

AVI BIOPHARMA INC
Form 10-Q
May 11, 2009
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, 2009

OR

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

For the transition period from to

Commission file number 001-14895

AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Oregon

(State or other jurisdiction of incorporation or organization)

93-0797222

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

4575 SW Research Way, Suite 200, Corvallis, Oregon

(Address of principal executive offices)

97333

(Zip Code)

Issuer's telephone number, including area code: **541-753-3635**

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
(Class)

85,644,698
(Outstanding at May 8, 2009)

Table of Contents

AVI BIOPHARMA, INC.

FORM 10-Q

INDEX

<u>PART I - FINANCIAL INFORMATION</u>		Page
<u>Item 1.</u>	<u>Financial Statements</u>	
	<u>Balance Sheets – March 31, 2009 and December 31, 2008 (unaudited)</u>	2
	<u>Statements of Operations – Three Months Ended March 31, 2009 and 2008 and from July 22, 1980 (Inception) through March 31, 2009 (unaudited)</u>	3
	<u>Statements of Cash Flows – Three Months Ended March 31, 2009 and 2008 and from July 22, 1980 (Inception) through March 31, 2009 (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>	15
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	18
<u>Item 4.</u>	<u>Controls and Procedures</u>	18
<u>PART II – OTHER INFORMATION</u>		
<u>Item 1.</u>	<u>Legal Proceedings</u>	19
<u>Item 1A.</u>	<u>Risk Factors</u>	19
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	26
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Securities Holders</u>	26
<u>Item 5.</u>	<u>Other Information</u>	26
<u>Item 6.</u>	<u>Exhibits</u>	27
<u>Signatures</u>		28
Exhibits		

Table of Contents

AVI BIOPHARMA, INC.

(A Development Stage Company)

BALANCE SHEETS

(unaudited)

(in thousands, except per share data)

	March 31, 2009	December 31, 2008
Assets		
Current Assets:		
Cash and cash equivalents	\$ 24,723	\$ 11,192
Short-term securities available-for-sale	285	282
Accounts receivable	3,126	4,971
Other current assets	645	599
Total Current Assets	28,779	17,044
Property and Equipment, net of accumulated depreciation and amortization of \$13,207 and \$12,919	4,934	5,189
Patent Costs, net of accumulated amortization of \$1,959 and \$1,927	3,269	3,268
Other assets	35	35
Total Assets	\$ 37,017	\$ 25,536
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	\$ 1,279	\$ 2,014
Accrued employee compensation	964	1,306
Long-term debt, current portion	75	74
Warrant liability	6,815	1,254
Deferred revenue	2,159	2,190
Other liabilities	324	450
Total Current Liabilities	11,616	7,288
Commitments and Contingencies		
Long-term debt, non-current portion	1,981	2,001
Other long-term liabilities	530	515
Shareholders Equity:		
Preferred stock, \$.0001 par value, 20,000,000 shares authorized; none issued and outstanding		
Common stock, \$.0001 par value, 200,000,000 shares authorized; 85,644,698 and 71,101,738 issued and outstanding	9	7
Additional paid-in capital	274,118	266,035
Accumulated other comprehensive income		
Deficit accumulated during the development stage	(251,237)	(250,310)
Total Shareholders Equity	22,890	15,732
Total Liabilities and Shareholders Equity	\$ 37,017	\$ 25,536

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
	2009	2008	(Inception) through March 31, 2009
Revenues from license fees, grants and research contracts	\$ 3,150	\$ 5,625	\$ 45,374
Operating expenses:			
Research and development	4,495	6,903	210,531
General and administrative	2,220	2,553	67,544
Acquired in-process research and development		9,916	29,461
	6,715	19,372	307,536
Other income (loss):			
Interest income and other, net	16	167	8,793
Gain (loss) on warrant liability	2,622	(1,435)	15,270
Realized gain on sale of short-term securities available-for-sale			3,863
Write-down of short-term securities available-for-sale			(17,001)
	2,638	(1,268)	10,925
Net loss	\$ (927)	\$ (15,015)	\$ (251,237)
Net loss per share - basic and diluted	\$ (0.01)	\$ (0.23)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share (in thousands)	80,759	65,188	

