of \$5 million from Charley's Fund to support a new product development program using proprietary exon skipping technologies developed by the Company to overcome the effects of certain genetic errors in the dystrophin gene.

In July 2009, the Company entered into a lease agreement with BMR-3450 Monte Villa Parkway LLC relating to the lease of 19,108 square feet of laboratory and office space in Bothell, Washington. The Company began occupying this space in August 2009, and has moved its headquarters and R&D functions to this new location. The term of the lease is approximately 63 months, although the Company has a one-time option to terminate the lease after 3 years' time upon payment of a termination fee. The Company will commence paying base rent of approximately \$43,000 per month after approximately 3 months. The amount of base rent is subject to an annual increase of 3%.

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

Note 8. Stock Compensation

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

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The fair market 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 weighted average assumptions:

| Three and Nine Months Ended September 30, | 2009 | 2008 |
|--|-------------|---------------|
| Risk-free interest rate | 1.2%-1.6% | 1.9%-4.4% |
| Expected dividend yield | 0% | 0% |
| Expected lives | 9.0 years | 3.6-9.1 years |
| Expected volatility | 92.0%-94.2% | 81.0%-90.7% |

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

As prescribed by ASC 718 10, 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.

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A summary of the Company's stock option compensation activity with respect to the nine months ended September 30, 2009 follows:

| Stock Options | Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|---|-------------|--|---|---------------------------------|
| Outstanding at January 1, 2009 | 7,540,873 | \$ 3.34 | | |
| Granted | 2,566,000 | \$ 1.07 | | |
| Exercised | (48,433) | \$ 1.71 | | |
| Canceled or expired | (1,129,337) | \$ 2.81 | | |
| Outstanding at September 30, 2009 | 8,929,103 | \$ 2.79 | 6.51 | \$ |
| Vested at September 30, 2009 and expected to vest | 8,853,919 | \$ 2.80 | 3.73 | \$ |
| Exercisable at September 30, 2009 | 5,169,920 | \$ 3.94 | 4.73 | \$ |

The weighted average fair value per share of stock-based payments granted to employees during the nine months ended September 30, 2009 and September 30, 2008 was \$1.07 and \$1.04, respectively. During the same periods, the total intrinsic values of stock options exercised were \$1.71 and \$1.31. The total fair value of stock options that vested for the three and nine month periods ended September 30, 2009, was \$446,000 and \$1,450,000, respectively. The total fair value of stock options that vested for the three and nine months of 2008 was \$1,019,000 and \$2,637,000, respectively.

As of September 30, 2009, there was \$3,262,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. These costs are expected to be recognized over a weighted-average period of 2.3 years. As of September 30, 2008, there was \$3,022,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. These costs were expected to be recognized over a weighted-average period of 2.0 years.

During the three and nine month periods ended September 30, 2009, 43,439 and 48,433 stock options were exercised. The Company is obligated to issue shares reserved under the 2002 Equity Incentive Plan upon the exercise of stock options. The Company does not currently expect to repurchase shares from any source to satisfy its obligations under the Plan.

The 2000 Employee Stock Purchase Plan (ESPP) provides that eligible employees may contribute, through payroll deductions, of up to 10% of their cash compensation toward the purchase of the Company's Common Stock at 85% of the fair market value at specific dates. On January 1, 2006, the Company adopted ASC 718 10, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors related to the ESPP, based on estimated fair values. During the three month and nine month periods ended September 30, 2009 and 2008, the total compensation expense for participants in the ESPP was immaterial.

In the three month period ended June 30, 2009, the Company granted a total of 25,000 shares of restricted stock to members of its Board of Directors. These shares vest over a period of one year. During the three and nine month periods ended September 30, 2009, the Company recognized compensation expense related to these shares of \$24,000 and \$27,000, respectively.

Also in the three month period ended June 30, 2009, the Company granted 100,000 shares of restricted stock to its Vice President of Business Development. These shares vest upon the achievement of certain performance milestones. During the three and nine month periods ended September 30, 2009, the Company did not recognize any compensation expense related to these shares as the achievement of the performance milestones was not considered probable.

In the three month period ended March 31, 2009, the Company granted 60,000 shares of restricted stock to its Chief Medical Officer. These shares vest over a period of 181 days. During the three and nine month periods ended September 30, 2009 the Company recognized compensation expense related to these shares of \$11,000 and \$82,000, respectively.

In the three month period ended March 31, 2008, the Company granted 333,000 shares of restricted stock to its new Chief Executive Officer. Of these shares, 100,000 vested immediately and the remaining 233,000 vest over a period of four years. During the three month periods ended September 30, 2009 and 2008, the Company recognized compensation expense related to these shares of \$16,000 and \$16,000, respectively. During the nine month period ended September 30, 2009 and 2008, the Company recognized compensation expense related to these shares of \$48,000 and \$150,000, respectively.

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

| (in thousands) | Three Months Ended September 30, 2009 | | Nine Months Ended September 30, 2009 | |
|----------------------------|--|-----|---|-------|
| Research and development | \$ | 205 | \$ | 826 |
| General and administrative | | 241 | | 624 |
| Total | \$ | 446 | \$ | 1,450 |

| (in thousands) | Three Months Ended September 30, 2008 | | Nine Months Ended September 30, 2008 | |
|----------------------------|--|-------|---|-------|
| Research and development | \$ | 342 | \$ | 1,233 |
| General and administrative | | 677 | | 1,404 |
| Total | \$ | 1,019 | \$ | 2,637 |

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with ASC 505 50, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The fair value of the options granted is expensed when the measurement date is known. The performance for services was satisfied on the grant date for stock options granted to non-employees.

