

AVI BIOPHARMA INC  
Form 10-Q  
November 09, 2010  
Table of Contents

**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, 2010

OR

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

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

Commission file number 001-14895

---

## AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

**Oregon**

(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)

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

---

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller reporting company)

Smaller Reporting Company

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

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

**Common Stock with \$0.0001 par value**  
(Class)

**112,323,950**  
(Outstanding as of November 4, 2010)

---

Table of Contents

AVI BIOPHARMA, INC.

FORM 10-Q

INDEX

	<b>Page</b>
<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements</u>
	<u>Balance Sheets – September 30, 2010 and December 31, 2009 (unaudited)</u> 2
	<u>Statements of Operations – Three Months and Nine Months Ended September 30, 2010 and 2009 and from July 22, 1980 (Inception) through September 30, 2010 (unaudited)</u> 3
	<u>Statements of Cash Flows – Nine Months Ended September 30, 2010 and 2009 and from July 22, 1980 (Inception) through September 30, 2010 (unaudited)</u> 4
	<u>Notes to Financial Statements (unaudited)</u> 5
<u>Item 2.</u>	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 13
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 21
<u>Item 4.</u>	<u>Controls and Procedures</u> 22
<u>PART II – OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u> 22
<u>Item 1A.</u>	<u>Risk Factors</u> 22
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 33
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u> 33
<u>Item 4.</u>	<u>(Removed and Reserved)</u> 33
<u>Item 5.</u>	<u>Other Information</u> 33
<u>Item 6.</u>	<u>Exhibits</u> 33
<u>Signatures</u>	34
<u>Exhibits</u>	35

Table of Contents**PART I FINANCIAL INFORMATION****Item 1. Financial Statements.**

AVI BIOPHARMA, INC.

(A Development Stage Company)

BALANCE SHEETS

(unaudited)

(in thousands, except per share data)

	September 30, 2010	December 31, 2009
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 35,967	\$ 48,275
Accounts receivable	5,241	2,085
Other current assets	1,106	950
Total Current Assets	42,314	51,310
Property held for sale	1,979	2,372
Property and Equipment, net of accumulated depreciation and amortization of \$14,678 and \$14,026	2,155	2,466
Patent Costs, net of accumulated amortization of \$1,870 and \$1,762	4,301	3,759
Other assets	111	120
Total Assets	\$ 50,860	\$ 60,027
<b>Liabilities and Shareholders Equity</b>		
Current Liabilities:		
Accounts payable	\$ 4,945	\$ 1,381
Accrued employee compensation	2,223	922
Long-term debt, current portion	80	77
Warrant valuation	33,118	27,609
Deferred revenue	3,335	3,428
Other liabilities	64	90
Total Current Liabilities	43,765	33,507
Commitments and Contingencies		
Long-term debt, non-current portion	1,863	1,924
Other long-term liabilities	1,069	966
Shareholders Equity:		
Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding		

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Common stock, \$.0001 par value, 200,000,000 shares authorized; 112,323,950 and 110,495,587 issued and outstanding		11		11
Additional paid-in capital		304,154		299,088
Deficit accumulated during the development stage		(300,002)		(275,469)
Total Shareholders' Equity		4,163		23,630
Total Liabilities and Shareholders' Equity	\$	50,860	\$	60,027

See accompanying notes to financial statements.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

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
	2010	2009	2010	2009	(Inception) through September 30, 2010
Revenues from license fees, grants and research contracts	\$ 8,702	\$ 6,353	\$ 13,903	\$ 12,448	\$ 73,712
Operating expenses:					
Research and development	9,059	7,473	22,080	17,770	252,512
General and administrative	3,440	1,800	11,017	6,226	85,037
Acquired in-process research and development					29,461
Operating loss	(3,797)	(2,920)	(19,194)	(11,548)	(293,298)
Other non-operating (loss) income:					
Interest (expense) income and other, net	82	(132)	170	(147)	8,493
(Increase) decrease on warrant valuation	(3,578)	(5,038)	(5,509)	(16,989)	(2,059)
Realized gain on sale of short-term securities available-for-sale					3,863
Write-down of short-term securities available-for-sale	(3,496)	(5,170)	(5,339)	(17,136)	(17,001)
					(6,704)
Net loss and comprehensive loss	\$ (7,293)	\$ (8,090)	\$ (24,533)	\$ (28,684)	\$ (300,002)
Net loss per share - basic and diluted	\$ (0.07)	\$ (0.08)	\$ (0.22)	\$ (0.33)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share (in thousands)	111,767	95,261	110,863	87,493	

See accompanying notes to financial statements.





Table of Contents

## AVI BIOPHARMA, INC.

(A Development Stage Company)

## STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine months ended September 30,		For the Period
	2010	2009	July 22, 1980 (Inception) through September 30, 2010
<b>Cash flows from operating activities:</b>			
Net loss	\$ (24,533)	\$ (28,684)	\$ (300,002)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	1,053	1,080	18,735
Loss on disposal of assets	274	221	1,579
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	393	128	1,321
Stock-based compensation	2,540	1,592	25,237
Conversion of interest accrued to common stock			8
Acquired in-process research and development			29,461
Increase (decrease) on warrant valuation	5,509	16,989	2,059
(Increase) decrease in:			
Accounts receivable and other current assets	(3,297)	(1,026)	(6,197)
Net increase in accounts payable, accrued employee compensation, and other liabilities	4,740	1,957	10,014
Net cash used in operating activities	(13,321)	(7,743)	(204,647)
<b>Cash flows from investing activities:</b>			
Purchase of property and equipment	(628)	(276)	(18,497)
Patent costs	(821)	(751)	(8,064)
Purchase of marketable securities	(5)	113	(112,991)
Sale of marketable securities			117,724
Acquisition costs			(2,389)
Net cash used in investing activities	(1,454)	(914)	(24,217)
<b>Cash flows from financing activities:</b>			
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants	2,525	47,782	265,462
Repayments of long-term debt	(58)	(49)	(245)
Buyback of common stock pursuant to rescission offering			(289)
Withdrawal of partnership net assets			(177)
Issuance of convertible debt			80
Net cash provided by (used in) financing activities	2,467	47,733	264,831

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Increase (decrease) in cash and cash equivalents	(12,308)		39,076		35,967
Cash and cash equivalents:					
Beginning of period	48,275		11,192		
End of period	\$ 35,967	\$	50,268	\$	35,967
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:					
Cash paid during the year for interest	\$ 70	\$	65	\$	375
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
Assumption of liabilities for Ercole assets	\$	\$	\$		2,124
Issuance of common stock and warrants in satisfaction of employee bonuses	\$	\$	239	\$	

See accompanying notes to financial statements.

