

AVI BIOPHARMA INC
Form 10-Q
May 10, 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 March 31, 2010

OR

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

For the transition period from to

Commission file number 001-14895

AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Oregon
(State or other jurisdiction of incorporation or
organization)

93-0797222
(I.R.S. Employer Identification No.)

3450 Monte Villa Parkway, Suite 101, Bothell, Washington
(Address of principal executive offices)

98021
(Zip Code)

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

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

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

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

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

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

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

Common Stock with \$.0001 par value

110,374,160

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

(Class)

(Outstanding as of May 8, 2010)

Table of Contents

AVI BIOPHARMA, INC.

FORM 10-Q

INDEX

	Page
<u>PART I - FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Financial Statements</u>
	<u>Balance Sheets</u> March 31, 2010 and December 31, 2009 (unaudited) 2
	<u>Statements of Operations</u> Three Months Ended March 31, 2010 and 2009 and from July 22, 1980 (Inception) through March 31, 2010 (unaudited) 3
	<u>Statements of Cash Flows</u> Three Months Ended March 31, 2010 and 2009 and from July 22, 1980 (Inception) through March 31, 2010 (unaudited) 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> 11
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 13
<u>Item 4.</u>	<u>Controls and Procedures</u> 13
<u>PART II - OTHER INFORMATION</u>	
<u>Item 1.</u>	<u>Legal Proceedings</u> 13
<u>Item 1A.</u>	<u>Risk Factors</u> 13
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u> 18
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 18
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u> 18
<u>Item 4.</u>	<u>Removed and Reserved</u> 18
<u>Item 5.</u>	<u>Other Information</u> 18
<u>Item 6.</u>	<u>Exhibits</u> 19
<u>Signatures</u>	20
Exhibits	

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)

	March 31, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	\$ 41,438	\$ 48,275
Short-term securities available-for-sale	172	171
Accounts receivable	1,648	2,085
Other current assets	891	779
Total Current Assets	44,149	51,310
Property held for sale	2,372	2,372
Property and Equipment, net of accumulated depreciation and amortization of \$14,138 and \$14,026	2,361	2,466
Patent Costs, net of accumulated amortization of \$1,787 and \$1,762	3,832	3,759
Other assets	111	120
Total Assets	\$ 52,825	\$ 60,027
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	\$ 1,761	\$ 1,381
Accrued employee compensation	495	922
Long-term debt, current portion	78	77
Warrant valuation	20,500	27,609
Deferred revenue	3,409	3,428
Other liabilities	98	90
Total Current Liabilities	26,341	33,507
Commitments and Contingencies		
Long-term debt, non-current portion	1,903	1,924
Other long-term liabilities	1,108	966
Shareholders' Equity:		

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding		
Common stock, \$.0001 par value, 200,000,000 shares authorized; 110,374,160 and 110,495,587 issued and outstanding	11	11
Additional paid-in capital	299,515	299,088
Deficit accumulated during the development stage	(276,053)	(275,469)
Total Shareholders' Equity	23,473	23,630
Total Liabilities and Shareholders' Equity	\$ 52,825	\$ 60,027

See accompanying notes to financial statements.

Table of Contents

AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three months ended March 31,		July 22, 1980
	2010	2009	(Inception) through March 31, 2010
Revenues from license fees, grants and research contracts	\$ 1,205	\$ 3,150	\$ 61,014
Operating expenses:			
Research and development	6,096	4,495	236,528
General and administrative	2,844	2,220	76,864
Acquired in-process research and development			29,461
Operating loss	(7,735)	(3,565)	(281,839)
Other income (loss):			
Interest income and other, net	42	16	8,365
(Increase) decrease on warrant valuation	7,109	2,622	10,559
Realized gain on sale of short-term securities available-for-sale			3,863
Write-down of short-term securities available-for-sale			(17,001)
	7,151	2,638	5,786
Net loss	\$ (584)	\$ (927)	\$ (276,053)
Net loss per share - basic and diluted	\$ (0.01)	\$ (0.01)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share (in thousands)	110,429	80,759	

See accompanying notes to financial statements.