The total fair value of the options granted to non-employees during the three months ended September 30, 2009 and 2008 was \$64,000 and \$63,000 respectively, which was expensed to general and administration. The total fair value of the options granted to non-employees during the nine months ended September 30, 2009 and 2008 was \$142,000 and \$180,000 respectively, which was expensed to general and administration.

Note 9. Warrants

Certain of the Company's warrants issued in connection with financing arrangements are classified as liabilities in accordance with ASC 815 40, *Accounting for derivative financial instruments indexed to, and potentially settled in, a Company's own stock*. These are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities. The fair market value of these warrants is recorded on the balance sheet at issuance and marked to market at each financial reporting period. The change in the fair value of the warrants is recorded in the Statement of Operations as an (increase) decrease of the warrant liability and is estimated using the Black-Scholes option-pricing model with the following weighted average assumptions:

| Three and Nine Months Ended September 30, | 2009 | 2008 |
|---|---------------|---------------|
| Risk-free interest rate | 0.2%-2.4% | 0.9%-3.0% |
| Expected dividend yield | 0% | 0% |
| Expected lives | 0.1-5.0 years | 0.2-4.2 years |
| Expected volatility | 83.2%-140.6% | 63.6%-78.50% |
| Warrants classified as liabilities | 30,203,466 | 9,121,946 |

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| | | | | |
|--|----|-----------|----|-----------|
| Warrants classified as equity | | 2,129,530 | | 2,129,530 |
| Market value of stock at beginning of year | \$ | 0.66 | \$ | 1.41 |
| Market value of stock at end of period | \$ | 1.72 | \$ | 1.21 |

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

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For warrants classified as permanent equity in accordance with ASC 815 40, the fair value of the warrants is recorded as additional paid-in capital and no further adjustments are made. A summary of the Company's warrant activity with respect to the nine months ended September 30, 2009 is as follows:

| Warrants | Shares | Weighted Average Exercisable Price | Weighted Average Remaining Contractual Term |
|-----------------------------------|-------------|---|---|
| Outstanding at January 1, 2009 | 10,123,759 | \$ 8.54 | |
| Granted (Note 12) | 24,369,238 | \$ 1.41 | |
| Canceled or expired | (2,160,001) | \$ | |
| Outstanding at September 30, 2009 | 32,332,996 | \$ 3.40 | 4.26 |

Note 10. Earnings Per Share

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

Three Months Ended September 30,**(amounts in thousands, except per-share data)**

| | 2009 | 2008 |
|---|------------|------------|
| Net loss | \$ (8,090) | \$ (6,047) |
| 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 | 95,261 | 71,151 |
| Dilutive effect of warrants and stock options after application of the treasury stock method | * | * |
| Weighted average number of common shares outstanding for computing diluted earnings per share | 95,261 | 71,151 |
| Net loss per share - basic and diluted | \$ (0.08) | \$ (0.08) |

Nine Months Ended September 30,**(amounts in thousands, except per-share data)**

| | 2009 | 2008 |
|---|-------------|-------------|
| Net loss | \$ (28,684) | \$ (22,812) |
| 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 | 87,493 | 69,160 |
| Dilutive effect of warrants and stock options after application of the treasury stock method | * | * |
| Weighted average number of common shares outstanding for computing diluted earnings per share | 87,493 | 69,160 |
| Net loss per share - basic and diluted | \$ (0.33) | \$ (0.33) |

* Warrants and stock options to purchase 41,262,099 and 19,877,459 shares of common stock as of September 30, 2009 and 2008, respectively, were excluded from the earnings per share calculation as their effect would have been anti-dilutive.

Note 11. Comprehensive Loss and Securities Available for Sale

For the three and nine month periods ended September 30, 2009 and 2008, the Company's comprehensive loss was equal to the net loss.

Note 12. Equity Financing

On January 30, 2009, the Company closed a registered equity financing for net proceeds of \$15.5 million with several institutional investors. The Company sold 14,224,202 shares of common stock at \$1.16 per share, and also issued warrants for the purchase of 14,224,202 common shares at \$1.16 per share. These warrants are exercisable starting July 30, 2009 and expire on July 30, 2014. In connection with the equity financing, the placement agent received a warrant for the purchase of an additional 426,726 common shares at \$1.45 per share. This warrant is exercisable starting January 30, 2009 and expires on January 30, 2014. All of these warrants have been classified as liabilities as discussed in Note 9, as they require the issuance of registered shares.

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On August 25, 2009, the Company closed a registered equity financing for net proceeds of \$32.3 million with several institutional investors. The Company sold 24,295,775 shares of common stock at \$1.42 per share, and also issued warrants for the purchase of 9,718,310 common shares at \$1.78 per share. These warrants are exercisable starting February 25, 2010 and expire on August 25, 2014. All of these warrants have been classified as liabilities as discussed in Note 9, as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

The Company plans to use the net proceeds from the offering to fund clinical trials for its lead product candidates, to fund the advancement of its pre-clinical programs, and for other research and development and general corporate purposes.