Table of Contents

**AVI BIOPHARMA, INC.**

**NOTES TO FINANCIAL STATEMENTS**

**(Unaudited)**

**Note 1. Basis of Presentation**

The accompanying unaudited condensed consolidated financial statements reflect the accounts of AVI BioPharma, Inc. (the Company) and its consolidated subsidiaries. The accompanying unaudited condensed consolidated balance sheet data as of December 31, 2009 was derived from audited financial statements not included in this report. The accompanying unaudited condensed consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (SEC) pertaining to interim financial statements. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

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

The accompanying unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's annual report on Form 10-K for the year ended December 31, 2009. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

***Reclassifications***

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

***Estimates and Uncertainties***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

*Commitments and Contingencies*

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

**Note 2. Fair Value Measurements**

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

- Level 1 quoted prices for identical instruments in active markets;
  
- Level 2 quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active, and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets; and
  
- Level 3 valuations derived from valuation techniques in which one or more significant value drivers are unobservable.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

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

	Total	Fair Value Measurement as of September 30, 2010		
		Level 1	Level 2	Level 3
(in thousands)				
Cash equivalents	\$ 35,967	\$ 35,967		
Other current assets	459		\$ 459	
Total assets	\$ 36,426	\$ 35,967	\$ 459	\$

	Total	Fair Value Measurement as of September 30, 2010		
		Level 1	Level 2	Level 3
(in thousands)				
Warrants	\$ 33,118			\$ 33,118
Total liabilities	\$ 33,118	\$	\$	\$ 33,118

	Total	Fair Value Measurement as of December 31, 2009		
		Level 1	Level 2	Level 3
(in thousands)				
Cash equivalents	\$ 48,275	\$ 48,275		
Other current assets	455		\$ 455	
Total assets	\$ 48,730	\$ 48,275	\$ 455	\$

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

A reconciliation of the change in value of the Company's warrants for the three months ended September 30, 2010 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3) (in thousands)	
Balance at June 30, 2010	\$	29,540
Change in value of warrants		3,578
Balance at September 30, 2010	\$	33,118

A reconciliation of the change in value of the Company's warrants for the nine months ended September 30, 2010 is as follows:

Fair Value Measurements Using  
Significant Unobservable Inputs  
(Level 3)

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

(in thousands)

Balance at December 31, 2009	\$	27,609
Change in value of warrants		5,509
Balance at September 30, 2010	\$	33,118

See Note 6 Warrants for additional information related to the determination of fair value of the warrants. The carrying amounts reported in the balance sheets for cash, accounts receivable, accounts payable, and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

### **Note 3. Property Held for Sale**

In 2009, the Company decided to outsource its large scale manufacturing activities listing for sale the industrial property located in Corvallis, Oregon and recorded a \$0.1 million impairment charge to reduce carrying value to fair value less estimated costs to sell. The Company recorded an additional impairment charge of \$0.4 million in the quarter ended September 30, 2010 to reduce its carrying value to the current appraised value. The Company has used a Level 3 fair value measure with the use of an independent appraisal to estimate value of this property.

Table of Contents

**Note 4. U.S. Government Contracts**

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. We recognize revenues from U.S. government research contracts during the period in which the related expenditures are incurred and present these revenues and related expenses gross in the consolidated financial statements. As of September 30, 2010, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of \$157.2 million for development of its product candidates, of which \$62.2 million had been billed to the U.S. government and \$95.0 million of which relates to development that has not yet been completed and has not been billed. The following is a description of such contracts.

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

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs under certain executed contracts. 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 RNA-based drugs against Ebola and Marburg viruses. As of September 30, 2010, the Company has recognized revenue of \$9.8 million with respect to these contracts.

***December 2006 Agreement (Ebola, Marburg and Junin Viruses)***

In December 2006, the Company entered into a two-year research contract with Defense Threat Reduction Agency ( DTRA ), an agency of the U.S. Department of Defense (the DoD ), pursuant to which the Company was entitled to \$28.0 million to fund its development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic fever viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by \$5.9 million to an aggregate of \$33.9 million. In June 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional \$11.5 million to an aggregate of \$45.4 million. In November 2010, the Company and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and be deemed concluded. As of September 30, 2010, the Company had recognized revenue of \$38.2 million with respect to this contract and does not expect significant further revenue.

***May 2009 Agreement (H1N1/Influenza)***

In May 2009, the Company entered into a contract with DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to \$4.1 million to the Company for the work involving the application of the Company's proprietary PMO and PMOplus antisense chemistry and the Company plans to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu®-resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by \$4.0 million to an aggregate of \$8.1 million. As of September 30, 2010, the Company has recognized revenue of \$4.5 million with respect to this contract.

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

On June 4, 2010, the Company entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by the Company, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program ( TMT ) of the DoD. The contract provides for funding of up to \$18 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug ( IND ) application with the U.S. Food and Drug Administration ( FDA ), the development of an intranasal delivery formulation, and the funding of a Phase 1 clinical program to obtain human safety data to support potential use under an Emergency Use Authorization. As of September 30, 2010, the Company has recognized revenue of \$4.6 million with respect to this contract.

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

On July 14, 2010, the Company was awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the Company's hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was instigated to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately \$291 million. Activity under the first segment, which began in July 2010, provides for funding to the Company of up to approximately \$80 million. Activities under the first segment include Phase 1 studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.



Table of Contents

After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to the Company of up to approximately \$291 million over a period of approximately six years. Under an earlier contract, the Company completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of September 30, 2010, the Company has recognized revenue of \$2.7 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government on the Company's results of operations for the three and nine months ended September 30, 2010 and 2009.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
January 2006 Agreements ( <i>Ebola and Marburg host factor, Dengue, Anthrax and Ricin</i> )	\$ 88	\$ 285	\$ 556	\$ 1,908
December 2006 Agreement ( <i>Ebola, Marburg and Junin Viruses</i> )	345	4,418	2,953	7,483
May 2009 Agreement ( <i>H1N1</i> )	1,358	780	2,802	1,136
June 2010 Agreement ( <i>H1N1</i> )	4,201		4,634	
July 2010 Agreement ( <i>Ebola and Marburg</i> )	2,716		2,716	
Other Agreements	(6)	870	242	1,921
Total	\$ 8,702	\$ 6,353	\$ 13,903	\$ 12,448

**Note 5. Stock Compensation***Stock Options*

The Company sponsors a 2002 Equity Incentive Plan (the "Plan") pursuant to which it may issue options to purchase its common stock to the Company's employees, directors and service providers. In general, stock options granted under the Plan vest over a three year period, with one-third of the underlying shares vesting on each anniversary of grant, and have a ten year term. As of September 30, 2010, 1,721,493 shares of common stock remain available for future grant under the Plan.

A summary of the Company's stock option compensation activity with respect to the nine months ended September 30, 2010 follows:

Stock Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
---------------	--------	--	---	---------------------------------

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Outstanding at December 31, 2009	8,932,811	\$	2.79		
Granted	3,432,865		1.56		
Exercised	(1,673,128)		1.18		
Canceled or expired	(2,287,491)		4.49		
Outstanding at September 30, 2010	8,405,057		2.14	7.24	\$ 2,763,892
Vested at September 30, 2010 and expected to vest	8,193,961		2.16	7.18	2,679,047
Exercisable at September 30, 2010	3,907,316		2.93	5.18	888,655

The weighted-average fair value per share of stock-based awards, including stock options and restricted stock grants, granted to employees during the nine months ended September 30, 2010 and 2009 was \$1.10 and \$1.07, respectively. During the same periods, the total intrinsic value of stock options exercised was \$955,000 and \$24,000, respectively, and the total grant date fair value of stock

Table of Contents

options that vested was \$2,555,000 and \$1,450,000, respectively. The total grant date fair value of stock options vested for the three months ended September 30, 2010 and 2009 was \$169,000 and \$446,000, respectively.