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
	2009	2008	July 22, 1980 (Inception) through March 31, 2009
Cash flows from operating activities:			
Net loss	\$ (927)	\$ (15,015)	\$ (251,237)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	367	349	16,670
Loss on disposal of assets	183	1	1,141
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			800
Issuance of common stock and warrants to vendors			2,903
Compensation expense on issuance of common stock and partnership units	45	118	1,073
Compensation expense to non-employees on issuance of options and warrants to purchase common stock or partnership units	78	104	3,213
Stock-based compensation	442	1,279	13,699
Conversion of interest accrued to common stock			8
Acquired in-process research and development		9,916	29,461
(Gain) loss on warrant liability	(2,622)	1,435	(15,270)
(Increase) decrease in:			
Accounts receivable and other current assets	1,799	(1,408)	(3,687)
Other assets			(35)
Net increase in accounts payable, accrued employee compensation, and other liabilities	(980)	(1,205)	3,982
Net cash used in operating activities	(1,615)	(4,426)	(184,141)
Cash flows from investing activities:			
Purchase of property and equipment	(37)	(150)	(16,975)
Patent costs	(259)	(189)	(6,439)
Purchase of marketable securities	(3)	(2)	(112,989)
Sale of marketable securities			117,613
Acquisition costs		(12)	(2,389)
Net cash used in investing activities	(299)	(353)	(21,179)
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		230,561
Repayments of long-term debt	(19)	(63)	(132)

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

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	15,445	(63)		230,043
Increase (decrease) in cash and cash equivalents	13,531	(4,842)		24,723
Cash and cash equivalents:				
Beginning of period	11,192		24,803	
End of period	\$ 24,723	\$	19,961	\$ 24,723
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:				
Cash paid during the year for interest	\$ 24	\$	25	\$ 232
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:				
Short-term securities available-for-sale received in connection with the private offering	\$	\$	\$	17,897
Issuance of common stock and warrants in satisfaction of liabilities	\$	\$	\$	545
Issuance of common stock for building purchase	\$	\$	\$	750
Assumption of long-term debt for building purchase	\$	\$	\$	2,200
Issuance of common stock for Ercole assets	\$	\$	8,075	\$ 8,075
Assumption of liabilities for Ercole assets	\$	\$	2,124	\$ 2,124
Issuance of common stock and warrants in satisfaction of employee bonuses	\$ 239	\$	\$	239

See accompanying notes to financial statements.

Table of Contents

PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

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, 2009 and 2008 and the financial information as of March 31, 2009 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, 2008 is derived from AVI BioPharma, Inc.'s (the Company's) Form 10-K. The interim financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company's Form 10-K. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

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

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

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

Note 2. Fair Value Measurements

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

The Company measures at fair value certain financial assets and liabilities. SFAS No. 157, Fair Value Measurements (SFAS No. 157), specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's market assumptions. These two types of inputs have created the following fair-value hierarchy:

Level 1 Quoted prices for identical instruments in active markets;

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

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

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

The Company's assets measured at fair value on a recurring basis consisted of the following as of March 31, 2009:

(in thousands)	Total	Fair Value Measurement as of March 31, 2009		
		Level 1	Level 2	Level 3
Short-term securities available-for-sale	\$ 285	\$ 285		
Total	\$ 285	\$ 285	\$	\$

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

(in thousands)	Total	Fair Value Measurement as of March 31, 2009		
		Level 1	Level 2	Level 3
Warrants	\$ 6,815			\$ 6,815
Total	\$ 6,815	\$	\$	\$ 6,815

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
Total unrealized gains included in earnings		(2,622)
Issuances		8,183
Balance at March 31, 2009	\$	6,815
The amount of total gains for the period included in earnings attributable to the change in unrealized gains relating to warrants still held at March 31, 2009	\$	2,622

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

Table of Contents

Note 3. Revenue Recognition

Government Research Contract Revenue. The Company recognizes revenues from federal research contracts during the period in which the related expenditures are incurred. The Company presents these revenues and related expenses at gross in the consolidated financial statements in accordance with EITF 99-19 *Reporting Revenue Gross as a Principal versus Net as an Agent*.

