AVI BIOPHARMA INC Form 10-Q November 10, 2008 Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

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 September 30, 2008

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
(State or other jurisdiction of incorporation or organization)

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

One SW Columbia Street, Suite 1105, Portland, Oregon 97258

(Address of principal executive offices)

(Zip Code)

Issuer s telephone number, including area code: 503-227-0554

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

Large accelerated filer O

Accelerated filer X

Non-accelerated filer O

Smaller Reporting Company O

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2)

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 (Class)

71,161,072

(Outstanding at November 7, 2008)

AVI BIOPHARMA, INC.

FORM 10-Q

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AVI BioPharma, Inc.

(A Development Stage Company) Balance SHEETS

(unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current Assets:		
Cash and cash equivalents	\$ 14,081,213	\$ 24,802,562
Short-term securities available-for-sale	279,528	271,851
Accounts receivable	4,076,586	2,869,760
Other current assets	1,222,654	767,278
Total Current Assets	19,659,981	28,711,451
Property and Equipment, net of accumulated depreciation and amortization of \$12,630,586		
and \$11,816,549	6,277,736	6,825,145
Patent Costs, net of accumulated amortization of \$1,858,214 and \$1,725,074	3,542,520	3,066,625
Other Assets	34,709	34,709
Total Assets	\$ 29,514,946	\$ 38,637,930
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	\$ 3,258,153	\$ 3,026,072
Accrued employee compensation	1,684,540	1,171,666
Long-term debt, current portion	73,672	71,099
Warrant liability	2,970,857	4,414,657
Deferred revenue	2,243,750	737,500
Other liabilities	435,086	331,335
Total Current Liabilities	10,666,058	9,752,329
Commitments and Contingencies		
Lang town debt non assessment nortice	2,015,124	2,070,704
Long-term debt, non-current portion Other long-term liabilities	495.002	433,149
Other long-term natinues	493,002	455,149
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; 71,161,072 and 64,449,094		
issued and outstanding	7,116	6,445
Additional paid-in capital	265,501,292	252,732,858
Deficit accumulated during the development stage	(249,169,646)	(226,357,555)
Total Shareholders Equity	16,338,762	26,381,748
Total Liabilities and Shareholders Equity	\$ 29,514,946	\$ 38,637,930

See accompanying notes to financial statements

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AVI BioPharma, Inc.

(A Development Stage Company) STATEMENTS OF OPERATIONS

(unaudited)

	Three months end 2008	ed Sep	otember 30, 2007	Nine months ended September 30, 2008 2007			July 22, 1980 (inception) through September 30, 2008	
Revenues from license fees, grants and research contracts	\$ 5,170,663	\$	2,911,406 \$	15,778,243	\$	5,798,872	\$ 36,744,253	
Operating expenses:								
Research and development	7,934,886		9,880,480	23,572,395		25,358,937	205,980,012	
General and administrative	3,173,942		1,544,512	6,853,417		7,879,193	57,006,310	
Acquired in-process research	2,2.2,5.1		2,2 11,2 22	0,000,107		,,,,,,,,,	01,000,000	
and development				9,916,271			29,461,299	
	11,108,828		11,424,992	40,342,083		33,238,130	292,447,621	
Other income (loss):								
Interest income, net	60,147		182,320	307,949		848,397	8,741,467	
Gain (loss) on warrant								
liability	(168,975)		1,296,322	1,443,800		3,550,330	10,931,101	
Realized gain on sale of								
short-term securities available-for-sale							2 962 502	
Write-down of short-term							3,862,502	
securities available-for-sale							(17,001,348)	
securities available-101-sale	(108,828)		1,478,642	1,751,749		4,398,727	6,533,722	
	(100,020)		1,170,012	1,751,717		1,370,727	0,333,722	
Net loss	\$ (6,046,993)	\$	(7,034,944) \$	(22,812,091)	\$	(23,040,531)	\$ (249,169,646)	
	(-)/		(1,712)2)	()= ,== ,		(= , = = , = ,	. (2, 22, 2	
Net loss per share - basic								
and diluted	\$ (0.08)	\$	(0.13) \$	(0.33)	\$	(0.43)		
Weighted average number of common shares outstanding for computing basic and								
diluted loss per share	71,150,972		53,693,693	69,160,118		53,500,250		

See accompanying notes to financial statements

AVI BioPharma, Inc.