**Valuation Assumptions**

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

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

	Three and Nine Months Ended	
	September 30,	
	2010	2009
Risk-free interest rate	1.39%-2.37%	1.2%-1.60%
Expected dividend yield	0%	0%
Expected lives	5.3-5.5 years	9.0 years
Expected volatility	83.3%-85.2%	92.0%-94.2%

The risk-free interest rate is estimated using an average of treasury bill interest rates that correlate to the prevailing interest rates at the time of grant. The expected dividend yield is zero as the Company has not paid any dividends to date and does not expect to pay dividends in the future. The expected lives are estimated using expected and historical exercise behavior. The expected volatility is estimated using historical calculated volatility of the Company's common stock. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

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

**Restricted Stock Awards**

In the three months ended June 30, 2010, the Company granted a total of 20,000 shares of restricted stock to members of its Board of Directors. These shares vest over a period of approximately one year. During the three and nine month periods ended September 30, 2010, the Company recognized compensation expense related to these shares of \$6,600 and \$9,600, respectively.

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

In the three months ended June 30, 2009, the Company granted 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 months ended September 30, 2009, the Company recognized compensation expense related to these shares of \$24,000 and \$27,000, respectively.

Also in the three months ended June 30, 2009, the Company granted 100,000 shares of restricted stock to its Chief Business Officer. These shares vest upon the achievement of certain performance milestones. No compensation expense related to these shares has been recognized in 2010 or 2009 as the achievement of the performance milestones was not accomplished and the restricted stock was cancelled.

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

In the three months ended March 31, 2008, the Company granted 333,000 shares of restricted stock to its former Chief Executive Officer. Of these shares, 100,000 vested immediately and the remaining 233,000 were scheduled to vest over a period of four years. In April 2010, the former Chief Executive Officer tendered his resignation at the request of the Board of Directors and pursuant to the terms of the related separation agreement, 116,500 shares of previously granted restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. During the three months ended September 30, 2010 and 2009, the Company recognized compensation expense related to these shares of \$0 and \$16,000, respectively. During the nine month periods

Table of Contents

ended September 30, 2010 and 2009, the Company recognized compensation expense related to these shares \$134,000 and \$48,000, respectively.

	Restricted Stock Awards	Weighted-Average Grant Date Fair Value (in thousands)	
Balance as of December 31, 2009	300	\$	1.09
Granted	20		1.30
Vested	(200)		1.09
Forfeited or canceled	(100)		1.10
Balance as of September 30, 2010	20	\$	1.30

The weighted-average grant-date fair value of restricted stock awards is based on the market price of the Company's common stock on the date of grant. There were no grants of restricted stock awards in the three months ended September 30, 2010 and the grant-date fair value of the restricted stock award made during the nine months ended September 30, 2010 was \$1.30. The grant-date fair value of the restricted stock awards made during the three and nine month periods ended September 30, 2009 was \$0 and \$1.01, respectively. The total grant-date fair values of restricted stock awards that vested during the nine months ended September 30, 2010 and 2009 were approximately \$219,000 and \$385,000, respectively.

***Stock-based Compensation Expense***

The amount of stock-based compensation expense recognized in the three months ended September 30, 2010 and 2009 related to stock options was \$509,000 and \$511,000, respectively. For the nine months ended September 30, 2010 and 2009, stock-based compensation expense was \$2,540,000 and \$1,592,000, respectively. A summary of the stock based compensation expense recognized in the statement of operations is as follows:

	Three Months Ended	
	September 30, 2010	September 30, 2009
	(in thousands)	
Research and development	\$ 250	\$ 205
General and administrative	259	306
Total	\$ 509	\$ 511

The following are the stock-based compensation expense recognized in the Company's statements of operations for the nine months ended September 30, 2010 and 2009:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
	(in thousands)	
Research and development	\$ 665	\$ 826
General and administrative	1,875	766

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Total	\$	2,540	\$	1,592
-------	----	-------	----	-------

As of September 30, 2010, there was \$3,570,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements, including stock options and restricted stock, granted under the Plan. These costs are expected to be recognized over a weighted-average period of 1.99 years.

Pursuant to the terms of the separation agreement between the Company's former Chief Executive Officer and the Company, unvested options previously granted to Dr. Hudson to purchase 1,166,833 shares of common stock and 116,500 shares of restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. The Company recorded a charge of stock compensation expense of \$1,181,292 as a result of the accelerated vesting of these shares in the second quarter of 2010.

Table of Contents**Note 6. Warrants**

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

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

	<b>Three and Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
Risk-free interest rate	0.1%-2.6%	0.2%-2.4%
Expected dividend yield	0%	0%
Expected lives	0.1-4.4 years	0.1-5.0 years
Expected volatility	62.3%-96.68%	83.2%-140.6%
Shares underlying warrants classified as liabilities	29,409,546	30,203,446

	<b>Three and Nine Months Ended September 30,</b>			
	<b>2010</b>		<b>2009</b>	
Market value of stock at beginning of year	\$	1.58	\$	0.66
Market value of stock at end of period		1.83		1.72
Weighted average exercise price		1.59		3.40

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

All other warrants issued by the Company other than the warrants issued in connection with its December 2007, January 2009 and August 2009 financings are classified as permanent equity in accordance with GAAP; the fair value of the warrants was recorded as additional paid-in capital and no further adjustments are made. For the three months ended September 30, 2010 and 2009, 255,895 and 2,129,530 shares, respectively, were underlying such warrants.

A summary of the Company's warrant activity with respect to the nine months ended September 30, 2010 is as follows:

**Warrants**

**Shares**

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

			Weighted Average Exercisable Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2010	32,332,996	\$	3.40	
Granted				
Exercised	(308,000)		1.78	
Canceled or expired	(2,359,555)		26.50	
Outstanding at September 30, 2010	29,665,441		1.59	3.55

**Note 7. Earnings Per Share**

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



Table of Contents

	<b>Three Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(in thousands, except per-share data)</b>	
Net loss	\$ (7,293)	\$ (8,090)
Weighted-average number of shares of common stock and common stock equivalents outstanding:		
Weighted-average number of common shares outstanding for computing basic earnings per share	111,767	95,261
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*
Weighted-average number of common shares outstanding for computing diluted earnings per share	111,767	95,261
Net loss per share - basic and diluted	\$ (0.07)	\$ (0.08)

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(in thousands, except per-share data)</b>	
Net loss	\$ (24,533)	\$ (28,684)
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	110,863	87,493
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	110,863	87,493
Net loss per share - basic and diluted	\$ (0.22)	\$ (0.33)

\* Warrants and stock options to purchase 38,070,498 and 41,262,099 shares of common stock as of September 30, 2010 and 2009, respectively, were excluded from the net loss per share calculation as their effect would have been anti-dilutive.

**Note 8. Liquidity**

Since its inception in 1980 through September 30, 2010 the Company has incurred losses of approximately \$300.0 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenue from product sales will be achieved. Moreover, even if the Company does achieve revenue from product sales, the Company expects to incur operating losses over the next several years.

At September 30, 2010, cash, cash equivalents and short-term investments were \$36.4 million, compared to \$48.7 million at December 31, 2009. The Company's principal sources of liquidity have been revenue from its U.S. government research contracts and equity financings. The Company's principal uses of cash have been research and development expenses, general and administrative expenses and other working capital requirements.

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

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. As of September 30, 2010, the Company had contracts with the U.S. government pursuant to which its is entitled to receive up to an aggregate of \$157.2 million for development of its product candidates, of which \$62.2 million had been billed to the U.S. government and \$95.0 million of which relates to development that has not yet been completed and has not been billed. See Note 4 U.S. Government Contracts for additional information.

In January and August 2009, the Company sold shares of its common stock and also issued warrants to purchase shares of its common stock in offerings registered under the Securities Act of 1933 (the Securities Act ). See Note 9 Equity Financing for more information.