Note 13. Income Taxes

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 September 30, 2009 and at December 31, 2008, and has not recognized interest and/or penalties in the statement of operations for the three and nine month periods ended September 30, 2009.

At September 30, 2009, the Company had net deferred tax assets of approximately \$103 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules under Section 382 could limit the future use of its net operating loss and R&D credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

Note 14. Property Held for Sale

The Company has listed for sale an industrial property located in Corvallis Oregon for a sales price of \$2.5 million. Selling and closing expenses are estimated to be \$0.1 million. The Company has decided to outsource its large scale manufacturing activities and has listed this property for sale with a commercial real estate agent.

Note 15. Recent Accounting Pronouncements

During the first fiscal quarter of 2009, the Financial Accounting Standards Board (FASB) issued ASC 820 10 65-65-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability has Significantly Decreased and the Identifying Transactions That Are Not Orderly*, ASC 320 10 65-65-1, *Recognition and Presentation of Other-Than-Temporary Impairments*, and ASC 825 10 65 65-1, *Interim Disclosures about Fair Value of Financial Instruments*. These were issued to clarify the application of ASC 820 10 65-65-4, *Fair Value Measurements* in the current economic environment, modify the recognition of other-than-temporary impairments of debt securities, and require companies to disclose the fair value of financial instruments in interim periods. These accounting updates are effective for interim and annual periods ending after September 15, 2009, with early adoption permitted for periods ending after March 15, 2009, if all three or both the

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fair-value measurement and other-than-temporary impairment are adopted simultaneously. The Company has adopted all three of these updates in the third quarter of 2009, and there was no material impact on the Company's Financial Statements or related disclosures.

In May 2009, the FASB issued ASC 855 10, *Subsequent Events*, which establishes the accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the Company to disclose the date through which subsequent events have been evaluated, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. The Company adopted ASC 855 10 during the second quarter of 2009. There was no material impact on the Company's financial statements.

In April 2009, the FASB issued ASC 320 10 65-65-1, *Recognition and Presentation of Other-Than-Temporary Impairments*, which requires the Company to disclose information for interim and annual periods that enables users of its financial statements to understand the types of available-for-sale and held-to-maturity debt and equity securities held, including information about investments in an unrealized loss position for which an other-than-temporary impairment has or has not been recognized. The provisions of this update and were adopted in the second quarter of 2009. There was no material impact on the Company's financial statements.

In April 2009, the FASB issued ASC 825 10 65 65-1, *Interim Disclosures about Fair Value of Financial Instruments*, which requires publicly traded companies to include disclosures about the fair value of its financial instruments whenever it issues summarized financial information for interim reporting periods. The provisions of this update were adopted in the second quarter of 2009. There was no material impact on the Company's financial statements.

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Note 16. Subsequent Events

The Company has evaluated all other subsequent events through November 9, 2009, the date of this filing, and determined there are no material recognized or unrecognized subsequent events.

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

This section should be read in conjunction with the same titled section contained in our Annual Report on Form 10-K as filed with the SEC for the year ended December 31, 2008 and the Risk Factors contained in the 10-K and this report.

Forward-Looking Information

The Financial Statements and Notes thereto should be read in conjunction with the following discussion. The discussion in this Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. Forward-looking statements are identified by such words as believe, expect, anticipate and words of similar import. 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. Such forward-looking statements involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the success of raising funds in the current offering or future offerings under our current shelf registration, the results of pre-clinical and clinical testing, the effect of regulation by FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the Company's Securities and Exchange Commission filings, that could cause actual results to differ materially from the expected results reflected in such forward looking statements.

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest, license fees, government and other grants and research contracts, we have had no material revenues from the sale of products or other sources and we do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development efforts and enter into additional collaborative efforts. As of September 30, 2009, our accumulated deficit was \$279 million.

Revenues for the third quarter of 2009 were \$6.3 million, compared to \$5.2 million in the prior-year period, reflecting increases in research contract revenue of \$1.1 million. Revenues for the first nine months of 2009 were \$12.4 million, compared to \$15.8 million in the first nine months of 2008, reflecting decreases in research contract revenues of \$3.4 million.

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The operating loss for the three months ended September 30, 2009 decreased to \$2.9 million from an operating loss of \$5.9 million from the same period in the prior year. The operating loss for the nine months ended September 30, 2009 decreased to \$11.6 million from \$24.6 million for the prior year period. The operating loss for the third quarter of 2009 was less than the loss from the third quarter of 2008 as the result of lower general and administrative costs associated with the resignation of former executive officers and relocation costs of new executive officers. Additionally, the operating loss reduction for the nine months period reflects the \$9.9 million expense for acquired in-process research and development from the Ercole acquisition present only in 2008 and lower spending in 2009 on research and development related primarily to government research contracts.