(A Development Stage Company) STATEMENTS OF CASH FLOws

(unaudited)

	Nine months ended	For the Period July 22, 1980 (Inception) to	
	2008	2007	September 30, 2008
Cash flows from operating activities:	(22.042.004)		(210.150.515)
Net loss \$	(22,812,091)	\$ (23,040,531) \$	(249,169,646)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	1,043,428	1,506,768	15,877,526
Loss on disposal of assets	10,797	58,584	385,356
Realized gain on sale of short-term securities available-for-sale			(3,862,502)
Write-down of short-term securities available-for-sale			17,001,348
Issuance of common stock and warrants to vendors	687,833	700,000	2,762,833
Compensation expense on issuance of common stock and			
partnership units	149,878		1,011,533
Compensation expense to non-employees on issuance of options			
and warrants to purchase common stock or partnership units	179,687	312,637	3,135,377
Stock-based compensation	3,103,180	3,933,926	12,703,587
Conversion of interest accrued to common stock			7,860
Acquired in-process research and development	9,916,271		29,461,299
Gain on warrant liability	(1,443,800)	(3,550,330)	(10,931,101)
Decrease (increase) in:			
Accounts receivable and other current assets	(1,181,175)	(1,916,573)	(4,818,213)
Other assets	(235,009)		(269,718)
Net increase (decrease) in accounts payable, accrued employee			
compensation, deferred revenue, and other liabilities	716,403	4,646,244	6,653,136
Net cash used in operating activities	(9,864,598)	(17,349,275)	(180,051,325)
Cash flows from investing activities:			
Purchase of property and equipment	(363,614)	(1,151,800)	(16,932,005)
Patent costs	(419,035)	(651,649)	(5,751,279)
Purchase of marketable securities	(7,677)	(110,417)	(112,983,890)
Sale of marketable securities		2,896,443	117,613,516
Acquisition costs	(11,375)		(2,388,991)
Net cash (used in) provided by investing activities	(801,701)	982,577	(20,442,649)
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	43,518	68,769	215,059,192
Repayments of long-term debt	(98,568)		(98,568)
Buyback of common stock pursuant to rescission offering			(288,795)
Withdrawal of partnership net assets			(176,642)
Issuance of convertible debt			80,000
Net cash provided by financing activities	(55,050)	68,769	214,575,187
(Decrease) increase in cash and cash equivalents	(10,721,349)	(16,297,929)	14,081,213

Cash and cash equivalents:			
Beginning of period	24,802,562	20,159,201	
End of period	\$ 14,081,213	\$ 3,861,272	\$ 14,081,213
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING			
ACTIVITIES AND FINANCING ACTIVITIES:			
Short-term securities available-for-sale received in connection			
with the private offering	\$	\$	\$ 17,897,000
Change in unrealized gain (loss) on short-term			
securities available-for-sale	\$	\$ (18,418)	\$
Issuance of common stock and warrants in satisfaction of			
liabilities	\$	\$	\$ 545,000
Issuance of common stock for building purchase	\$	\$ 750,000	\$ 750,000
Assumption of long-term debt for building purchase	\$	\$ 2,199,792	\$ 2,199,792
Issuance of common stock for Ercole assets	\$ 8,075,233	\$	\$
Assumption of liabilities for Ercole assets	\$ 2,124,274	\$	\$

See accompanying notes to financial statements

AVI BIOPHARMA, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Note 1. Basis of Presentation

The financial information included herein for the three and nine-month periods ended September 30, 2008 and 2007 and the financial information as of September 30, 2008 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, 2007 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.