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

The Company defers recognition of non-refundable upfront fees if it has continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of Company performance under the other elements of the arrangement. In addition, if the Company has continuing involvement through research and development services that are required because its know-how and expertise related to the technology is proprietary to the Company, or can only be performed by the Company, then such up-front fees are deferred and recognized over the period of continuing involvement. At March 31, 2009, the Company had deferred revenue of \$2.2 million, which represents up-front fees received from third parties pursuant to certain contractual arrangements. The Company will recognize the revenue from these contracts upon the achievement of certain performance milestones, as specified in the agreements.

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

Note 4. Patents

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

Note 5. Acquisition of Ercole

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

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

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

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

Ercole has been a development stage company since inception and does not have a product for sale. The Company has retained a limited number of Ercole employees and plans on incorporating in-process technology of Ercole into the Company's processes. The acquisition of Ercole did not meet the definition of a business under EITF 98-3, Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business, and, therefore, is being accounted for as an asset acquisition.

Note 6. Other Current Assets

Amounts included in other current assets are as follows:

(in thousands)	March 31, 2009	December 31, 2008
Prepaid expenses	\$ 253	\$ 316
Prepaid rents	108	
Restricted cash	284	283
Other current assets	\$ 645	\$ 599

Starting in April 2006, the Company was required to pledge \$150,000 as collateral for company credit cards

Table of Contents

issued to certain employees. Starting in April 2007 the Company was required to pledge \$125,000 as collateral for payments on long-term debt. The Company classifies these amounts as restricted cash. As of March 31, 2009, restricted cash including accrued interest was \$285,000. The remaining components of other current assets include normally occurring prepaid expenses and rents.

Note 7. Liquidity

The Company is in the development stage. Since its inception in 1980 through March 31, 2009, the Company has incurred losses of approximately \$251 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development reflecting two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenues from product sales, the Company expects to incur operating losses over the next several years.

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

In December 2006, the Company announced the execution of a two-year \$28 million research contract with the Defense Threat Reduction Agency (DTRA), an agency of the United States Department of Defense (DoD). The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. During the quarters ended March 31, 2009 and 2008, the Company recognized \$1.7 million and \$3.9 million, respectively, in research contract revenue from this contract. To date, the Company has recognized revenues of \$26.5 million from this contract. Funding of the remainder of the contract is anticipated in 2009.

In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company's ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company's technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company has received signed contracts

Table of Contents

for all four of these projects. The Company expects that funding under these signed contracts will be completed over the next 12 months. During the quarters ended March 31, 2009 and 2008, the Company recognized \$1.4 million and \$1.6 million, respectively, in research contract revenue from these contracts. To date, the Company has recognized revenues of \$8.3 million on these contracts. Funding of the remainder of these contracts is anticipated in 2009.

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

Note 8. Stock Compensation

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

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

Three Months Ended March 31,	2009	2008
Risk-free interest rate	1.2%-1.4%	1.9%-2.4%
Expected dividend yield	0%	0%
Expected lives	9.0 years	3.6-9.1 years
Expected volatility	92.0%-92.8%	81.0%-90.3%

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

As part of the requirements of SFAS 123R, 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.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

A summary of the Company's stock option compensation activity with respect to the fiscal quarter ended March 31, 2009 follows:

Stock Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2009	7,540,873	\$ 3.34		
Granted	1,874,000	\$ 1.01		
Exercised		\$		
Canceled or expired	(834,221)	\$ 2.96		
Outstanding at March 31, 2009	8,580,652	\$ 2.87	6.76	\$
Vested at March 31, 2009 and expected to vest	8,507,722	\$ 2.88	3.91	\$
Exercisable at March 31, 2009	4,934,162	\$ 4.09	4.87	\$

The weighted average fair value per share of stock-based payments granted to employees during the three months ended March 31, 2009 and March 31, 2008 was \$0.86 and \$0.99, respectively. During the same periods, the total intrinsic value of stock options exercised were \$0 and \$0, and the total fair value of stock options that vested was \$442,000 and \$877,000, respectively.