The net loss for the third quarter of 2009 was \$8.1 million, or \$(0.08) per share, compared with a net loss for the third quarter of 2008 of \$6.0 million, or \$(0.08) per share. The net loss for the third quarter of 2009 includes a non-cash expense for an increase in the warrant valuation liability of \$5.0 million compared to a loss from the same source of \$0.2 million during the third quarter of 2008. For the nine months ending September 30, 2009, the Company reported a net loss of \$28.7 million, or \$(0.33) per share, compared with a net loss for the comparable period in 2008 of \$22.8 million, or \$(0.33) per share. The net loss for the nine months ending September 30, 2009 includes a non-cash expense for warrant liability of \$17.0 million compared to a gain of \$1.4 million during the same period of 2008. These are non-cash charges, the Company is not required to expend any cash to settle these liabilities. An increase in warrant valuation is a non-cash expense and is the result of new warrants issued and the increase in the Company's stock price subsequent to the issuance of new warrants as a part of the equity financings that closed in January and August of 2009. The increase or decrease on the warrant valuation will fluctuate as the market price of the Company's stock fluctuates.

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Results of Operations

Three Months Ended September 30, 2009 Compared to the Three Months Ended September 30, 2008

Revenues from license fees, grants and research contracts increased to \$6.3 million in the three months ended September 30, 2009 from \$5.2 million in the comparable period in 2008. The increase in research contracts revenues was the result of the increase in revenues from government research contracts.

Operating loss decreased to \$2.9 million in the three months ended September 30, 2009 compared to \$5.9 million in the comparable period in 2008. The operating loss declined in the third quarter of 2009 as the result of higher government revenues combined with lower research and development expenses and lower general and administrative expenses.

Research and development expenses decreased to \$7.5 million in the three months ended September 30, 2009 compared to \$7.7 million in the comparable period in 2008. This decrease was due primarily to decreases in research and development costs related to the government research contracts. General and administrative expenses declined to \$1.8 million in the three months ended September 30, 2009 compared to \$3.4 million in the comparable period in 2008. The third quarter of 2008 contained higher severance and stock compensation expenses from the resignation of a former executive officer and the relocation costs of new executive officers.

Interest expense and other net for the three months ended September 30, 2009 includes a write down of \$0.1 million for property held for sale. The increase on warrant liability valuation for the three months ended September 30, 2009 of \$5.0 million is a non-cash expense and is the result of the increase in the Company's stock price subsequent to the issuance of warrants as a part of the equity financings that closed in January and August of 2009. The decrease or increase on the warrant liability valuation will fluctuate as the market price of the Company's stock fluctuates.

Nine Months Ended September 30, 2009 Compared to the Nine Months Ended September 30, 2008

Revenues from license fees, grants and research contracts decreased to \$12.4 million in the nine months ended September 30, 2009 compared to \$15.8 million in the comparable period in 2008. The decrease in research contracts revenues was the result of the decline in revenues from government research contracts.

Operating loss decreased to \$11.6 million in the nine months ended September 30, 2009 compared to \$24.6 million in the comparable period in 2008. In the nine months ended September 30, 2008, the operating loss included a one-time charge of \$9.9 million for acquired in-process research and development associated with the acquisition of Ercole Biotech, Inc. The operating loss in the nine months ended September 30, 2009 also decreased compared to the comparable period in 2008 as a result of lower research and development expenses and lower general and administrative expenses.

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Research and development expenses decreased to \$17.8 million in the nine months ended September 30, 2009 compared to \$22.3 million in the comparable period in 2008 due to lower spending in 2009 on research and development related primarily to government research projects.

General and administrative expenses decreased to \$6.2 million in the nine months ended September 30, 2009 compared to \$8.2 million in the comparable period in 2008. The decrease in general and administrative expenses was due primarily to non-cash costs recognized in the nine months ended September 30, 2008 primarily due to stock compensation paid to Ercole executives related to the 2008 acquisition, severance and stock compensation expenses related to the resignation of former executive officers, and relocation costs for new executive officers.

Net interest income declined in the nine months ended September 30, 2009 as compared to the comparable period in 2008 primarily due to declines in market rates of interest on the Company's interest-earning investments and the write off of valuations for patents, property and equipment.

The increase in the warrant liability valuation of \$17.0 million for the nine months ended September 30, 2009 compared to the decrease in the warrant liability valuation of \$1.4 million in the comparable period in 2008, is a non-cash expense and is the result of new warrants issued and the increase in the Company's stock price subsequent to the issuance of new warrants as a part of the equity financings that closed in January and August of 2009. The decrease or increase on the warrant liability valuation fluctuates as the market price of the Company's stock fluctuates.

Liquidity and Capital Resources

We have financed our operations since inception primarily through sales of common stock and other forms of equity totaling \$262.9 million and from revenues from license fees, grants and research contracts of \$54.7 million from various sources. In January 2009, we raised net proceeds of \$15.5 million in financing through the sale of 14,224,202 shares of common stock pursuant to a registered direct offering to a select group of institutional investors. The investors also received warrants to purchase 14,224,202 shares of the Company's common stock. These warrants are exercisable starting July 30, 2009 and expire on July 30, 2014. In addition, the placement agent used for the equity financing received a warrant for the purchase of an additional 426,726 common shares at \$1.45 per share. This warrant is exercisable starting January 30, 2009 and expires on January 30, 2014. All of these warrants have been classified as liabilities as discussed in Note 9, as they require the issuance of registered shares.