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 recognized 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 four years.

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

Three and Nine Months Ended September 30,	2008	2007
Risk-free interest rate	1.9%-4.4%	4.5%-5.1%
Expected dividend yield	0%	0%
Expected lives	3.6-9.1 years	3.7-8.7 years
Expected volatility	81.0%-90.7%	84.1%-90.6%

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.

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 will be 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 will be recognized through a cumulative catch-up in the period of change and will also impact the amount of stock compensation expense to be recognized in future periods.

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A summary of the Company s stock option compensation activity with respect to the nine months ended September 30, 2008 is as follows:

Stock Options	Shares	Weighted Average Exercisable Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2008	6,304,453	\$ 4.60		
Granted	2,741,007	\$ 1.27		
Exercised	(6,761)	\$ 1.31		
Canceled or expired	(898,636)	\$ 5.09		
Outstanding at September 30, 2008	8,140,063	\$ 3.42	6.14	\$
Vested at September 30, 2008 and expected to vest	8,080,095	\$ 3.44	6.11	\$
•				
Exercisable at September 30, 2008	5,141,665	\$ 4.29	4.12	\$

The weighted average fair value per share of stock-based payments granted to employees during the nine months ended September 30, 2008 and September 30, 2007 was \$1.04 and \$2.26, respectively. During the same periods, the total intrinsic value of stock options exercised were \$1,831 and \$4,937, and the total fair value of stock options that vested were \$2,486,455 and \$2,876,554, respectively.

As of September 30, 2008, there was \$3,022,123 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 2.0 years.

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

	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
Research and development	\$ 342,246	\$ 1,232,762
General and administrative	660,597	1,253,693
Total	\$ 1,002,843	\$ 2,486,455

	Three Months Ended September 30,2007	Nine Months Ended September 30, 2007
Research and development	\$ 497,002	\$ 1,381,687
General and administrative	282,088	1,494,867
Total	\$ 779,090	\$ 2,876,554

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

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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 and nine-month periods ended September 30, 2008 and 2007, the total compensation expense for participants in the ESPP was immaterial.

After the acquisition of Ercole Biotechnology, Inc. (Ercole) in March 2008, the Company recognized severance payments to certain Ercole employees of \$616,725 paid using the Company s common stock.

On March 27, 2007, in connection with his resignation, the Company entered into a Separation and Release Agreement with AVI s former Chairman and Chief Executive Officer. Pursuant to this agreement, he may exercise his previously granted options until the earlier of the termination date specified in the respective stock option grant agreements or March 28, 2010. This modification of these stock options increased compensation costs by \$1,057,372 for the nine months ended September 30, 2007.

In the first quarter of 2008, the Company granted 333,000 shares of restricted stock to its new Chief Executive Officer. These shares vest over a period of four years. During the three and nine-month periods ended September 30, 2008, the Company recognized compensation expense related to these shares of \$16,003 and \$149,878, respectively.

On September 18, 2008, the Company s President and Chief Operating Officer resigned. In accordance with his existing employment agreement, he may exercise his previously granted options until the earlier of the termination date specified in the respective stock option grant agreements or March 18, 2010. This acceleration of the vesting of these stock options resulted in additional compensation costs of \$382,419 for the three and nine-month periods ended September 30, 2008.

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 with no performance or market conditions is expensed when the measurement date is known.

In the third quarter of 2008, the Company granted options to purchase 100,000 shares to a non-employee. Of these options, 20,000 vested immediately and were expensed as of the grant date, 60,000 had market conditions and 20,000 had performance conditions. Of the 60,000 options with market conditions, the criteria with respect to 40,000 were not met, and such options were canceled during the quarter; the fair value of the remaining 20,000 options with market conditions was not material. Of the 20,000 options with performance conditions, the performance conditions were not considered probable as of September 30, 2008, and therefore no expense was recognized during the period.