Table of Contents

AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three months ended March 31,		For the Period
	2010	2009	July 22, 1980 (Inception) through March 31, 2010
Cash flows from operating activities:			
Net loss	\$ (584)	\$ (927)	\$ (276,053)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	347	367	18,029
Loss on disposal of assets	189	183	1,494
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			928
Stock-based compensation	426	565	23,123
Conversion of interest accrued to common stock			8
Acquired in-process research and development			29,461
(Gain) loss on warrant liability	(7,109)	(2,622)	(10,559)
(Increase) decrease in:			
Accounts receivable, other current assets, and other assets	334	1,799	(2,566)
Net increase in accounts payable, accrued employee compensation, deferred revenue, and other liabilities	85	(980)	5,359
Net cash used in operating activities	(6,312)	(1,615)	(197,638)
Cash flows from investing activities:			
Purchase of property and equipment	(207)	(37)	(18,076)
Patent costs	(297)	(259)	(7,540)
Purchase of marketable securities	(1)	(3)	(112,987)
Sale of marketable securities			117,724
Acquisition costs			(2,389)
Net cash used in investing activities	(505)	(299)	(23,268)
Cash flows from financing activities:			
Proceeds from sale of common stock, warrants, and partnership units, net of offering costs, and exercise of options and warrants		15,464	262,937
Repayments of long-term debt	(20)	(19)	(207)
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	(20)	15,445	262,344
Increase (decrease) in cash and cash equivalents	(6,837)	13,531	41,438
Cash and cash equivalents:			

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Beginning of period		48,275		11,192	
End of period	\$	41,438	\$	24,723	\$ 41,438

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid during the year for interest	\$	19	\$	24	\$ 324
--	----	----	----	----	--------

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

See accompanying notes to financial statements.

Table of Contents

AVI BIOPHARMA, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Note 1. Basis of Presentation

The financial information included herein for the three-month period ended March 31, 2010 and 2009 and the financial information as of March 31, 2010 is unaudited; however, such information reflects all adjustments consisting only of normal recurring adjustments, which, in the opinion of management, are necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The financial information as of December 31, 2009 is derived from AVI BioPharma, Inc.'s (the Company's) Form 10-K. The interim financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Form 10-K. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

Estimates and Uncertainties. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

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

Note 2. Fair Value Measurements

The Company measures at fair value certain financial assets and liabilities. Accounting principles generally accepted in the United States require a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs have created the following fair-value hierarchy:

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

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

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

(in thousands)	Fair Value Measurement as of March 31, 2010			
	Total	Level 1	Level 2	Level 3
Cash equivalents	\$ 41,438	\$ 41,438		
Short-term securities available-for-sale & other current assets	\$ 457		\$ 457	
Total Assets	\$ 41,895	\$ 41,438	\$ 457	\$

(in thousands)	Fair Value Measurement as of March 31, 2010			
	Total	Level 1	Level 2	Level 3
Warrants	\$ 20,500			\$ 20,500
Total Liabilities	\$ 20,500	\$	\$	\$ 20,500

Table of Contents

(in thousands)	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
Cash equivalents	\$ 48,275	\$ 48,275		
Short-term securities available-for-sale & other current assets	\$ 455		\$ 455	
Total Assets	\$ 48,730	\$ 48,275	\$ 455	\$

(in thousands)	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
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 March 31, 2010 is as follows:

(in thousands)	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
Balance at January 1, 2010	\$	27,609
Change in value of warrants		(7,109)
Balance at March 31, 2010	\$	20,500

A reconciliation of the change in value of the Company's warrants for the three months ended March 31, 2009 is as follows:

(in thousands)	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
Balance at January 1, 2009	\$	1,254
Change in value of warrants		(2,622)
Issuances		8,183
Balance at March 31, 2009	\$	6,815

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. Revenue Recognition

Revenue is recorded from research contracts and grants as the services are performed and payment is reasonably assured. Upfront, nonrefundable fees and other fees associated with license and development arrangements are recognized as revenue ratably over the performance period. Revenue associated with research and development arrangements is recognized under the proportional performance method, using the payment received method. To date, revenue from non-government research and development arrangements has not been material.

Note 4. Property Held for Sale

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

Note 5. Liquidity

Since its inception in 1980 through March 31, 2010 the Company has incurred losses of approximately \$276.0 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.