### **Note 9. Equity Financing**

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

Table of Contents

In August 2009, the Company sold approximately 24.3 million shares of its common stock and also issued warrants to purchase approximately 9.7 million shares of its common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately \$32.3 million. The warrants issued to the investors in the offering have an exercise price of \$1.78 per share and are exercisable at any time on or before August 25, 2014. The warrants issued in connection with the January and August 2009 offerings are classified as a liability due to their settlement terms. Accordingly, the fair value of the warrants is recorded on the consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in the consolidated statement of operations as described in greater detail in Note 6 Warrants . These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

**Note 10. Income Taxes**

The Company has not recognized any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on its balance sheet at September 30, 2010 or December 31, 2009, and has not recognized interest and/or penalties in the statement of operations for the three and nine months ended September 30, 2010.

At December 31, 2009, the Company had net deferred tax assets of approximately \$111 million. The deferred tax assets are primarily composed of U.S. federal and state tax net operating loss carryforwards, U.S. federal and state research and development credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules could limit the future use of its net operating loss and research and development credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

**Note 11. Recent Accounting Pronouncements**

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

In April 2010, the FASB issued guidance on applying the milestone method of revenue recognition for milestone payments for achieving specific performance measures when those payments are related to uncertain future events. The scope of this guidance is limited to transactions involving research or development. Under the guidance, the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestone will be achieved. The

guidance is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning after June 15, 2010, with early adoption permitted. The Company, based on its current revenue contracts, does not believe that this guidance will have a material impact on the Company's financial statements.

**Note 12. Subsequent Events**

In October 2010, the Company received notification from the Treasury Department that they had been awarded grants totaling approximately \$1.2 million under the U.S. Government's Qualifying Therapeutic Discovery Project (QTDP) program. AVI was awarded grants for each of the five project applications submitted for the company's Duchenne muscular dystrophy program and four infectious disease programs.

The QTDP was part of the March 2010 Patient Protection and Affordable Care Act and provides a tax credit or grant equal to 50 percent of eligible costs and expenses for tax years 2009 and 2010. Under the program, a total of \$1 billion in grant or tax credits was made available to companies with 250 or fewer employees. The grant received by AVI for each application was approximately \$244,000.

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

*This section should be read in conjunction with our condensed consolidated financial statements and related notes included in Part I, Item 1 of this report and the section contained in our annual report on Form 10-K for the year ended December 31, 2009 under the caption Part II-Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations. This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act.*

*Forward-looking statements are identified by such words as believe, expect, anticipate and words of similar import and are based on current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. 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, expectations regarding future expenses, funding from government and other sources, the results of research and development efforts, the adequacy of funds to support or future operations, the results of pre-clinical and clinical testing, the effect of regulation by FDA and other agencies, the impact of competitive products,*

Table of Contents

*product development, commercialization and technological difficulties. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A Risk Factors, and elsewhere in this report. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments.*

*In this report, we, our, us, AVI, and Company refers to AVI BioPharma, Inc.*

**Overview**

We are a biopharmaceutical company focused on the discovery and development of novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, our technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. We believe that these broad capabilities represent highly competitive RNA-based technology platforms and a strong intellectual property position, both of which are the result of advances across several areas of science, including over 20 years of research and development work in chemistry and biology. Our patent estate includes 205 patents (foreign and domestic) issued to or licensed by us and 186 patent applications (domestic and foreign).

We are leveraging our discovery and development capabilities to build a pipeline of RNA-based therapeutic drug candidates to develop independently and in collaboration with larger pharmaceutical and biotechnology partners. Current applications of our RNA technology platform include genetic diseases (Duchenne Muscular Dystrophy, or DMD), infectious diseases (including Ebola, Marburg and H1N1 Influenza viruses), and other early discovery targets. Several of our antiviral programs, including Ebola, Marburg, Junín and H1N1, have been or are currently funded by the U.S. government as described in greater detail below. Some of our other programs have received funding from non-government sources.

On June 4, 2010, we were awarded a new contract with the U.S. Defense Threat Reduction Agency, or DTRA, an agency of the U.S. Department of Defense, or DoD, to advance the development of AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus (swine flu) in cooperation with the Transformational Medical Technologies program, or TMT, of the DoD. The contract provides for funding of up to \$18 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, the development of an intranasal delivery formulation and the funding of a Phase 1 clinical program to obtain human safety data to support potential use under an Emergency Use Authorization.

On July 14, 2010, we were awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of our hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately \$291 million. Activity under the first segment began in July 2010 and provides us funding of up to approximately \$80 million. After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to us of up to approximately \$291 million. Under an earlier contract, we completed development activities that culminated in the opening of IND applications

for both AVI-6002 and AVI-6003.

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

On April 20, 2010, our chief executive officer and president, Leslie Hudson, Ph.D., tendered his resignation at the request of our Board of Directors. Pursuant to his separation agreement, Dr. Hudson will receive total cash severance payments of \$1,412,170 (comprised of two times the sum of (i) his annual base salary in effect as of the Separation Date (\$494,400), (ii) the average of his last two annual bonuses (\$188,669), and (iii) the annual cost of Pfizer retiree healthcare coverage for him and his spouse (\$23,016). The cash severance payments are paid to Dr. Hudson in 24 equal monthly installments, less required deductions and withholdings following the effective date of the separation agreement. In addition, as of the effective date of the separation agreement, unvested options to purchase 1,166,833 shares of our common stock and 116,500 shares of restricted stock previously granted to Dr. Hudson became fully vested and exercisable, which resulted in a charge to stock compensation expense of \$1,181,292 in the second quarter of 2010.

As previously disclosed, on April 20, 2010, we entered into a settlement agreement with a shareholder group that had sought a special meeting of our shareholders to replace certain members of our Board of Directors. Pursuant to such settlement agreement, among other things, (i) our Board of Directors sought Dr. Hudson's resignation and appointed J. David Boyle II, our Chief Financial Officer, as interim Chief Executive Officer and President, (ii) our bylaws were amended to reduce the size of our Board of Directors,

Table of Contents

(iii) Dr. Hudson and K. Michael Forrest resigned as directors to facilitate the reduction in the size of the Board of Directors, and (iv) Anthony R. Chase was appointed to fill the vacancy created by Dr. Hudson's resignation. In addition, for a period of one year, the shareholder group agreed not to engage in the solicitation of any proxy relating to the voting of our common stock and not to take certain actions relating to our Board of Directors or the management of our company.

At our 2010 annual meeting of shareholders, Chris Garabedian and Hans Wigzell were elected to our Board of Directors, replacing Christopher Henney and Michael D. Casey who did not stand for reelection.

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. As the result of new Influenza, Ebola and Marburg U.S. government research contracts, we expect future revenues and research and development cost to increase. We have been unprofitable since inception and, other than limited interest, license fees, grants and research contracts, we have had no material revenue from the sale of products or other sources, other than from government grants and research contracts, and we do not expect material revenue for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development efforts and seek to enter additional collaborative efforts. As of September 30, 2010, our accumulated deficit was \$300.0 million.

**Government Contracts**

In the periods presented, substantially all of the revenue generated by our company was derived from research contracts with the U.S. government. As of September 30, 2010, we had contracts with the U.S. government pursuant to which we are entitled to receive up to an aggregate of \$157.2 million for development of its product candidates, of which \$62.2 million had been billed to the U.S. government and \$95.0 million of which relates to development that has not yet been completed and has not been billed. The following is a description of such contracts.