For the nine months ended September 30, 2008 and 2007, the Company recognized \$179,687 and \$312,637, respectively, in research and development expenses for options granted to non-employees.

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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 non-cash gain (loss) and is estimated using the Black-Scholes option-pricing model with the following assumptions:

Three and Nine Months Ended September 30,	2008	2007
Risk-free interest rate	0.9%-3.0%	3.9%-4.0%
Expected dividend yield	0%	0%
Expected lives	0.2-4.2 years	1.2-2.6 years
Expected volatility	63.6%-78.5%	57.6%-71.2%
Market value of stock at beginning of year	\$1.41	\$3.18
Market value of stock at end of period	\$1.21	\$2.55

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.

A summary of the Company s warrant activity with respect to the nine months ended September 30, 2008 is as follows:

W	ÇI.	Weighted Average Exercisable	Weighted Average Remaining Contractual
Warrants	Shares	Price	Term
Outstanding at January 1, 2008	13,856,411	\$ 8.12	
Granted	445,985	\$ 1.77	
Canceled or expired	(2,565,000)	\$ 7.00	
Outstanding at September 30, 2008	11,737,396	\$ 8.12	2.66

For warrants classified as permanent equity in accordance with EITF 00-19, the fair value of the warrants is recorded in shareholders equity and no further adjustments are made.

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.

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Fair Value of Financial Instruments. The Company measures at fair value certain financial assets and liabilities, including cash equivalents. 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;

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.

	Fair Value Measurement as of September 30, 2008						
		Total		Level 1	Level 2		Level 3
Cash and cash equivalents	\$	14,081,213	\$	14,081,213			
Short-term securities available-for-sale		279,528		279,528			
Warrants classified as liabilities		2,970,857				\$	2,970,857
Total	\$	17,331,598	\$	14,360,741		\$	2,970,857

The Company has deferred the adoption of SFAS No. 157 with respect to nonfinancial assets and liabilities in accordance with the provisions of FSP FAS 157-2. Effective Date of FASB Statement No. 157. Items in this classification include intangible assets and certain other items.

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.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FASB Statement No. 115* (Statement 159). Statement 159 gives the Company the irrevocable option to carry most financial assets and liabilities at fair value that are not currently required to be measured at fair value. If the fair value option is elected, changes in fair value would be recorded in earnings at each subsequent reporting date. SFAS 159 is effective for the Company s 2008 fiscal year. The Company is currently evaluating the impact the adoption of this statement could have on its financial condition, results of operations and cash flows.

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

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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 the Company s 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.

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.

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

Income Taxes. In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109 (FIN 48). FIN 48 clarifies the accounting for uncertainty in income taxes by prescribing the recognition threshold a tax position is required to meet before being recognized in the financial statements. It also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. The provisions of FIN 48 are effective for the Company as of January 1, 2007, with the cumulative effect, if any, of applying FIN 48 recorded as an adjustment to opening retained earnings in the year of adoption. The Company adopted FIN 48 on January 1, 2007, which did not have a material impact on the consolidated financial statements. See Note 9.

Note 2. Liquidity

Since its inception in 1980 through September 30, 2008, the Company has incurred losses of approximately \$249 million, and is still in the development stage. 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 will require substantial additional financing. There is no assurance that such financing will be available when needed or that the

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Company s planned products will be commercially successful. The Company believes it has adequate cash for the next twelve months, subject to its ability to secure additional government awards, collaboration agreements, or capital in the equity markets. For 2008, the Company expects expenditures for operations, net of government funding, including collaborative efforts and GMP facilities to be approximately \$14 to \$16 million. Expenditures for 2008 could exceed this level if the Company undertakes additional collaborative efforts.