The Company believes it has sufficient cash to fund operations at least through the following twelve months, exclusive of future receipts from billings on existing government contracts. For 2010, the Company expects expenditures for operations, net of government funding, including collaborative efforts and research and development activities, to be approximately \$23 to \$27 million. The Company believes it will continue to receive funding from government and other sources to pursue the development of its product candidates and has assumed certain revenue from these awards in providing this guidance. Should the Company not continue to

Table of Contents

receive funding from its current contracts or not receive additional funding, or should the timing be delayed, the Company's expectations may be negatively impacted to a significant extent.

The Company's cash, cash equivalents and short-term securities were \$41.6 million at March 31, 2010, compared with \$48.4 million at December 31, 2009. The decrease of \$6.8 million was due primarily to cash used in operations of \$6.3 million and \$0.5 million of costs related to acquisitions of patents and fixed assets.

In January 2009, the Company raised net proceeds of \$15.5 million in financing through the sale of 14,224,202 shares of common stock pursuant to a registered direct offering to a select group of institutional investors. The investors also received warrants to purchase 14,224,202 shares of the Company's common stock at an exercise price of \$1.16 per share. These warrants are exercisable starting July 30, 2009 and expire on July 30, 2014. In addition, the placement agent used for the equity financing received a warrant for the purchase of an additional 426,726 common shares at \$1.45 per share. This warrant is exercisable starting January 30, 2009 and expires on January 30, 2014. All of these warrants have been classified as liabilities as discussed in Note 7, as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

On August 25, 2009, the Company closed a registered equity financing for net proceeds of \$32.3 million with several institutional investors. The Company sold 24,295,775 shares of common stock at \$1.42 per share, and also issued warrants for the purchase of 9,718,310 common shares at an exercise price of \$1.78 per share. These warrants are exercisable starting February 25, 2010 and expire on August 25, 2014. All of these warrants have been classified as liabilities as discussed in Note 7, as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

The Company currently has a total of \$65.7 million of contracted development studies. As of March 31, 2010, \$49.6 million has been billed to the government. The Company has \$16.1 million in development contracts remaining that have not yet been completed and have not been billed.

Note 6. Stock Compensation

Valuation Assumptions

Stock-based compensation costs are generally based on the fair value calculated from the Black-Scholes option-pricing model on the date of grant for stock options. 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 market values of stock options granted during the periods presented were measured on the date of grant using the Black-Scholes option-pricing model, with the following assumptions:

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Three Months Ended March 31,	2010	2009
Risk-free interest rate	2.83%	1.2%-1.4%
Expected dividend yield	0%	0%
Expected lives	5.76 years	9.0 years
Expected volatility	87.87%	92.0%-92.8%

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

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

Stock Options

A summary of the Company's stock option compensation activity with respect to the fiscal quarter ended March 31, 2010 follows:

Stock Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2010	8,932,811	\$ 2.79		
Granted	2,235,365	\$ 1.45		
Exercised		\$		
Canceled or expired	(1,996,786)	\$ 4.84		
Outstanding at March 31, 2010	9,171,390	\$ 2.01	7.87	\$ 483,911
Vested at March 31, 2010 and expected to vest	9,060,380	\$ 2.02	7.85	\$ 478,418
Exercisable at March 31, 2010	4,070,875	\$ 2.90	6.25	\$ 158,761

Table of Contents

The weighted-average fair value per share of stock-based payments granted to employees during the three months ended March 31, 2010 and March 31, 2009 was \$1.06 and \$0.86, respectively. During the same periods, there were no stock options exercised, and the total fair value of stock options that vested was \$838,000 and \$442,000, respectively.

Stock-based Compensation Expense

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

(in thousands)	Three Months Ended March 31, 2010		Three Months Ended March 31, 2009	
Research and development	\$	199	\$	356
General and administrative		227		209
Total	\$	426	\$	565

As of March 31, 2010, there was \$4,339,000 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Plan. These costs are expected to be recognized over a weighted-average period of 2.2 years.

Non-Employee Stock Options

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with accounting principles generally accepted in the United States. The total expense of the options granted to non-employees during the three months ended March 31, 2010 and 2009 was \$18,000 and \$78,000, respectively, which was expensed to research and development.