As of March 31, 2009, there was \$3,255,000 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 2.5 years.

During the first quarter of fiscal 2009, no stock options were exercised. The Company is obligated to issue shares reserved under the 2002 Equity Incentive Plan upon the exercise of stock options. The Company does not currently expect to repurchase shares from any source to satisfy its obligations under the Plan.

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

(in thousands)	Three Months Ended March 31, 2009	Three Months Ended March 31, 2008
Research and development	\$ 278	\$ 504
General and administrative	164	373
Total	\$ 442	\$ 877

The 2000 Employee Stock Purchase Plan (ESPP) provides that eligible employees may contribute, through payroll, deductions of up to 10% of their earnings toward the purchase of the Company's Common Stock at 85% of the fair market value at specific dates. On January 1, 2006, the Company adopted SFAS 123R, which requires the measurement and recognition of compensation expense for all share-based payment awards made to the Company's employees and directors related to the ESPP, based on estimated fair values. During the three-month periods ended March 31, 2009 and 2008, the total compensation expense for participants in the ESPP was immaterial.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

After the acquisition of Ercole in the first quarter of 2008, the Company recognized severance payments to certain Ercole employees of \$617,000 paid using the Company's common stock.

In the first quarter of 2009, the Company granted 60,000 shares of restricted stock to its Chief Medical Officer. These shares vest over a period of 181 days. During the three-month period ended March 31, 2009, the Company recognized compensation expense related to these shares of \$29,000.

In the first quarter of 2008, the Company granted 333,000 shares of restricted stock to its new Chief Executive Officer. Of these shares, 100,000 vested immediately and the remaining 233,000 vest over a period of four years. During the three-month periods ended March 31, 2009 and 2008, the Company recognized compensation expense related to these shares of \$16,000 and \$118,000, respectively.

Table of Contents

The Company records the fair value of stock options granted to non-employees in exchange for services in accordance with EITF 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. The fair value of the options granted is expensed when the measurement date is known. The performance for services was satisfied on the grant date for stock options granted to non-employees. The total fair value of the options granted to non-employees during the three months ended March 31, 2009 and 2008 was \$78,000 and \$104,000, respectively, which was expensed to research and development.

Note 9. Warrants

Certain of the Company's warrants issued in connection with financing arrangements are classified as liabilities in accordance with EITF 00-19, *Accounting for derivative financial instruments indexed to, and potentially settled in, a Company's own stock*. 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,	2009	2008
Risk-free interest rate	0.2%-1.9%	1.6%-2.5%
Expected dividend yield	0%	0%
Expected lives	0.3-5.5 years	0.7-4.7 years
Expected volatility	83.2%-140.6%	61.2%-77.0%
Warrants classified as liabilities	22,645,157	9,607,866
Warrants classified as equity	2,129,530	4,694,530
Market value of stock at beginning of year	\$ 0.66	\$ 1.41
Market value of stock at end of period	\$ 0.66	\$ 1.84

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 EITF 00-19, the fair value of the warrants is recorded as additional paid-in capital and no further adjustments are made.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

A summary of the Company's warrant activity with respect to the three months ended March 31, 2009 is as follows:

Warrants	Shares	Weighted Average Exercisable Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2009	10,123,759	\$ 8.54	
Granted (Note 12)	14,650,928	\$ 1.17	
Canceled or expired		\$	
Outstanding at March 31, 2009	24,774,687	\$ 4.18	4.11

Note 10. Earnings Per Share

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)	2009	2008
Net loss	\$ (927)	\$ (15,015)
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	80,759	65,188
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	80,759	65,188
Net loss per share - basic and diluted	\$ (0.01)	\$ (0.23)

* Warrants and stock options to purchase 33,355,341 and 21,499,569 shares of common stock as of March 31, 2009 and 2008, respectively, were excluded from the earnings per share calculation as their effect would have been anti-dilutive.