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

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of \$11.0 million to fund our ongoing defense-related programs under certain executed contracts. Net of government administrative costs, it is anticipated that we will receive up to \$9.8 million under this allocation. Our technology is expected to be used to continue developing RNA based drugs against Ebola and Marburg viruses. We have received signed contracts for all of these projects. As of September 30, 2010, we have recognized revenue of \$9.8 million with respect to these contracts and expect to receive the remaining funding under these contracts in 2010.

***December 2006 Agreement (Ebola, Marburg and Junin Viruses)***

In December 2006, we entered into a two-year research contract with the DTRA pursuant to which we were entitled to \$28 million to fund development of our antisense therapeutic candidates Ebola, Marburg and Junin hemorrhagic viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by \$5.9 million to an aggregate of \$33.9 million. In June 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional \$11.5 million to an aggregate of \$45.4 million. In November 2010, we and DTRA agreed that the key activities under this contract had been completed and that

further activities under this contract would cease and this contract would be deemed concluded. As of September 30, 2010, we had recognized revenue of \$38.2 million with respect to this contract and does not expect significant further revenue.

***May 2009 Agreement (H1N1/Influenza)***

In May 2009, we entered into a contract with the DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to \$4.1 million to our company for the work involving the application of our proprietary PMO and PMO*plus* antisense chemistry and we plan to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu® resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by \$4.0 million to an aggregate of \$8.1 million. As of September 30, 2010, we have recognized revenue of \$4.5 million with respect to this contract and expect to receive the remaining funding under this contract in 2010.



Table of Contents**June 2010 Agreement (H1N1/Influenza)**

On June 4, 2010, we entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by us, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the TMT. The contract provides for funding of up to \$18 million to advance the development of AVI-7100, including studies enabling an IND application with the FDA, the study of an intranasal delivery formulation, and the funding of a Phase 1 clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization. As of September 30, 2010, we have recognized revenue of \$4.6 million with respect to this contract and expect to receive the remaining funding under this contract in 2010 and 2011.

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

On July 14, 2010, we were awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the our hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately \$291 million. Activity under the first segment began in July 2010 and provides for funding to us of up to approximately \$80 million. Activities under the first segment include Phase 1 studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.

After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to the us of up to approximately \$291 million over a period of approximately six years. Under an earlier contract, we completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of September 30, 2010, we have recognized revenue of \$2.7 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government on our results of operations for the three and nine months ended September 30, 2010 and 2009.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
January 2006 Agreements (Ebola and Marburg host factor, Dengue, Anthrax and Ricin)	\$ 88	\$ 285	\$ 556	\$ 1,908
December 2006 Agreement (Ebola, Marburg and Junin Viruses)	345	4,418	2,953	7,483
May 2009 Agreement (H1N1)	1,358	780	2,802	1,136
June 2010 Agreement (H1N1)	4,201		4,634	

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

July 2010 Agreement ( <i>Ebola and Marburg</i> )	2,716			2,716		
Other Agreements	(6)	870		242	1,921	
Total	\$ 8,702	\$ 6,353	\$ 13,903	\$ 12,448		

**Key Financial Metrics**

*Revenue*

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

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

We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate

Table of Contents

and independent of our company performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement. As of September 30, 2010, we had deferred revenue of \$3.3 million, which represents up-front fees received from third parties pursuant to certain contractual arrangements and will be recognized as performance obligations are satisfied.

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

*Expenses*

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

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

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

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

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

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

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

*Change in Fair Value of Warrants.* Warrants issued in connection with our December 2007 and January and August 2009 financings are classified as liabilities as opposed to equity due to their settlement terms. These warrants are non-cash liabilities; we are not required to expend any cash to settle these liabilities. The fair market value of these warrants was recorded on the balance sheet at issuance and the warrants are marked to market each financial reporting period, with changes in the fair value recorded as a gain or loss in our statement of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model, which requires the use of significant judgment and estimates for the inputs used in the model. For more information, see Note 6 Warrants of the unaudited condensed consolidated financial statements included elsewhere in this report.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements included elsewhere in this report. The preparation of our financial statements in accordance with accounting principles generally accepted in the United States, or GAAP, requires us to make estimates and judgments that affect the reported

Table of Contents

amounts of assets, liabilities, revenue and expenses and related disclosure of contingent assets and liabilities for the periods presented. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our consolidated financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

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

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

Our critical accounting policies and significant estimates are detailed in our annual report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 16, 2010 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 and filed with the SEC on August 9, 2010.

***Warrant Liability***

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

The fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option pricing model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. If, for example, the market value of our common stock or its volatility at December 31, 2009 were 10% higher or lower than used in the valuation of such warrants, our valuation of the warrants would have increased by up to \$4.4 million or decreased up to \$4.3 million, respectively, with such

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

difference reflected in our statement of operations.

**Results of Operations for the Three and Nine Months Ended September 30, 2010 and 2009**

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

	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
	2010 (In thousands, except per share amounts)	2009		2010 (In thousands, except per share amounts)	2009	
Revenue:	\$ 8,702	\$ 6,353	37%	\$ 13,903	\$ 12,448	12%
Expenses:						
Research and development	9,059	7,473	21%	22,080	17,770	24%
General and administrative	3,440	1,800	91%	11,017	6,226	77%
Operating loss	(3,797)	(2,920)		(19,194)	(11,548)	
Other income (loss):						
Interest(expense) income and other, net	82	(132)	+	170	(147)	+
(Increase) decrease on warrant valuation	(3,578)	(5,038)	+	(5,509)	(16,989)	+
Net loss	\$ (7,293)	\$ (8,090)		\$ (24,533)	\$ (28,684)	
Basic and diluted loss per share	\$ (0.07)	\$ (0.08)		\$ (0.22)	\$ (0.33)	

---

+ Not meaningful

Table of Contents

***Revenue***

Revenue for the three months ended September 30, 2010 increased by \$2.3 million, or 37%, compared to the three months ended September 30, 2009 due to a \$3.3 million increase in revenue from U.S. government research contracts offset, in part, from lower revenue associated with the Children's National Medical Center contract related to DMD.

Revenue for the nine months ended September 30, 2010 increased by \$1.4 million, or 12%, compared to the nine months ended September 30, 2009 due to a \$3.2 million increase in government research contracts as detailed in the table above, partially offset by a \$1.7 million decrease in revenue from the Children's National Medical Center.

***Research and Development Expenses***

Research and development expenses for the three months ended September 30, 2010 increased by \$1.6 million, or 21%, compared to the three months ended September 30, 2009 due primarily to \$1.1 million for upfront payments to a contract research organization primarily related to our H1N1 program and \$0.5 million in increased salaries and employee costs from new staff additions.

Research and development expenses for the nine months ended September 30, 2010 increased by \$4.3 million, or 24%, compared to the nine months ended September 30, 2009 due primarily to \$1.4 million in costs for active investigational therapeutic components, \$1.1 million for contract research organizations costs for the H1N1 program, \$1.1 million for toxicology studies for the Junin and H1N1 programs and \$0.9 million in increased salaries and employee costs from the addition of new staff.

***General and Administrative Expenses***

General and administrative expenses for the three months ended September 30, 2010 increased by \$1.6 million, or 91%, compared to the three months ended September 30, 2009. The significant increase in the three months ended September 30, 2010 is primarily due to \$0.5 million in salaries related to increased staff and \$0.5 million increase in professional consulting and legal costs. In addition, there was a \$0.4 million reduction in the fair value of property held for sale in Corvallis, Oregon, investor relations costs increased by \$0.2 million and technology costs increased \$0.1 million.