Restricted Stock Awards

	Restricted Stock Awards (in Thousands)		Weighted-Average Grant Date Fair Value
Balance as of December 31, 2009	300	\$	1.09
Granted			
Vested	(58)		1.09
Forfeited or canceled	(100)		1.10
Balance as of March 31, 2010	142	\$	1.09

The weighted-average grant-date fair value of restricted stock rights is based on the quoted market price of our common stock on the date of grant. There were no restricted stock awards granted during the three months ended March 31, 2010. The weighted-average grant-date fair values of restricted stock rights granted during the three months ended March 31, 2009 were \$1.00. The total grant-date fair values of restricted

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

stock awards that vested during the three months ended March 31, 2010 and March 31, 2009 was approximately \$63,000 and \$303,000, respectively.

In the second quarter of 2009, the Company granted 100,000 shares of restricted stock to its Senior Vice President of Business Development. These shares vest upon the achievement of certain performance milestones. During the quarter ended March 31, 2010, the Company did not recognize any compensation expense related to these shares since the performance milestones were not achieved. The Company believes that it is unlikely that these milestones will be achieved.

Table of ContentsNote 7. Warrants

Certain of the Company's warrants issued in connection with financing arrangements are classified as liabilities in accordance with accounting principles generally accepted in the United States, whereby, the fair market value of these warrants is recorded on the balance sheet at issuance and marked to market at each financial reporting period. The change in the fair value of the warrants is recorded in the Statement of Operations as a gain (loss) and is estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Three Months Ended March 31,	2010	2009
Risk-free interest rate	0.1%-2.6%	0.2%-1.9%
Expected dividend yield	0%	0%
Expected lives	0.1-4.41 years	0.3-5.5 years
Expected volatility	62.3%-93.0%	83.2%-140.6%
Warrants classified as liabilities	30,203,466	22,645,157
Warrants classified as equity	2,129,530	2,129,530
Market value of stock at beginning of year	\$ 1.58	\$ 0.66
Market value of stock at end of period	\$ 1.18	\$ 0.66

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

For warrants classified as permanent equity in accordance with accounting principles generally accepted in the United States, the fair value of the warrants is recorded as additional paid-in capital and no further adjustments are made.

A summary of the Company's warrant activity with respect to the three months ended March 31, 2010 is as follows:

Warrants	Shares	Weighted Average Exercisable Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2010	32,332,996	\$ 3.40	
Granted		\$	
Canceled or expired		\$	
Outstanding at March 31, 2010	32,332,996	\$ 3.40	3.76

Note 8. Earnings Per Share

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

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

Three Months Ended March 31,

(amounts in thousands, except per-share data)

	2010	2009
Net loss	\$ (584)	\$ (927)
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	110,429	80,759
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	110,429	80,759
Net loss per share - basic and diluted	\$ (0.01)	\$ (0.01)

* Warrants and stock options to purchase 41,504,386 and 33,355,341 shares of common stock as of March 31, 2010 and 2009, respectively, were excluded from the earnings per share calculation as their effect would have been anti-dilutive.

Table of Contents

Note 9. Equity Financing

On January 30, 2009, the Company closed a registered equity financing for net proceeds of \$15.5 million with several institutional investors. The Company sold 14,224,202 shares of common stock at \$1.16 per share, and also issued warrants for the purchase of 14,224,202 common shares at \$1.16 per share. The warrants had fair value at the date of issue of \$8.2 million. These warrants are exercisable starting July 30, 2009 and expire on July 30, 2014. In connection with the equity financing, the placement agent received a warrant for the purchase of an additional 426,726 common shares at \$1.45 per share. This warrant is exercisable starting January 30, 2009 and expires on January 30, 2014. All of these warrants have been classified as liabilities as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company does not expect to expend any cash to settle these liabilities.

On August 25, 2009, the Company closed a registered equity financing for net proceeds of \$32.3 million with several institutional investors. The Company sold 24,295,775 shares of common stock at \$1.42 per share, and also issued warrants for the purchase of 9,718,310 common shares at \$1.78 per share. The warrants had fair value at the date of issue of \$9.0 million. These warrants are exercisable starting February 25, 2010 and expire on August 25, 2014. All of these warrants have been classified as liabilities as they require the issuance of registered shares. These warrants are non-cash liabilities; the Company does not expect to expend any cash to settle these liabilities.