Note 11. Comprehensive Loss and Securities Available for Sale

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, 2009 and

December 31, 2008, the Company's investments in

Table of Contents

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,	
	2009	2008
Net loss	\$ (927)	\$ (15,015)
Unrealized loss on marketable securities		
Total comprehensive loss	\$ (927)	\$ (15,015)

Note 12. Equity Financing

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

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

Note 13. Income Taxes

The Company adopted the provisions of FASB interpretation No. 48, Accounting for the Uncertainty in Income Taxes, an interpretation of SFAS 109 (FIN 48) on January 1, 2007. The adoption of FIN 48 did not materially impact its consolidated financial statements, and no unrecognized tax benefits were recorded as of the date of adoption. As a result of the implementation of FIN 48, the Company did not recognize 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, 2009 and at December 31, 2008, and has not recognized interest and/or penalties in the statement of operations for the three months ended March 31, 2009.

At March 31, 2009, the Company had net deferred tax assets of approximately \$103 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules under Section 382 could limit the future use of its net operating loss and R&D credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

Table of Contents

Note 14. Recent Accounting Pronouncements

During the first fiscal quarter of 2009, the Financial Accounting Standards Board issued Staff Positions SFAS No. 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability has Significantly Decreased and the Identifying Transactions That Are Not Orderly*, SFAS No. 115-2 and SFAS No. 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments*, and SFAS No. 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments*. These Staff Positions were issued to clarify the application of SFAS No. 157, *Fair Value Measurements* in the current economic environment, modify the recognition of other-than-temporary impairments of debt securities, and require companies to disclose the fair value of financial instruments in interim periods. The Staff Positions are effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009, if all three Staff Positions or both the fair-value measurement and other-than-temporary impairment Staff Positions are adopted simultaneously. The Company plans to adopt the Staff Positions in the second quarter of fiscal 2009 and is currently evaluating the impact, if any, the adoption will have on the Company's Condensed Consolidated Financial Statements.

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

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

Forward-Looking Information

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

Table of Contents

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 revenues from the sale of products or other sources, other than from government grants and research contracts, and we do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development efforts and enter additional collaborative efforts. As of March 31, 2009, our accumulated deficit was \$251 million.

Results of Operations

Revenues from license fees, grants and research contracts decreased to \$3.2 million in the first quarter of 2009 from \$5.6 million in the comparable period in 2008. The decrease in research contracts revenues was the result of the decline in revenues from government research contracts for the development of therapeutic agents for use in defending against biological threats.

Operating expenses decreased to \$6.7 million in the first quarter of 2009 from \$19.4 million in the first quarter of 2008. In the first quarter of 2008, operating expenses included the \$10 million of acquired in-process research and development associated with the acquisition of Ercole Biotechnology, Inc (Ercole).

In addition, research and development expenses decreased to \$4.5 million in the first quarter of 2009 from \$6.9 million in the first quarter of 2008. This research and development decrease was due primarily to decreases in research and development costs related to the government research contracts for the development of therapeutic agents for use in defending against biological threats.

General and administrative expenses decreased to \$2.2 million in the first quarter of 2009, from \$2.6 million in the first quarter of 2008. The decrease in general and administrative expenses was due primarily to one time, non-cash costs for stock compensation paid to Ercole executives related to the 2008 acquisition. Net interest income declined primarily due to declines in market rates of interest on the Company's interest-earning investments.

The gain on warrant liability of \$2.6 million was the result of the decline in the Company's stock price subsequent to the issuance of warrants as a part of the registered equity financing that closed in January 2009. The gain or (loss) on warrant liability fluctuates as the market price of the Company's stock fluctuates.