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On August 25, 2009, the Company closed a registered equity financing for net proceeds of \$32.3 million with several institutional investors. The Company sold 24,295,775 shares of common stock at \$1.42 per share, and also issued warrants for the purchase of 9,718,310 common shares at \$1.78 per share. These warrants are exercisable starting February 25, 2010 and expire on August 25, 2014. All of these warrants have been classified as liabilities as discussed in Note 9, as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

We plan to use the net proceeds from these offering to fund clinical trials for our lead product candidates, to fund the advancement of our pre-clinical programs, and for other research and development and general corporate purposes.

We expect to continue to incur losses as we continue to expand our research and development activities and related regulatory work and increase our collaborative efforts. For 2009, we expect our expenditures for operations, net of government funding, including our collaborative efforts, and our GMP facilities to be approximately \$10 to \$12 million. This cost could increase if we undertake additional collaborative efforts. However, if necessary in 2009, we believe we can reduce our expenditures because a significant amount of our costs are variable. Those estimated expenditures include amounts necessary to fulfill our obligations under our various collaborative, research and licensing agreements during 2009. The Company believes it will continue to receive funding from government and other sources to pursue the development of its product candidates, and has assumed certain revenues from these awards in providing this guidance. Should the Company not continue to receive funding from its current contracts or not receive additional funding, or should the timing be delayed, it may have a significant negative impact on the Company's guidance.

Because of the cost (up to \$1.318 billion) and timeframe (of 10 to 15 years) as published (Wiley InterScience, ©2007 John Wiley and Sons, LTD), and generally associated with developing a potential drug or pharmaceutical product to the point of approval by the FDA or other regulatory agencies for human use, our business strategy is to develop our products up to Phase II human clinical trials and then look for third parties to fund further development of the product and to market the product through strategic partnerships, license agreements or other relationships. We also look for collaborative and other efforts, such as our relationship with Cook, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We believe that this strategy will reduce the potential costs we would otherwise incur in developing a product and bringing it to market. Our expected costs under our various contracts and for various drug development products can be estimated for the next year or two, but not much beyond that due to the uncertainty of clinical trial results, research results and the timing of securing one or more partners to develop and market a potential drug.

Because of the various factors noted above and the expectation that, until we establish revenue sources, we will license or jointly develop our prospective products to or with strategic partners, we review, at least annually, each research program and clinical trial based on results and progress during the prior year and estimate our needs for that program or trial for the coming year, making adjustments based on the progress of the program during the year.

The Company is in the development stage. Since its inception in 1980 through September 30, 2009, the Company has incurred losses of approximately \$279 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company expects to incur operating losses over the next several years.

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The financial statements have been prepared assuming that the Company will continue as a going concern. The Company's ability to achieve a profitable level of operations in the future will depend in large part on completing product development of its RNA-based products, obtaining regulatory approvals for such products, and bringing these products to market. During the period required to develop these products, the Company may require substantial additional financing. There can be no assurance that such financing will be available when needed or that the Company's planned products will be commercially successful. The Company believes it has sufficient cash to fund operations at least through the following twelve months, exclusive of future receipts from billings on existing government contracts. For 2009, the Company expects expenditures for operations, net of government funding, including collaborative efforts and research and development activities to be approximately \$10 to \$12 million. This could increase if the Company undertakes additional collaborative efforts. However, if necessary in 2009, the Company believes it can reduce its expenditures because a significant amount of its costs are variable. Those estimated expenditures include amounts necessary to fulfill the Company's obligations under its various collaborative, research and licensing agreements during 2009. The Company believes it will continue to receive funding from government and other sources to pursue the development of its product candidates, and has assumed certain revenues from these awards in providing this guidance. Should the Company not continue to receive funding from its current contracts or not receive additional funding, or should the timing be delayed, it may have a significant negative impact on the Company's guidance.

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The Company currently has a total of \$61.7 million of contracted development studies. As of September 30, 2009, \$44 million has been billed, of which \$38.3 million has been received in cash and \$5.7 million is in accounts receivable. The Company has \$17.7 in development contracts remaining that have not yet been completed and have not been billed. The Company expects to complete the remaining contract activity and receive the contracted revenue in 2010 and early 2011.

In December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. In May 2009, the Company received an amendment from DTRA to extend the contract performance period to November 29, 2009 and a cost modification of an additional \$5.9 million, increasing the total contract amount to \$33.9 million. In September 2009, the Company received a second amendment from DTRA to extend the contract performance period to February 28, 2011 and a cost modification of an additional \$11.5 million, increasing the total contract amount to \$45.4 million.

During the three month periods ended September 30, 2009 and 2008, the Company recognized \$4.4 million and \$4.9 million, respectively, in research contract revenue from this contract. During the nine month periods ended September 30, 2009 and 2008, the Company recognized \$7.5 million and \$13.6 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenues of \$32.3 million from this contract. Funding of the remainder of the contract is anticipated in 2010 and 2011.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company's technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company has received signed contracts for all of these projects. The Company expects that funding under these signed contracts will be completed over the next 12 months. During the three month periods ended September 30, 2009 and 2008, the Company recognized \$0.3 million and \$0.2 million, respectively, in research contract revenue from these contracts. During the nine month periods ended September 30, 2009 and 2008, the Company recognized \$1.9 million and \$2.1 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenues of \$8.8 million on these contracts. Funding of the remainder of these contracts is anticipated in 2010.