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

Note 10. Income Taxes

The Company accounts for its income taxes as provided by accounting principles generally accepted in the United States. The Company has not recognized any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

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

At March 31, 2010, the Company had net deferred tax assets of approximately \$111 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules could limit the future use of its net operating loss and R&D credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

Note 11. Comprehensive Loss and Securities Available for Sale

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Comprehensive loss includes charges or credits to equity that did not result from transactions with shareholders. The Company's only component of other comprehensive loss is unrealized gain (loss) on cash equivalents and short-term securities available-for-sale. Accordingly, such investment securities are stated on the balance sheet at their fair market value. The Company classifies its investment securities with an original maturity of three months or less from the date of purchase as cash equivalents. The Company classifies its investment securities with an original maturity of more than three months from the date of purchase as short-term securities available-for-sale. Any unrealized difference between the adjusted cost and the fair market value of these securities is reflected as a separate component of shareholders' equity. At March 31, 2010 and March 31, 2009, the Company's investments in marketable securities had gross unrealized gains (losses) of \$0 and \$0, respectively. The following table sets forth the calculation of comprehensive income for the period indicated:

(in thousands)	Three Months Ended March 31,	
	2010	2009
Net loss	\$ (584)	\$ (927)
Unrealized loss on marketable securities		
Comprehensive loss	\$ (584)	\$ (927)

Note 12. Recent Accounting Pronouncements

In January 2010, the 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 issue is limited to transactions involving research or development. Under the consensus, 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 consensus 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 is still evaluating the impact of this guidance to determine the impact on the Company's financial statements.

Note 13. Subsequent Events

On April 20, 2010, the Company's Chief Executive Officer and President, Leslie Hudson, Ph.D., tendered his resignation at the request of the Board of Directors. Dr. Hudson's Employment Agreement dated February 8, 2008, included a Separation Agreement and pursuant to the terms of the Separation Agreement, Dr. Hudson will receive total cash severance payments of \$1,412,170 (the Cash Severance Payments), calculated by reference to two (2) 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 will be made to Dr. Hudson in twenty-four (24) equal monthly installments, less required deductions and withholdings, over the twenty-four (24) month period following the effective date of the Separation Agreement. In addition, as of the effective date of the Separation Agreement, previously granted options to Dr. Hudson will become fully vested and exercisable. The Company intends to recognize a charge for the cash compensation and stock compensation in the second quarter of 2010.

Table of Contents

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

This section should be read in conjunction with the same titled section contained in our Annual Report on Form 10-K as filed with the SEC for the year ended December 31, 2009 and the Risk Factors contained in the 10-K and this report.

Forward-Looking Information

The Financial Statements and Notes thereto should be read in conjunction with the following discussion. The discussion in this Form 10-Q contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. Forward-looking statements are identified by such words as believe, expect, anticipate and words of similar import. All statements other than historical or current facts, including, without limitation, statements about our business strategy, plans and objectives of management and our future prospects, are forward-looking statements. Such forward-looking statements involve risks and uncertainties, including, but not limited to, the results of research and development efforts, the success of raising funds in future offerings under our current shelf registration, the results of pre-clinical and clinical testing, the effect of regulation by FDA and other agencies, the impact of competitive products, product development, commercialization and technological difficulties, and other risks detailed in the Company's Securities and Exchange Commission filings, that could cause actual results to differ materially from the expected results reflected in such forward looking statements.

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest, license fees, 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 enter additional collaborative efforts. As of March 31, 2010, our accumulated deficit was \$276 million.

Results of Operations

Revenue from license fees, grants and research contracts decreased to \$1.2 million in the first quarter of 2010 from \$3.2 million in the comparable period in 2009. The decrease in research contracts revenue was the result of the decline in revenue from government research contracts.

Operating loss increased to \$7.7 million in the first quarter of 2010 compared to \$3.6 million in the first quarter of 2009. The increase in the operating loss is the result of lower revenue, higher research and development expenses and higher general and administration expenses.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Research and development expenses increased to \$6.1 million in the first quarter of 2010 from \$4.5 million in the first quarter of 2009. This research and development increase was due primarily to increases in research and development costs related to the Duchenne Muscular Dystrophy project.

General and administrative expenses increased to \$2.8 million in the first quarter of 2010, from \$2.2 million in the first quarter of 2009. The increase in general and administrative expenses was due primarily to higher legal costs, rent for the new Bothell, Washington location and relocation expenses.

The decrease on warrant liability of \$7.1 million in the first quarter of 2010 was the result of the decline in the Company's stock price. In the first quarter of 2009, the warrant liability also decreased \$2.6 million also as the result of the decline in the Company's stock price subsequent to the issuance of warrants as a part of the equity financing that closed in January 2009. The decrease or (increase) on warrant liability fluctuates as the market price of the Company's stock fluctuates.