Liquidity and Capital Resources

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

We have financed our operations since inception primarily through sales of common stock and other forms of equity totaling \$230.6 million and from grants and contract research funding of \$45.4 million from various sources. In January 2009, we raised net proceeds of \$15.5 million in financing through the sale of 14,224,202 shares of common stock pursuant to a registered direct offering to a select group of institutional investors. The investors also received warrants to purchase 14,224,202 shares of the Company's common stock. These warrants are exercisable starting July 30, 2009 and expire on July 30, 2014. In addition, the placement agent

Table of Contents

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

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

Because of the cost (up to \$1.7 billion) and timeframe (up to 15 years) generally associated with developing a potential drug or pharmaceutical product to the point of approval by the FDA or other regulatory agencies for human use, our business strategy is to develop our products up to Phase II human clinical trials and then look for third parties to fund further development of the product and to market the product through strategic partnerships, license agreements or other relationships. We also look for collaborative and other efforts, such as our relationship with Cook, to utilize other technology to increase the potential variety and reduce the cost of identifying products. We believe that this strategy will reduce the potential costs we would otherwise incur in developing a product and bringing it to market. Our expected costs under our various contracts and for various drug development products can be estimated for the next year or two, but not much beyond that due to the uncertainty of clinical trial results, research results and the timing of securing one or more partners to develop and market a potential drug.

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

In December 2006, we 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). In February 2008, the contract was extended into the first five months of 2009. The contract is directed toward funding the Company's development of antisense therapeutics to treat the effects of Ebola, Marburg and Junin hemorrhagic viruses, which are seen by DoD as potential biological warfare and bioterrorism agents. We recognized \$1.7 million in revenue from this contract during the first quarter of 2009 and have recognized \$26.5 million in total revenues to date from this contract. Funding of the remainder of the contract is anticipated in 2009.

In January 2006, we announced that the final version of the 2006 Defense Appropriations Act had been approved, which included an allocation of \$11.0 million to fund our ongoing defense-related programs. Net of government administrative costs, we anticipate that we will receive up to \$9.8 million under this allocation. The

Table of Contents

Company's technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. We have received signed contracts for all four of these projects. We expect that funding under these signed contracts will be received over the next 12 months. We recognized \$1.4 million in research contract revenue from these contracts during the three months ended March 31, 2009, and have recognized \$8.3 million in total revenues to date on these contracts. Funding of the remainder of these contracts is anticipated in 2009.

Our cash, cash equivalents and short-term securities were \$25.0 million at March 31, 2009, compared with \$11.5 million at December 31, 2008. The increase of \$13.5 million was due primarily to net proceeds of \$15.5 million from the sale of common stock and issuance of stock warrants as part of a registered equity financing that closed in January 2009. This cash from financing activities was partially offset by cash used in operations of \$1.6 million and costs related to acquisitions of patents and fixed assets of \$0.3 million.

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

Critical Accounting Policies and Estimates

The discussion and analysis of the Company's financial condition and results of operations are based upon its financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. The Company's critical accounting policies and estimates are consistent with the disclosure in the Company's Form 10-K, with the exception of FIN 48 (see Note 13).

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Disclosure Controls and Procedures

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

As of March 31, 2009, the Company carried out an evaluation, under the supervision and with the participation of its management, including its Chief Executive Officer and its Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures pursuant to Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on this review of its disclosure controls and procedures, the Chief Executive Officer and the Chief Financial Officer have concluded that its disclosure controls and procedures are effective in timely alerting them to material information relating to the Company that is required to be included in our periodic SEC filings.

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.

Table of Contents

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None

Item 1A. Risk Factors.

Risks Affecting Future Operating Results

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

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

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

Table of Contents

If necessary, potential sources of additional funding could include strategic relationships, public or private sales of shares of our stock, or 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 are 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 therapeutics 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 clearances. 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 clearances. We have not received any significant revenues from the sale of products and we may not successfully develop marketable products that will increase sales and, given adequate margins, make us profitable. Third parties may develop superior or equivalent, but less expensive, products.

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

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

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

Table of Contents

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 necessary regulatory approvals, we will be unable to develop and commercialize our products.

All of our products are subject to extensive regulation by the United States Food and Drug Administration, or FDA, and by comparable agencies in other countries. The FDA and these agencies require new pharmaceutical products to undergo lengthy and detailed preclinical and clinical testing procedures and other costly and time-consuming compliance procedures. We do not know when, or if, we will be able to submit our products for regulatory review. Even if we submit a new drug application, there may be delays in obtaining regulatory approvals, if we obtain them at all. Sales of our products outside the United States will also be subject to regulatory requirements governing clinical trials and product approval. These requirements vary from country to country and could delay introduction of our products in those countries. We cannot assure you that any of our products will receive marketing approval from the FDA or comparable foreign agencies.