In May 2009, the Company entered into a contract with the U.S. Defense Threat Reduction Agency (DTRA) to develop swine flu drugs. Under this contract, DTRA will pay up to \$4.1 million to the Company for the work to be performed by the Company. The work will involve the application of the Company's proprietary PMO and PMO*plus* antisense chemistry and the Company plans to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. During the three month period ended September 30, 2009, the Company recognized \$0.7 million in revenue under this contract. During the nine month period ended September 30, 2009, the Company recognized \$1.1 million in revenue under this contract.

Also in May 2009, the Company entered into a \$2.5 million contract with Children's National Medical Center in Washington, D.C. to support preclinical studies in the development of AVI-4658 for treatment of Duchenne Muscular Dystrophy. The work will be conducted with Children's National collaborators Eric Hoffman, Ph.D., an authority on DMD and Professor of Pediatrics, and Edward Connor, M.D., Director, Office of Investigational Therapeutics and Professor of Pediatrics. AVI will serve as a subcontractor to a grant awarded to Children's National by the U.S. Department of Defense. During the three month period ended September 30, 2009, the Company recognized \$0.8 million in revenue under this contract. During the nine month period ended September 30, 2009, the Company recognized \$1.8 million in revenue under this contract.

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In September 2009, the Company and Charley's Fund, Inc. (Charley's Fund), a nonprofit organization that funds drug discovery and development initiatives specific to DMD, entered into the First Amendment to an existing Sponsored Research Agreement (the Amendment). The Amendment pertains to certain provisions of the Sponsored Research Agreement by and between the Company and Charley's Fund entered into effective October 12, 2007 (the Agreement). Under the terms of the Amendment, the Company was awarded an additional \$3 million in sponsored research funds, for a total of \$5 million from Charley's Fund to support a new product development program using proprietary exon skipping technologies developed by the Company to overcome the effects of certain genetic errors in the dystrophin gene.

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In July 2009, the Company entered into a lease agreement with BMR-3450 Monte Villa Parkway LLC relating to the lease of 19,108 square feet of laboratory and office space in Bothell, Washington. The Company began occupying this space in August 2009, and has moved its headquarters and R&D functions to this new location. The term of the lease is approximately 63 months, although the Company has a one-time option to terminate the lease after 3 years time upon payment of a termination fee. The Company will commence paying base rent of approximately \$43,000 per month after approximately 3 months. The amount of base rent is subject to an annual increase of 3%.

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

Our cash, cash equivalents and short-term securities were \$50.4 million at September 30, 2009, compared with \$11.5 million at December 31, 2008. The increase of \$38.9 million was due primarily to net proceeds of \$47.8 million from the sale of common stock and issuance of stock warrants from two separate equity financing transactions that closed in January and August of 2009.

The cash from financing activities was partially offset by cash used in operations of \$7.7 million and costs related to acquisitions of patents and fixed assets of \$1.0 million.

We do not expect any material revenues in 2009 from our business activities except for revenues from U.S. government contracts and other agreements. We expect that our cash requirements for the next twelve months will be satisfied by existing cash resources and these revenues. To fund our operations beyond the next twelve months, we may need to raise additional capital. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility and do not intend to seek one.

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. The Company's critical accounting policies and estimates are consistent with the disclosure in the Company's Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There has been no material change in the Company's market risk exposure since the filing of our 2008 Annual Report on Form 10-K.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of September 30, 2009, the Company carried out an evaluation, under the supervision and with the participation of its management, including its Chief Executive Officer and its Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures pursuant to Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on this review of its disclosure controls and procedures, the Chief Executive Officer and the Chief Financial Officer have concluded that its disclosure controls and procedures are effective in timely alerting them to material information relating to the Company that is required to be included in our periodic SEC filings.

Changes in Internal Controls Over Financial Reporting

There were no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

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PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None

Item 1A. Risk Factors.

Risks Affecting Future Operating Results

The following factors should be considered in evaluating our business and prospects for the future. If risks described below actually occur, our operating results and financial condition would likely suffer and the trading price of our common stock may fall, causing a loss of some or all of an investment in our common stock. In addition, there may be additional risks not known to us or understood by us, which may adversely affect our financial condition, results of operations, and the price of our stock.

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

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

If necessary, potential sources of additional funding could include strategic relationships, public or private sales of shares of our stock, debt, or other arrangements. We may not be able to obtain additional funding when we need it on terms that will be acceptable to us or at all. If we raise funds by selling additional shares of our common stock or securities convertible into our common stock, the ownership interest of our existing shareholders will be diluted. If we were unable to obtain financing when needed, our business and future prospects would be materially adversely affected.

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

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

We rely on U.S. government contracts to support several important R&D programs.

We rely on U.S. government contracts and awards to fund several of our development programs, including those for the Ebola, Marburg, Junin and swine flu viruses. The termination of one or more of these 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 revenues lost as a result of any termination of our contracts.

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. In the event that 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 sales under such a 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 accepted by the government. A termination arising out of our default could expose us to liability and have a negative impact on our ability to obtain future contracts.

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If we fail to receive or experience delays in receiving necessary regulatory approvals, we will be unable to develop and commercialize our products.