Table of Contents

The net loss decreased to \$0.6 million in the first quarter of 2010 from \$0.9 million in the first quarter of 2009. The net loss decreased slightly primarily due to the increase in the operating loss offset by the decrease on the warrant liability.

Liquidity and Capital Resources

Since its inception in 1980 through March 31, 2010, the Company has incurred losses of approximately \$276.0 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.

The Company believes it has sufficient cash to fund operations at least through the following twelve months, exclusive of future receipts from billings on existing government contracts. For 2010, the Company expects expenditures for operations, net of government funding, including collaborative efforts and research and development activities to be approximately \$23 to \$27 million. The Company believes it will continue to receive funding from government and other sources to pursue the development of its product candidates and has assumed certain revenue from these awards in providing this guidance. Should the Company not continue to receive funding from its current contracts or receive additional funding, or should the timing be delayed, it may have a significant negative impact on the Company's operating results.

Our cash, cash equivalents and short-term securities were \$41.6 million at March 31, 2010, compared with \$48.4 million at December 31, 2009, respectively. The decrease of \$6.8 million was due primarily to cash used in operations of \$6.3 million and costs of \$0.5 million related to acquisitions of patents and fixed assets.

The Company currently has a total of \$65.7 million of contracted development studies. As of March 31, 2010, \$49.6 million has been billed to the government. The Company has \$16.1 million in development contracts remaining that have not yet been completed and have not been billed.

In December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junín hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. In May 2009, the Company received an amendment from DTRA to extend the contract performance period to November 29, 2009 and a cost modification of an additional \$5.9 million, increasing the total contract amount to \$33.9 million. In September 2009, the Company received a second amendment from DTRA to extend the contract performance period to February 28, 2011 and a cost modification of an additional \$11.5 million, increasing the total contract amount to \$45.4 million. During the three months ended March 31, 2010 and 2009, the Company recognized \$0.5 million and \$1.7 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenue of \$35.8 million from this contract. Funding of the remainder of the contract is anticipated in 2010 and 2011.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company's technology is expected to be used to continue developing

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

RNA based drugs against Ebola and Marburg viruses. The Company has received signed contracts for all of these projects. During the three months ended March 31, 2010 and 2009, the Company recognized \$0.3 million and \$1.4 million, respectively, in research contract revenue from these contracts. To date, the Company has recognized revenue of \$9.5 million on these contracts. Funding of the remainder of these contracts is anticipated in 2010.

Starting in 2009, the Company entered into a contract with DTRA to develop H1N1 drugs. Under this contract, DTRA will pay up to \$8.1 million for the work to be performed by the Company. The work will involve the application of analogs based on the Company's proprietary PMO and PMO*plus* antisense chemistry and the Company plans to conduct preclinical development of at least one drug candidate and demonstrate its effectiveness by testing it in virus infected animals. During the three months ended March 31, 2010, the Company recognized \$0.3 million in revenue under this contract. To date, the Company has recognized revenue of \$2.0 million under this contract. Funding of the remainder of these contracts is anticipated in 2010.

We do not expect any material revenue in 2010 from our business activities except for revenue from U.S. government contracts. We expect that our cash requirements for the next twelve months to be satisfied by existing cash resources and this revenue. To fund our operations beyond the next twelve months, we may need to raise additional capital. We will continue to look for opportunities to finance our ongoing activities and operations through accessing corporate partners or the public equity markets, as we currently have no credit facility, and do not intend to seek one.

Table of Contents

Critical Accounting Policies and Estimates

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There has been no material change in the Company's market risk exposure since the filing of our 2009 Annual Report on Form 10-K, as amended by the filing of Amendment No. 1 on Form 10-K/A filed with the SEC on April 28, 2010.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We carried out an evaluation as of the end of period covered by this report, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures pursuant to paragraph (b) of Rule 13a-15 and 15d-15 under the Exchange Act. Based on that review, the Chief Executive Officer and Chief Financial Officer has concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act (1) is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and (2) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Internal Controls and Procedures

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

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None

Item 1A. Risk Factors.

Risks Affecting Future Operating Results

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

We may get unexpected positive or negative results or outcomes during any stage of product development.