We may have difficulty gaining regulatory drug approvals using the Animal Rule pathway.

We expect to develop the therapeutic product candidates to treat Ebola Virus and Marburg Virus under defined regulatory pathways using the so called Animal Rule mechanism. This mechanism has become available only relatively recently and has been infrequently used. The process has yet to be well tested and may present challenges for gaining final regulatory approval for these product candidates.

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

The loss of key employees could significantly delay the achievement of our goals. Competition for qualified personnel in our industry is intense, and our success will depend on our ability to attract and retain highly skilled personnel. To date, we have been successful in attracting and retaining key personnel.

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

Our success will depend on our existing patents and licenses (213 patents (domestic and foreign) issued or licensed to us and 185 (domestic and foreign) pending patent applications) and our ability to obtain additional patents in the future. We license patents from other parties for certain complementary technologies.

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

We cannot be certain that pending patent applications will result in patents being issued in the United States or foreign countries. In addition, the patents that have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours that do not conflict with our patents. Pharmaceutical research and development is highly competitive; others may file patents first. We are aware of a patent that has been allowed and will soon issue that may provide the basis for the patent holder to assert that our drug AVI-4658 infringes on such patent. We intend to vigorously defend any such claim if it should be asserted and believe that we may be able to invalidate some or all of the claims covered by this patent. In any case, we believe that we have freedom to move forward with our ongoing clinical trials and drug development efforts for this drug candidate.

Table of Contents

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

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

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 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. The transactions contemplated by our agreements with strategic partners, including the equity purchases and cash payments, are subject to numerous risks and conditions. The occurrence of any of these events could severely harm our business.

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

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

Table of Contents

We may get unexpected results from, or have trouble conducting, our clinical studies.

Not only do any clinical studies need to be agreed with regulatory authorities beforehand, especially in the case of phase III or pivotal studies, but they have to be successfully executed. Preclinical as well as clinical studies are experiments designed to test a theory or hypothesis, and by their very nature, the result is unknown at the time the study is started. Sometimes unexpected results occur and the product does not demonstrate effectiveness (even though it may be effective), or an unexpected safety issue is encountered. In addition in rare diseases, other companies may be testing their products which will prevent AVI from testing its candidate products.

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

We incurred a net loss of \$0.9 million in the first quarter of 2009 and \$24.0 million for the year ended December 31, 2008. As of March 31, 2009, our accumulated deficit was \$251.2 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from selling, 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 have obtained patents for their intellectual property rights that could preclude other companies from using similar technologies in their product development. Moreover, companies which are focused on the treatment of similar diseases are in effect competing for the same limited number of potential patients. Even if we are able to develop new products for market, there can be no assurance that we will be able to compete effectively or profitably against our competitors.

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

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

We use hazardous substances in our research activities.

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

We use organic and inorganic solvents and reagents in our clinical development that are customarily used in pharmaceutical development and synthesis. Some of these chemicals, such as methylene chloride, isopropyl alcohol, ethyl acetate and acetone, 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

Table of Contents

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 local fire departments, without any material noncompliance issues in such inspections to date. Based on our limited use of such chemicals, the nature of such chemicals and the safeguards undertaken by the Company for storage, use and disposal, we believe we do not have any material exposure for toxic tort liability. Further, the cost of such compliance is not a material cost in our operating budget. While we do not have toxic tort liability insurance at this time, we believe our current insurance coverage is adequate to cover most liabilities that may arise from our use of such substances. If we are wrong in any of our beliefs, we could incur a liability in certain circumstances that would be material to our finances and the value of an investment in our securities.