All of our products are subject to extensive regulation by the United States Food and Drug Administration, or FDA, and by comparable agencies in other countries. The FDA and these agencies require new pharmaceutical products to undergo lengthy and detailed preclinical and clinical testing procedures and other costly and time-consuming compliance procedures. We do not know when, or if, we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies. We expect to develop the therapeutic product candidates to treat Ebola Virus and Marburg Virus under defined regulatory pathways using the Animal Rule mechanism. This mechanism has become available only relatively recently and has been infrequently used. This process has yet to be well tested and may present challenges for gaining final regulatory approval for these product candidates.

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

The loss of key employees could significantly delay the achievement of our goals. Competition for qualified personnel in our industry is intense, and our success will depend on our ability to attract and retain highly skilled personnel. To date, we have been successful in attracting and retaining key personnel. We now have added emphasis on product development in our business plan. In addition, we are building a new chemistry-led research capability in Bothell, Washington and have outsourced our large scale manufacturing capability in Corvallis, Oregon. This short term transformation of our skill base has placed additional emphasis on our ability to attract and retain skilled personnel.

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 environment is highly competitive and competing intellectual property could limit our ability to protect our products.

Our success will depend on our existing patents and licenses (185 patents (domestic and foreign) issued or licensed to us and 176 (domestic and foreign) pending patent applications) and our ability to obtain additional patents in the future. We license patents from other parties for certain complementary technologies.

Some of our patents on core technologies expired in 2008, including for our general PMO chemistry. Based on patented improvements and inventive additions to such core patents, however, we believe the patent protection for our products in development extend beyond 2020.

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. We are aware of a patent that has issued that may provide the basis for the patent holder to assert that our drug AVI-4658 infringes on such patent. We intend to vigorously defend any such claim if it should be asserted and believe that we may be able to invalidate some or all

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of the claims covered by this patent. In any case, we believe that we have freedom to and are moving forward with our ongoing clinical trials and drug development efforts for this drug candidate.

Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of biotechnology firms generally is highly uncertain, involves complex legal and factual questions, and has recently been the subject of much litigation. No consistent policy has emerged from the United States Patent and Trademark Office (USPTO) or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition, there is a substantial backlog of biotechnology patent applications at the USPTO and the approval or rejection of patents may take several years.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. Any required license may not be available to us on acceptable terms, or at all. If we fail to obtain a license, our business might be materially adversely affected.

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

We depend on our partners and contractors for critical functions. Therefore, if our collaborations or strategic relationships are unsuccessful, our business could be harmed.

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

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

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

We may get unexpected results from, or encounter challenges from our clinical studies.

All clinical studies, including phase III or pivotal studies, need to be agreed with regulatory authorities beforehand and successfully executed. Preclinical as well as clinical studies are experiments designed to test a theory or hypothesis, and by their very nature, the result is unknown at the time the study is started. Sometimes unexpected results occur and the product does not demonstrate effectiveness (even though it might be effective), or an unexpected safety issue may be encountered.

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

We incurred a net loss of \$28.7 million for the nine months ended September 30, 2009 and \$24.0 million for the year ended December 31, 2008. As of September 30, 2009, our accumulated deficit was \$279 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

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business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

Our ability to be successful against our competitors cannot be assured.

The biopharmaceutical industry is highly competitive, with a number of well-established firms performing leading-edge research for the development of new products to treat a wide range of diseases. These companies have obtained patents for their intellectual property rights that could preclude other companies from using similar technologies in their product development. Moreover, companies that are focused on the treatment of similar diseases are in effect competing for the same limited number of potential patients. Even if we are able to develop new products for market, there can be no assurance that we will be able to compete effectively or profitably against our competitors.

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

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

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We use hazardous substances in our research activities.

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

Risks Related to Share Ownership

Our right to issue preferred stock, our classified Board of Directors and Oregon Anti-Takeover laws may delay a takeover attempt and prevent or frustrate any attempt to replace or remove the then current management of the Company by shareholders.

Our authorized capital consists of 200 million shares of common stock and 20 million shares of preferred stock. Our Board of Directors, without any further vote by the shareholders, has the authority to issue preferred shares and to determine the price, preferences, rights and restrictions, including voting and dividend rights, of these shares. The rights of holders of any preferred shares that our Board of Directors may issue in the future may affect the rights of the holders of shares of common stock. For example, our Board of Directors may allow the issuance of preferred shares with more voting rights, preferential dividend payments or more favorable rights upon dissolution than the shares of common stock or special rights to elect directors.

In addition, we have a classified Board of Directors, which means that only one-half of our directors are eligible for election each year. Therefore, if shareholders wish to change the composition of our Board of Directors, it could take at least two years to remove a majority of the existing directors or to change all directors. Having a classified Board of Directors may, in some cases, delay mergers, tender offers or other possible transactions that may be favored by some or a majority of our shareholders and may delay or frustrate action by shareholders to change the then current Board of Directors and management.

The Oregon Control Share Act and Business Combination Act may limit parties that acquire a significant amount of voting shares from exercising control over us for specific periods of time. These acts may lengthen the period for a proxy contest or for a person to vote their shares to elect the majority of our Board and change management.

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

Historically, the market price of our stock has been highly volatile. The following types of announcements could have a significant impact on the price of our common stock: positive or negative results of testing and clinical trials by ourselves, strategic partners, or competitors; delays in entering into corporate partnerships; technological innovations or commercial product introductions by ourselves or competitors; changes in government regulations; developments concerning proprietary rights, including patents and litigation matters; public concern relating to the commercial value or safety of any of our products; financing or other corporate transactions; or general stock market conditions.