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. The Company recognized \$4,924,791 and \$13,555,621 in research contract revenues from this contract in the third quarter and first nine months of 2008, respectively, and has recognized \$21,574,010 in total revenues to date from this contract. Funding under this contract is expected over three years, with approximately \$24.5 million committed through the end of 2008 (including amounts received in 2007). The Company has requested a no-cost extension of this contract, which the Company expects to be granted, the result of which is that the Company anticipates receiving the remaining \$3.5 million during the first five months of 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 NeuGerie technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and Dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company has received signed contracts for all four of these projects. The Company expects that funding under these signed contracts will be completed over the next 12 months. During the three and nine months ended September 30, 2008, the Company recognized \$193,391 and \$2,100,106, respectively, in research contract revenue from these contracts. As of September 30, 2008, approximately \$5.0 million in additional funding remains available under these contracts.

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 3. Recent Accounting Pronouncements

In June 2008, the FASB ratified EITF Issue No. 07-5, Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock (EITF 07-5). Equity-linked instruments (or embedded features) that otherwise meet the definition of a derivative as outlined in SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities, are not accounted for as derivatives if certain criteria are met, one of which is that the instrument (or embedded feature) must be indexed to the entity s stock. EITF 07-5 provides guidance on

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determining if equity-linked instruments (or embedded features) such as warrants to purchase our stock, our convertible notes and convertible note hedges are considered indexed to our stock. EITF 07-5 is effective for the financial statements issued for fiscal years and interim periods within those fiscal years, beginning after December 15, 2008 and will be applied to outstanding instruments as of the beginning of the fiscal year in which it is adopted. Upon adoption, a cumulative effect adjustment will be recorded, if necessary, based on amounts that would have been recognized if this guidance had been applied from the issuance date of the affected instruments. The Company is currently determining the impact, if any, that EITF 07-05 will have on its financial statements.

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations (SFAS 141(R)) and SFAS No. 160, Accounting and Reporting of Noncontrolling Interests in Consolidated Financial Statements an amendment of ARB No. 51 (SFAS 160). These standards will significantly change the accounting and reporting for business combination transactions and noncontrolling (minority) interests in consolidated financial statements, including capitalizing at the acquisition date the fair value of acquired in-process research and development (IPR&D), and testing for impairment and writing down these assets, if necessary, in subsequent periods during their development. These new standards will be applied prospectively for business combinations that occur on or after January 1, 2009, except that presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively.

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Note 4. 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.

The Company s basic and diluted EPS were as follows for the periods indicated:

Three Months Ended September 30,	2008	2007
Net loss	\$ (6,046,993)	\$ (7,034,944)
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	71,150,972	53,693,693
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	71,150,972	53,693,693
Net loss per share - basic and diluted	\$ (0.08)	\$ (0.13)
Nine Months Ended September 30,	2008	2007
Nine Months Ended September 30, Net loss	\$ 2008 (22,812,091) \$	
	\$ 	
Net loss	\$ 	
Net loss Weighted average number of shares of common stock and common stock	\$ 	
Net loss Weighted average number of shares of common stock and common stock equivalents outstanding:	\$ 	
Net loss Weighted average number of shares of common stock and common stock equivalents outstanding: Weighted average number of common shares outstanding for computing	\$ (22,812,091) \$	(23,040,531)
Net loss 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	\$ (22,812,091) \$	(23,040,531)
Net loss 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 Dilutive effect of warrants and stock options after application of the	\$ (22,812,091) S 69,160,118	53,500,250
Net loss 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 Dilutive effect of warrants and stock options after application of the treasury stock method	\$ (22,812,091) S 69,160,118	53,500,250

^{*} Warrants and stock options to purchase 19,877,459 and 14,807,629 shares of common stock as of September 30, 2008 and 2007, respectively, were excluded from the earnings per share calculation as their effect would have been antidilutive.