General and administrative expenses for the nine months ended September, 2010 increased by \$4.8 million, or 77%, compared to the nine months ended September 30, 2009 primarily due to \$2.6 million in severance costs and stock compensation related to the departure, in April 2010, of our former chief executive officer. Other increases include legal costs of \$0.6, salary costs related to additional staff of \$0.5 million, rent expense of \$0.4 million for the addition of our new Bothell, Washington facility, \$0.4 million impairment charge for property held for sale in Corvallis, Oregon, \$0.2 million of investor relations costs and \$0.1 million for technology costs.

*Interest Income (Expense) and Other, Net*

The increase in interest income (expense) and other, net for the three and nine months ended September 30, 2010 compared to the three and nine months ended September 30, 2009 was attributable to increased rental income from the sublease of excess space in our Corvallis, Oregon facility.

*Change in Fair Value of Warrant Liability*

The significant changes in fair value of warrant liability for the three and nine months ended September 30, 2010 compared to the three month and nine month periods ended September 30, 2009 was attributable to changes in our stock price. See Key Financial Metrics Change in Fair Value of Warrants, Critical Accounting Policies Warrant Liability, and Note 6 to the financial statements included elsewhere in this report.

*Net loss*

The decrease in net loss of \$0.8 million for the three months ended September 30, 2010 compared to the prior year period was attributable primarily to the change in warrant liability. The decrease in net loss of \$4.2 million for the nine months ended September 30, 2010 compared to the prior year period was primarily attributable to a decrease in warrant liability partially offset by an increase in operating expenses.



Table of Contents

**Liquidity and Capital Resources**

At September 30, 2010, cash, cash equivalents and short-term investments were \$36.4 million, compared to \$48.7 million at December 31, 2009. Our principal sources of liquidity are revenue from our U.S. government research contracts and equity financings. Our principal uses of cash are research and development expenses, general and administrative expenses and other working capital requirements. Based on the factors described below, we believe that our currently available cash, cash equivalents and short-term investments, exclusive of receipt of future proceeds pursuant to our contracts with the U.S. government, are sufficient to finance our operations for at least the next 12 months

*Sources of Funds*

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

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

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

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

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

*Uses of Funds*

From inception in 1980 through the date of this report, our accumulated deficit is \$300.0 million. Our principal uses of cash have been research and development expenses, general and administrative expenses, costs associated with the acquisition of in-process research and development and other working capital requirements.

*Historical Trends*

	<b>Nine Months Ended September 30,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(in thousands)</b>	
Cash provided by (used in):		
Operating activities	\$ (13,321)	\$ (7,743)
Investing activities	(1,454)	(914)
Financing activities	2,467	47,733
Increase (decrease) in cash and equivalents	\$ (12,308)	\$ 39,076

Table of Contents

*Operating Activities.* We used \$13.3 million of cash in operating activities for the nine months ended September 30, 2010, an increase of \$5.6 million compared to \$7.7 million of cash used in operating activities for the nine months ended September 30, 2009. The increase net cash used in operating activities during the comparative periods was primarily attributable to increased research and development costs, higher general and administrative expenses and the increase in accounts receivable.

*Investing Activities.* We used \$1.5 million of cash in investing activities for the nine months ended September 30, 2010, an increase of \$0.6 million compared to \$0.9 million of cash used in investing activities for the nine months ended September 30, 2009. The increase of cash used for investing activities was attributable to increased spending on patents and fixed assets, and no liquidation of certificate of deposit in 2010 as occurred in 2009.

*Financing Activities.* We had financing activities of \$2.5 million that consisted of stock option and warrant exercises and debt repayment for the nine months ended September 30, 2010. The \$47.7 million of cash generated by financing activities for the nine months ended September 30, 2009 was attributable to our January and August 2009 equity financings.

Our future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term. These requirements include our ability to meet the requirements of our U.S. government research projects, the progress of our research and development programs and our pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, our ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of our products. Our cash requirements are expected to continue to increase as we advance our research, development and commercialization programs.

**Contractual Obligations and Contingencies**

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and acquisition of technology access rights, among others. The following table presents contractual obligations arising from these arrangements as of September 30, 2010:

	Total	Payments Due by Period			
		Less than 1 Year	1-3 Years (in thousands)	3-5 Years	More than 5 Years
Operating leases premises	\$ 17,304	\$ 1,881	\$ 3,922	\$ 3,545	\$ 7,956
Royalty payments	634	80	160	160	234

**Off Balance Sheet Arrangements**

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

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

### **Recent Accounting Pronouncements**

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

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

#### **Interest Rate Sensitivity**

We had cash, cash equivalents, and short-term investments of \$36.4 million and \$48.7 million at September 30, 2010 and December 31, 2009, respectively. We do not enter into investments for trading or speculative purposes; our cash equivalents are invested in money market accounts and our short-term investments consisted of short-term certificates of deposit. We believe that we do not have any material exposure to changes in the fair value of these assets in the near term due to extremely low rates of investment interest and to the short term nature of our cash, cash equivalents, and short-term investments. Future declines in interest rates, however, would reduce investment income, but are not likely to be a material source of revenue to our company in the foreseeable future.

Table of Contents

**Item 4. Controls and Procedures.**

**Evaluation of Disclosure Controls and Procedures**

We carried out an evaluation as of the end of period covered by this report, under the supervision and with the participation of our management, including our interim chief executive officer and our chief accounting officer, of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our interim chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of September 30, 2010, our disclosure controls and procedures were effective.

**Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**PART II - OTHER INFORMATION**

**Item 1. Legal Proceedings.**

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

**Item 1A. Risk Factors.**

*Set forth below and elsewhere in this report and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable*

*indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also affect our results of operations and financial condition.*

### **Risks Relating to Our Business**

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

Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, AVI-4658 is in clinical trials, we have open INDs for AVI-6002 in Ebola and AVI-6003 in Marburg, and the rest of our product candidates are in preclinical development. We expect that much of our effort and many of our expenditures over the next few years will be devoted to development activities associated with AVI-4658 in Duchenne Muscular Dystrophy, or DMD, AVI-6002 in Ebola, AVI-6003 in Marburg and AVI-7100 in influenza. With current resources, we may be restricted or delayed in our ability to develop other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including AVI-4658, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates. However, in July 2010 we received notification from the U.S. Food and Drug Administration, or FDA, that our Investigational New Drug, or IND, application, required to start clinical testing in the United States, had been allowed. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payers and the medical

Table of Contents

community. Assuming that any of our product candidates receives the required regulatory approvals, commercial success will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety;
- cost-effectiveness of the product;
- the product's potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs; and
- marketing and distribution support for the product.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States, and other regulatory authorities in other countries, which regulations differ from country to country. Marketing of our product candidates in the United States or foreign countries is not permitted until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we may never receive regulatory approval for the commercial sale of any of our product candidates. Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured. We have no experience in preparing and filing the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which

may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

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

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

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical and clinical studies; that the product candidate is safe and effective in humans. Ongoing and future clinical trials



Table of Contents

of our product candidates may not show sufficient safety or efficacy to obtain regulatory approvals. We expect to develop the therapeutic product candidates to treat Ebola and Marburg viruses 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 is currently under evaluation by the FDA. This may present challenges for gaining final regulatory approval for these product candidates.