The significant number of our shares of Common Stock eligible for future sale may cause the price of our common stock to fall.

We have outstanding 110,433,113 shares of common stock as of September 30, 2009 and all are eligible for sale under Rule 144 or are otherwise freely tradable. In addition:

- Our employees and others hold options to buy a total of 8,929,103 shares of common stock, of which 5,169,920 options were exercisable at September 30, 2009. The options outstanding have exercise prices between \$0.60 and \$7.35 per share. The shares of common stock to be issued upon exercise of these options have been registered, and, therefore, may be freely sold when issued.
- There are outstanding warrants to buy 32,332,996 shares of common stock as of September 30, 2009 with exercise prices ranging from \$.0003 to \$35.63 per share. Outstanding warrants to buy 30,203,466 shares of common stock are issuable upon exercise of outstanding warrants for common stock registered for resale and may be freely sold when issued, subject to the limitations imposed by applicable securities laws.

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Warrants to purchase an aggregate of 2,129,530 shares of common stock are not registered for resale. These warrants include warrants to purchase an aggregate of shares of common stock were issued to ISIS Pharmaceuticals, Inc. (ISIS) in exchange for warrants to purchase shares of Ercole capital stock previously issued by Ercole to ISIS prior to the Company's acquisition of Ercole. Warrants to purchase an aggregate of 1,683,545 shares of common stock issued in 2000 and prior were issued as a part of a technology licensing agreement and to a former employee.

- We may issue options to purchase up to an additional 703,374 shares of common stock as of September 30, 2009 under our stock option plans, which also will be fully saleable when issued except to the extent limited under Rule 144 for resales by our officers and directors.
- We are authorized to sell up to 48,196 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate.

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

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. If a listed company fails to meet the \$1.00 minimum bid price per share requirement for 30 consecutive days, it will receive a notice from NASDAQ mandating that the company achieve compliance with the minimum bid price per share listing requirement within 90 calendar days. Our stock price is currently above \$1.00; however, our stock price was priced at \$0.99 as recently as May 11, 2009. There can be no assurance that we will be able to maintain compliance with the minimum bid price per share requirement in the future.

On October 16, 2008, NASDAQ suspended the minimum bid price per share requirement and market value for publicly held shares requirements for all listed companies through August 2, 2009. Recently, NASDAQ announced that it reinstated the minimum bid price per share requirement and market value for publicly held shares requirements for all listed companies on August 3, 2009. As of the date of this report, we meet these listing requirements.

In addition to the foregoing, if we are not listed on The NASDAQ Stock Market and/or if our public float remains below \$75 million, we may be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations might have a material adverse effect on our ability to raise the capital we need.

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

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

Item 1B. Unresolved Staff Comments.

None.

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

None.

Item 3. Defaults Upon Senior Securities.

None

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

None.

Item 5. Other Information.

None.

Table of Contents**Item 6. Exhibits**

| Exhibit No | Exhibit Description | Form | Incorporated by Reference to Filings Indicated | | | Filed Herewith |
|------------|--|-----------|--|---------|-------------|----------------|
| | | | File No. | Exhibit | Filing Date | |
| 3.1 | Third Restated Articles of Incorporation of AntiVirals Inc. | SB-2 | 333-20513 | 3.1 | 5/29/97 | |
| 3.2 | First Restated Bylaws of AVI BioPharma, Inc. | 8-K | 1-14895 | 3.5 | 2/7/08 | |
| 3.3 | First Amendment to Third Restated Articles of Incorporation | 8-K | 0-22613 | 3.3 | 9/30/98 | |
| 3.4 | Amendment to Article 2 of the Company s Third Restated Articles of Incorporation | s DEF 14A | 1-14895 | N/A | 4/11/02 | |
| 4.4 | Form of Common Stock Purchase Warrant | 8-K | 1-14895 | 4.4 | 1/30/09 | |
| 4.5 | Form of Common Stock Purchase Warrant | 8-K | 1-14895 | 4.1 | 8/24/09 | |
| 10.76 | Lease by and between BMR-3450 MONTE VILLA PARKWAY LLC, a Delaware limited liability company, and AVI BIOPHARMA, INC., an Oregon corporation | | | | | X |
| 10.77 | Amendment of Contract between AVI BioPharma, inc. and the U.S. Defense Threat Reduction Agency (contract no HDTRA 1-07-C-0010), effective September 30, 2009 | | | | | X |
| 31.1 | Certification of the Company s President and Chief Executive Officer, Leslie Hudson, Ph.D, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 31.2 | Certification of Chief Financial Officer, J . David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 | | | | | X |
| 32 | Certification of the Company s Chief Executive Officer, Leslie Hudson, Ph.D, and Chief Financial Officer, J. David Boyle II, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | | | | | X |

Portions of the materials in the exhibits marked with a + have been omitted pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Securities and Exchange Commission

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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: November 9, 2009

AVI BIOPHARMA, INC.

By: /s/ LESLIE HUDSON, Ph.D.
Leslie Hudson, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ J. DAVID BOYLE II
J. David Boyle II
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)