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

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2009

OR

o **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	**93-0797222**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
4575 SW Research Way, Suite 200, Corvallis, Oregon	**97333**
(Address of principal executive offices)	(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 x No o

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 o No o

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

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

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

Common Stock with $.0001 par value	**85,644,698**
(Class)	(Outstanding at May 8, 2009)

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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

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AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three months ended March 31, 2009	2008	July 22, 1980 (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.

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AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three months ended March 31, 2009	2008	For the Period 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)

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.

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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

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;

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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.

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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.

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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

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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

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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		