Phase 1 clinical trials generally are not designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and dosing schedules in healthy volunteers. Delays in establishing the appropriate dosage levels can lead to delays in the overall clinical development of a product candidate. As of the date of this report, we do not believe that we have identified a consistently effective dose in DMD patients for AVI-4658. We are expeditiously moving to start a U.S.-based clinical trial for AVI-4658 at higher doses to further explore and identify a more consistently effective dose that may be more appropriate for future clinical trials and that can serve as a basis for approval by governmental regulatory authorities; however, we can not assure you that these efforts will be successful. If a consistently effective dose is found in the U.S. based clinical trial we will expect to engage in discussions with regulatory authorities about the design and subsequent execution of any further studies required. This might include an open label extension study for all patients who have previously received AVI-4658, as well as other patients (e.g., non-ambulant patients) and any additional placebo-controlled pivotal study or studies.

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

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

We rely on U.S. government contracts and awards to fund several of our development programs, including those for the Ebola, Marburg, Junín and H1N1 viruses and for all of our current revenue.

The funding of U.S. government programs is subject to Congressional appropriations. Congress generally appropriates funds on a fiscal year basis even though a program may extend over several fiscal years. Consequently, programs are often only partially funded initially and additional funds are committed only as Congress makes further appropriations. If appropriations for one of our programs become unavailable, or are reduced or delayed our contracts may be terminated or adjusted by the government, which could have a negative impact on our future revenue under such 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

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

be entitled to payments for our allowable costs and would receive some allowance for profit on the work performed. If one of our contracts is terminated for default, we would generally be entitled to payments for our work that has been completed to that point. A termination arising out of our default could expose us to liability and have a negative impact on our ability to obtain future contracts.

The termination of one or more of these contracts, whether due to lack of funding, for convenience, or otherwise, or the occurrence of delays or product failures in connection with one or more of these contracts, could negatively impact our financial condition. Furthermore, we can give no assurance that we would be able to procure new U.S. government contracts to offset the revenue lost as a result of termination of any of our contracts.

Table of Contents

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

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

- the Federal Acquisition Regulation and supplements, which regulate the formation, administration and performance of U.S. Government contracts;
- the Truth in Negotiations Act, which requires certification and disclosure of cost and pricing data in connection with contract negotiations; and
- the Cost Accounting Standards, which impose accounting requirements that govern our right to reimbursement under certain cost-based government contracts.

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

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

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

We recently completed a Phase1b/2 clinical trial for AVI-4658 in the UK and are currently completing the analysis and reporting of data from this study. We expect to commence additional trials of AVI-4658 and other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs. In addition, for some programs (e.g., DMD and Ebola and Marburg infections) there are currently no approved drugs to compare against and an agreement about how to measure efficacy has yet to be reached with the FDA and then demonstrated.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are

Table of Contents

conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

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

- lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups may demand additional clinical trials even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials are unwarranted. Any disagreement with patient advocacy groups may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial may necessitate it to be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board, (DSMB), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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

We incurred a net loss of \$24.5 million for the nine months ended September 30, 2010 and \$25.2 million for the year ended December 31, 2009. As of September 30, 2010, our accumulated deficit was \$300.0 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, partner one or more programs, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

Table of Contents

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

We expect that we will require additional capital from time to time in the future in order to continue the development of product candidates in our pipeline and to expand our product portfolio. The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include the success of our research and development efforts, the status of our pre-clinical and clinical testing, costs relating to securing regulatory approvals and the costs and timing of obtaining new patent rights, regulatory changes, competitive and technological developments in the market. An unforeseen change in these factors, or others, might increase our need for additional capital. We may need funds sooner than currently anticipated.

We would expect to seek additional financing from the sale and issuance of equity or debt securities or the entry into strategic relationships, and we cannot predict that financing will be available when and as we need financing or that, if available, the financing terms will be commercially reasonable. If we are unable to obtain additional financing when and if we require, or on commercially reasonable terms, it would have a material adverse effect on our business and results of operations. To the extent we issue additional equity securities, our existing shareholders could experience substantial dilution.

Further, we plan to enter into relationships with pharmaceutical or biotechnology companies to conduct clinical trials and to market our products. We currently do not have a strategic relationship with a third party to assist us in funding the continued development and commercialization of AVI-4658. If we are unable to enter into partnerships or strategic relationships with respect to AVI-4658 or our other product candidates on favorable terms it may impede our ability to develop and commercialize our product candidates.

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

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling and labeling of vials and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, fill vials and store sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we are unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

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

disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Our contract manufacturers are required to produce our clinical product candidates under current Good Manufacturing Practice, or cGMP, conditions in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with GMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. Any difficulties or delays in our contractors' manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, make us postpone or cancel clinical trials, prevent or delay regulatory approval by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our product candidates, or cause our products to be recalled or withdrawn.



Table of Contents

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

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

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

Our RNA-based platform, utilizing proprietary antisense technology, has not been incorporated into a commercial product and is still at a relatively early stage of development. This antisense technology is used in all of our therapeutic candidates, including AVI-4658. We are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we have initiated clinical trials for AVI-4658, additional preclinical studies may be required for AVI-4658 and before other product candidates enter human clinical trials. For example, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038, our preclinical PPMO drug candidate for DMD that is based on a different chemistry, derived from the PMO chemistry used in AVI-4658. Based on those findings, we are conducting additional preclinical work to help clarify the therapeutic index of AVI-5038, which will guide decision making on continued development of this candidate. In addition, preclinical models to study patient toxicity and activity of compounds are not necessarily predictive of toxicity or efficacy of these compounds in the treatment of human disease and there may be substantially different results in clinical trials from the results obtained in preclinical studies. Any failures or setbacks utilizing our antisense technology, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to maintain and/or enter into new corporate collaborations regarding these technologies, which would negatively affect our business and financial position.

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

Our ability to perform our U.S. government contracts, growth prospects and operating results depend on highly-skilled personnel to conduct product development and we intend to recruit, hire and retain significant numbers of additional personnel in the near term. Competition for qualified personnel in our industry, particularly those with experience with the infectious diseases we are target, is intense. In addition, we expect to meet some of our short-term personnel needs by engaging contractors who may be difficult to retain if they are offered permanent positions with other companies that guarantee a wider range of employee benefits not typically offered to contractors. If we are unable to attract, assimilate or retain such personnel or manage our growth effectively, our continued growth, expansion and ability to perform our U.S. government contracts would be adversely affected.

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

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

Our operations and our ability to execute our business strategy are highly dependent on the efforts of our executive management team. In April 2010, our chief executive officer and president resigned in connection with the settlement with a group of our shareholders. Following his departure, our board of directors appointed J. David Boyle II, our chief financial officer, to serve as interim chief executive officer and president, and we have hired an executive to assist Mr. Boyle with his responsibilities as chief financial officer. We are conducting a nationwide search for a new chief executive officer, but the departure of our chief executive officer and president and the circumstances surrounding his departure could have a disruptive effect on our ability to attract and retain qualified team members and execute our strategic plan. An extended period of time without a permanent chief executive officer could materially and adversely affect our business, financial condition or operating results. In the event we are unable to effect a smooth transition from our interim chief executive officer to a permanent chief executive officer, or if a new chief executive officer should unexpectedly prove to be unsuitable, the resulting disruption could negatively affect our operations and impede our ability to execute our strategic plan. In addition, although the members of our senior management team have employment agreements with us, these agreements may not provide sufficient incentives for these officers to continue employment with us. The loss of one or more of the members of our senior management team could adversely affect our operations.