Clinical studies at all phases of clinical investigation, must be granted permission to proceed by the regulatory authorities and Institutional Review Boards (IRBs) or Ethics Committees (ECs) before they may start and these agencies review progress and safety information during the course of any study. Clinical studies are experiments designed to test a theory or hypothesis, and by their very nature, the result is unknown at the time the study is started, therefore, unexpected results or outcomes may occur that may provide positive or negative new information. Examples of unexpected results or outcomes that may occur include results that are either better than or not as good as predicted during hypothesis generation, including for example a result where the product performs better than expected and as a result of the clinical benefit a longer time is taken to reach a predefined clinical endpoint that is based on worsening disease factors, or the product may not demonstrate the predicted level of effectiveness in a specific study, or an unexpected serious adverse event may occur. These kinds of results or outcomes may result in the company voluntarily discussing the clinical study design, results and outcomes, and future development plans with the regulatory agencies, IRBs or ECs; any such discussions, changes in study designs or changes to the overall development plans may either accelerate or delay development of the product. Similarly, unexpected results or outcomes may occur in nonclinical animal studies or in manufacturing and quality control. This might also lead to changes in the developmental plan which could shorten or extend the time to a final study result.

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, we may be unable to continue to successfully develop our products.

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

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

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

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

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

We rely on U.S. government contracts and awards to fund several of our development programs, including those for the Ebola, Marburg, Junín and H1N1 viruses. The termination of one or more of these contracts, whether due to lack of funding, for convenience, or otherwise, or the occurrence of delays or product failures in connection with one or more of these contracts, could negatively impact our financial condition. Furthermore, we can give no assurance that we would be able to procure new U.S. government contracts to offset the revenue lost as a result of any termination of our contracts.

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

our future sales under such a contract or subcontract. From time to time, when a formal appropriation bill has not been signed into law before the end of the U.S. government's fiscal year, Congress may pass a continuing resolution that authorizes agencies of the U.S. government to continue to operate, generally at the same funding levels from the prior year, but does not authorize new spending initiatives, during a certain period. During such a period (or until the regular appropriation bills are passed), delays can occur in government procurement due to lack of funding and such delays can affect our operations during the period of delay.

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

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

All of our products are subject to extensive regulation by the United States FDA, and by comparable agencies in other countries. The FDA and these agencies require new pharmaceutical products to undergo lengthy and detailed preclinical and clinical testing

Table of Contents

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

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

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

Effective April 20, 2010, our Chief Executive Officer and President, Dr. Hudson, resigned and our current Chief Financial Officer, David Boyle, was appointed Interim Chief Executive Officer and President while retaining his title and responsibilities as Chief Financial Officer. The Company expects to initiate a search for a permanent Chief Executive Officer. In the interim, the Company expects to hire a temporary Chief Financial Officer so that Mr. Boyle may devote his time to his responsibilities as Chief Executive Officer. In addition, effective April 20, 2010, Dr. Hudson and K. Michael Forrest resigned from the Board of Directors. The Company added one replacement director to fill the unexpired term of Dr. Hudson. Also, as a result of the decisions by two of our existing directors not to stand for reelection, the Company has nominated two individuals as replacement for such directors. All of the foregoing personnel changes pose risks to the Company operations as a result of the reallocation of responsibilities, changes in experience and perspectives and the general disruption that often accompany changes in strategic personnel.

Asserting, defending and maintaining our intellectual property rights could be challenging and costly, and our failure to do so could harm our ability to compete and impair the outcome of our operations. The pharmaceutical, 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 (195 patents (domestic and foreign) issued or licensed to us and 178 (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. We are aware of a patent that was issued that may provide the basis for the patent holder to assert that our drug AVI-4658 infringes on such patent. We intend to vigorously defend against any such claim if one should be asserted and believe that we may be able to invalidate some or all of the claims covered by this patent. In any case, we believe that we have freedom to operate and are moving forward with our

ongoing clinical trials and drug development efforts for this drug candidate.

Others may challenge our patents and, as a result, our patents could be narrowed or invalidated. The patent position of 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 United States Patent and Trademark Office (USPTO) or the courts regarding the breadth of claims allowed or the degree of protection afforded under biotechnology patents. In addition, there is a substantial backlog of pharmaceutical and biotechnology patent applications at the USPTO and the approval or rejection of patents may take several years.