Risks Related to Share Ownership

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

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

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

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

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

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

Edgar Filing: AVI BIOPHARMA INC - Form 10-Q

Table of Contents

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 85,644,698 shares of common stock as of March 31 2009 and all are eligible for sale under Rule 144 or are otherwise freely tradeable. In addition:

- Our employees and others hold options to buy a total of 8,580,652 shares of common stock, of which 4,934,162 options were exercisable at March 31, 2009. The options outstanding have exercise prices between \$0.60 and \$7.35 per share. The shares of common stock to be issued upon exercise of these options have been registered, and, therefore, may be freely sold when issued;
- There are outstanding warrants to buy 24,774,687 shares of common stock as of March 31, 2009 with exercise prices ranging from \$.0003 to \$35.63 per share. Other than warrants to purchase an aggregate of 445,985 shares of common stock 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, all of the shares of common stock issuable upon exercise of outstanding warrants are registered for resale and may be freely sold when issued, subject to the limitations imposed by applicable securities laws;
- We may issue options to purchase up to an additional 1,285,258 shares of common stock as of March 31, 2009 under our stock option plans, which also will be fully saleable when issued except to the extent limited under Rule 144 for resales by our officers and directors;
- We are authorized to sell up to 124,213 shares of common stock under our Employee Stock Purchase Plan to our full-time employees, nearly all of whom are eligible to participate; and

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

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

Our common stock is listed on The NASDAQ Global Market. The NASDAQ Global Market has several quantitative and qualitative requirements with which companies must comply in order to maintain this listing, including a \$1.00 minimum bid price per share and \$50 million minimum value of listed securities. If a listed company fails to meet the \$1.00 minimum bid price per share requirement for 30 consecutive days, it will receive a notice from NASDAQ mandating that the company achieve compliance with the minimum bid price per share listing requirement within 90 calendar days. Our stock price is currently below \$1.00, and there can be no assurance that we will be able to maintain compliance with the minimum bid price per share requirement. Likewise, based on a closing price of \$0.55 per share on such date, the aggregate market value for our listed securities has gone below the \$50 million minimum value of listed securities as recently as March 12, 2009, and there can be no assurance that we will be able to maintain compliance with this listing requirement.

On October 16, 2008, NASDAQ suspended the minimum bid price per share requirement and market value for publicly held shares requirements for all listed companies through January 16, 2009. Recently, NASDAQ extended the suspension of the minimum bid price per share requirement and market value for publicly held shares requirements for all listed companies through July 19, 2009, with enforcement of these rules presently scheduled to resume on July 20, 2009.

Table of Contents

In order to maintain our listing on NASDAQ, we may seek to transfer our securities listing to The NASDAQ Capital Market, but any such proposed transfer would be subject to our ability to satisfy the listing standards for The NASDAQ Capital Market, which includes, among other things, a \$35 million minimum value of listed securities. The level of trading activity of our common stock may decline if it is no longer listed on The NASDAQ Global Market or The NASDAQ Capital Market. As such, if our common stock ceases to be listed for trading on The NASDAQ Stock Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to buy or sell shares of our common stock.

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

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

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

Item 1B. Unresolved Staff Comments.

None.

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

None.

Item 3. Defaults Upon Senior Securities.

None

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

None

Item 5. Other Information.

None

Table of Contents**Item 6. Exhibits**

Exhibit No	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed Herewith
			File No.	Exhibit	Filing Date	
1.3	Engagement Letter dated January 28, 2009 between the Company and Rodman & Renshaw, LLC	8-K	1-14895	1.3	1/30/09	
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	
4.4	Form of Common Stock Purchase Warrant	8-K	1-14895	4.4	1/30/09	
10.69	Securities Purchase Agreement dated January 29, 2009 between the Company and the Purchasers	8-K	1-14895	10.69	1/30/09	
10.70	Letter Agreement Regarding Board of Director Representation between the Company and Eastbourne Capital Management, LLC	8-K	1-14895	10.70	1/30/09	
10.71	Employment Agreement dated January 26, 2009 by and between AVI BioPharma, Inc. and Stephen B. Shrewsbury, M.D.					X
31.1	Certification of the Company's President and Chief Executive Officer, Leslie Hudson, Ph.D, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32	Certification of the Company's Chief Executive Officer, Leslie Hudson, Ph.D, and Chief Financial Officer, J. David Boyle II, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

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

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 11, 2009

AVI BIOPHARMA, INC.

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

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