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

As previously disclosed on April 20, 2010, we entered into a settlement agreement with a shareholder group that had sought a special meeting of our shareholders to replace certain members of our board of directors. In connection with such settlement

Table of Contents

agreement, among other things, we experienced the change in our executive leadership described above and our board of directors underwent significant change. Such changes may disrupt our operations as our company adjusts to the reallocation of responsibilities and assimilate new leadership and, potentially, differing perspectives on our strategic direction. The dispute with the shareholder group required the expenditure of significant time and resources by us and if we are involved in a similar dispute in the future, we may incur significant additional expenditures and it may be a significant distraction for our management and employees.

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

Our success will depend in significant part on our existing patents and licenses 205 patents (domestic and foreign) issued or licensed to us and 186 (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.

We cannot be certain that pending patent applications will result in patents being issued in the United States or foreign countries. In addition, the patents that have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours that do not conflict with our patents. Pharmaceutical research and development is highly competitive; others may file patents first that cover our products or technology. We are aware of a European patent to which Prosensa has rights that may provide the basis for Prosensa or other parties that have rights to patent to assert that our drug AVI-4658 infringes on such patent. We are currently opposing this patent in the Opposition Division of the European Patent Office and believe that we may be able to invalidate some or all of the claims covered by this patent and non-U.S. foreign equivalents. Final resolution of this opposition proceeding may take a number of years. In any case, we have freedom to operate with respect to our ongoing clinical trials for this drug candidate.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe on their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. If any patent related to our products or technology issues, and if our activities are determined to be covered by such a patent, we cannot assure you that we will be able to obtain or maintain a license, which could have a material adverse effect on our business, financial condition, operating results and ability to obtain and/or maintain our strategic business relationships.

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

To help protect our proprietary rights in unpatented trade secrets, we require our employees, consultants and advisors to execute confidentiality agreements and invention assignment agreements. However, such agreements may not provide us with adequate protection if confidential information is used or disclosed improperly. In addition, in some situations these agreements may conflict with, or be subject to, the rights of

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

third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Further, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets.

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

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antisense technology or that are developing alternative approaches to or therapeutics for the disease indications on which we are focused. Some of these competitors are developing or testing product candidates that do now, or may in the future, compete

Table of Contents

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

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

- develop safer or more effective products;
  
- implement more effective approaches to sales and marketing;
  
- develop less costly products;
  
- obtain quicker regulatory approval;
  
- have access to more manufacturing capacity;
  
- develop products that are more convenient and easier to administer;
  
- form more advantageous strategic alliances; or
  
- establish superior proprietary positions.

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

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

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

Our research and development activities involve the use of hazardous materials, including organic and inorganic solvents and reagents. Accordingly, we are subject to federal, state, and local laws and regulations governing the use, storage, handling, manufacturing, exposure to, and disposal of these hazardous materials. In addition, we are subject to environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Although we believe that our activities conform in all material respects with such environmental laws, there can be no assurance that violations of these laws will not occur in the future as a result of human error, accident, equipment failure, or other causes. Liability under environmental, health and safety laws can be joint and several and without regard to fault or negligence. The failure to comply with past, present, or future laws could result in the imposition of substantial fines and penalties,

Table of Contents

remediation costs, property damage and personal injury claims, loss of permits or a cessation of operations, and any of these events could harm our business and financial conditions. We expect that our operations will be affected by other new environmental and health and workplace safety laws on an ongoing basis, and although we cannot predict the ultimate impact of any such new laws, they may impose greater compliance costs or result in increased risks or penalties, which could harm our business.

**Risks Related to Our Common Stock**

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

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

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

In addition, the Oregon Control Share Act and Business Combination Act may limit parties that acquire a significant amount of voting shares from exercising control over us for specific periods of time. These provisions could discourage, delay or prevent a transaction involving a change of control, even if doing so would benefit our shareholders. These provisions also could discourage proxy contests and make it more

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

difficult for shareholders to elect directors of their choosing or cause us to take other corporate actions, such as replacing or removing management or members of our board of directors.

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

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

- positive or negative results of testing and clinical trials by ourselves, strategic partners, or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to our company;
- technological innovations or commercial product introductions by ourselves or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our products;
- financing or other corporate transactions;
- comments by securities analysts;



Table of Contents

- the perception that shares of our common stock may be delisted from The NASDAQ Stock Market; or
- general market conditions in our industry or in the economy as a whole.

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

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

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

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

***We expect that we will seek to raise additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.***

We expect that we will seek to raise additional capital from time to time in the future. For example, in connection with our December 2007, January 2009 and August 2009 financings, we sold an aggregate of 29.7 million shares of our common stock and issued warrants to purchase an additional 29.7 million shares of our common stock. Future financings may involve the issuance of debt, equity and/or securities convertible into or exercisable or exchangeable for our equity securities. These financings may not be available to us on reasonable terms or at all when and as we require funding. If we are able to consummate such financings, the trading price of our common stock could be adversely affected and/or the terms of such financings may adversely affect the interests of our existing shareholders. Any failure to obtain additional working capital when required would have a material adverse effect on our business and financial condition and would be expected to result in a decline in our stock price. Any issuances of our common stock, preferred stock, or securities such as warrants or notes that are convertible into, exercisable or

exchangeable for, our capital stock, would have a dilutive effect on the voting and economic interest of our existing shareholders.

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

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

Table of Contents

market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

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

None.

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

None.

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

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

Exhibit No	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed Herewith
			File No.	Exhibit	Filing Date	
10.85	AVI BioPharma, Inc. Non-Employee Director Compensation Policy	8-K	1-14895	10.85	10/1/10	
10.86*	Contract Number W9113M-10-C-0056 between U.S. Army Space and Missile Defense Command and the Company dated July 14, 2010					X
31.1	Certification of the Company's Interim President and Chief Executive Officer and Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Company's Controller and Chief Accounting Officer, Melinda K. Miles, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

32.1 Certification of the Company's Interim President  
and Chief Executive Officer, and Senior Vice  
President and Chief Financial Officer, J. David  
Boyle II, pursuant to Section 906 of the  
Sarbanes-Oxley Act of 2002

---

X

\* Confidential treatment has been requested for portions of this exhibit. These portions are omitted from this Quarterly Report on Form 10-Q and have been filed separately with the Securities and Exchange Commission.

Table of Contents

**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, 2010

**AVI BIOPHARMA, INC.**

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

By: */s/ MELINDA K. MILES*  
Melinda K. Miles  
Chief Accounting Officer  
  
(Principal Accounting Officer)

Table of Contents**EXHIBIT INDEX**

Exhibit No	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed Herewith
			File No.	Exhibit	Filing Date	
10.85	AVI BioPharma, Inc. Non-Employee Director Compensation Policy	8-K	1-14895	10.85	10/1/10	
10.86*	Contract Number W9113M-10-C-0056 between U.S. Army Space and Missile Defense Command and the Company dated July 14, 2010					X
31.1	Certification of the Company's Interim President and Chief Executive Officer and Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Company's Controller and Chief Accounting Officer, Melinda K. Miles, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of the Company's Interim President and Chief Executive Officer, and Senior Vice President and Chief Financial Officer, J. David Boyle II, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

---

\* Confidential treatment has been requested for portions of this exhibit. These portions are omitted from this Quarterly Report on Form 10-Q and have been filed separately with the Securities and Exchange Commission.