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

Table of Contents

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

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

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

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

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

We may increase our external contract resources to expand our ability to execute additional projects. Additional outsourced resources may include clinical resource organizations, scientific research and animal studies, manufacturing, contracted administrative and other services. If we are unable to identify and enter into constructive relationships with these organizations, it could negatively impact our ability to execute additional projects.

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

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

We incurred a net loss of \$0.6 million for the first quarter of 2010 and \$25.2 million for the year ended December 31, 2009. As of March 31, 2010, our accumulated deficit was \$276.0 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, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

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

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

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

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

Table of Contents

significant legal defense costs, thereby increasing our expenses, lowering our earnings and, depending on revenue, potentially resulting in additional losses.

We use hazardous substances in our research activities.

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

Risks Related to Share Ownership

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

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

In addition, we have a classified Board of Directors, which means that approximately one-half of our directors are eligible for election each year. Therefore, if shareholders wish to change the composition of our Board of Directors, it could take at least two years to remove a majority of the existing directors or to change all directors. Having a classified Board of Directors may, in some cases, delay mergers, tender offers or other possible transactions that may be favored by some or a majority of our shareholders and may delay or frustrate action by shareholders to change the then current Board of Directors and management. The Oregon Control Share Act and Business Combination Act may limit parties that acquire a significant amount of voting shares from exercising control over us for specific periods of time. These acts may lengthen the period for a proxy contest or for a person to vote their shares to elect the majority of our Board and change management.

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

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

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

We have outstanding 110,374,160 shares of common stock as of March 31, 2010 and all are eligible for sale under Rule 144 or are otherwise freely tradable. In addition:

- Our employees and others hold options to buy a total of 9,171,390 shares of common stock, of which 4,070,875 options were exercisable at March 31, 2010. The options outstanding have exercise prices between \$0.60 and \$7.35 per share. The shares of common stock to be issued upon exercise of these options have been registered, and, therefore, may be freely sold when issued.

Table of Contents

- There are outstanding warrants to buy 32,332,996 shares of common stock as of March 31, 2010 with exercise prices ranging from \$.0003 to \$35.63 per share. Outstanding warrants to buy 30,203,466 shares of common stock are issuable upon exercise of outstanding warrants for common stock registered for resale and may be freely sold when issued, subject to the limitations imposed by applicable securities laws.

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

- We may issue options to purchase up to an additional 2,653,288 shares of common stock as of March 31, 2010 under our stock option plans, which also will be fully saleable when issued except to the extent limited under Rule 144 for resales by our officers and directors.

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

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

Our common stock is listed on The NASDAQ Global Market. The NASDAQ Global Market has several quantitative and qualitative requirements with which companies must comply in order to maintain this listing, including a \$1.00 minimum bid price per share and \$50 million minimum value of listed securities. If a listed company fails to meet the \$1.00 minimum bid price per share requirement for 30 consecutive days, it will receive a notice from NASDAQ mandating that the company achieve compliance with the minimum bid price per share listing requirement within 180 calendar days. Our stock price is currently above \$1.00; however, our stock price was priced at \$0.99 as recently as May 11, 2009. There can be no assurance that we will be able to maintain compliance with the minimum bid price per share requirement in the future.

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

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

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

Item 1B. Unresolved Staff Comments.

None.

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

None.

Item 3. Defaults Upon Senior Securities.

None

Item 4. Removed and Reserved.

Item 5. Other Information.

None

Table of Contents**Item 6. Exhibits**

Exhibit No	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed Herewith
			File No.	Exhibit	Filing Date	
3.1	Third Restated Articles of Incorporation of AntiVirals Inc.	SB-2	333-20513	3.1	5/29/97	
3.2	First Restated Bylaws of AVI BioPharma, Inc.	8-K	1-14895	3.5	2/7/08	
3.3	First Amendment to Third Restated Articles of Incorporation	8-K	0-22613	3.3	9/30/98	
3.4	Amendment to Article 2 of the Company's Third Restated Articles of Incorporation	DEF 14A	1-14895	N/A	4/11/02	
10.81+	Amendment of Contract between AVI BioPharma, Inc. and the U.S. Defense Threat Reduction Agency (contract no HDTRA 1-09-C-0046), effective March 25, 2010					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
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

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

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: May 10, 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 and Principal Financial and Accounting Officer)