Note 5. 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 September 30, 2008 and December 31, 2007, there were no unrealized gains on the Company s investments in marketable securities. The following table sets forth the calculation of comprehensive loss for the periods indicated:

	Three Months Ended September 30,			Nine Months Ended September 30,			
	2008		2007	2008		2007	
Net loss	\$ (6,046,993)	\$	(7,034,944) \$	(22,812,091)	\$	(23,040,531)	
Unrealized loss on marketable securities						(18,418)	
Total comprehensive loss	\$ (6,046,993)	\$	(7,034,944) \$	(22,812,091)	\$	(23,058,949)	

Note 6. Acquisition of Ercole

On March 20, 2008, the Company acquired all of the stock of Ercole Biotechnology, Inc. (Ercole) in exchange for 5,647,016 shares of AVI common stock. The transaction included the assumption of \$1.5 million in liabilities of Ercole. The AVI common stock was valued at approximately \$8.1 million. AVI also issued warrants to purchase AVI stock to settle certain outstanding warrants held in Ercole, which were valued at \$0.4 million. 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.

Ercole has been a development stage company since inception and does not have a product for sale. The Company is retaining 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.

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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.

Note 7. Other current assets

Amounts included in other current assets are as follows:

	September 30, 2008		December 31, 2007	
Prepaid expenses	\$	828,340	\$ 388,371	
Prepaid rents		113,254	96,077	
Restricted cash		281,060	282,830	
Other current assets	\$	1,222,654	\$ 767,278	

Starting in April 2006, the Company was required to pledge \$150,000 as collateral for Company credit cards 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 September 30, 2008, restricted cash, including accrued interest, was \$281,060. The remaining components of other current assets include normally occurring prepaid expenses and rents.

Note 8. Deferred Revenue

At September 30, 2008, the Company had deferred revenue of \$2,243,750, 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.

Note 9. Income Taxes

The Company adopted the provisions of FIN 48 on January 1, 2007, which did not materially impact its consolidated financial statements. 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

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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 September 30, 2008 and at December 31, 2007, and has not recognized interest or penalties in the statement of operations for the nine months ended September 30, 2008.

At September 30, 2008, the Company had net deferred tax assets of approximately \$95 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryforwards, federal and state R&D credit carryforwards, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax assets. 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.

Item 2. Management s Discussion and Analysis or Plan 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, 2007 and the Risk Factors contained in such report.

Forward-Looking Information

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

Overview

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. We have been unprofitable since inception and, other than limited interest, license fees, grants and research contracts, have had no material revenues from the sale of products or other sources, and do not expect material revenues for the foreseeable future. We expect to continue to incur losses for the

foreseeable future as we continue our research and development efforts and enter into additional collaborative efforts. As of September 30, 2008, the Company $\,$ s accumulated deficit was \$249,169,646.

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Results of Operations

Revenues, from license fees, grants and research contracts, increased to \$5,170,663 in the third quarter of 2008 from \$2,911,406 in the third quarter of 2007, primarily due to increases in research contract revenues of \$2,270,078, partially offset by a decrease in grant revenues of \$10,821. For the nine months ended September 30, 2008, revenues, from license fees, grants and research contracts, increased to \$15,778,243 from \$5,798,872 for the comparable period in 2007, due to increases in research contract revenues of \$10,012,002, partially offset by a decrease in grant revenues of \$35,132.

Operating expenses decreased to \$11,108,828 in the third quarter of 2008 from \$11,424,992 in the third quarter of 2007. This decrease was due to a decline in research and development, which decreased to \$7,934,886 in the third quarter of 2008 from \$9,880,480 in the third quarter of 2007, partially offset by an increase in general and administrative to \$3,173,942, compared with \$1,544,512 for the third quarter of 2007.

The decrease in research and development in the third quarter of 2008 was due primarily to decreases of approximately \$2,876,000 in contracting costs for the production of GMP subunits, which are used by the Company to manufacture compounds for future clinical trials, decreases in the purchases of equipment for government research contracts of approximately \$323,000, and decreases in amortization of leaseholds of approximately \$136,000, partially offset by increases in net clinical expenses of approximately \$1,379,000 and government research contract expenses of approximately \$180,000. The increase in general and administrative costs was primarily due to a \$1,380,000 increase in employee compensation in the third quarter of 2008 as compared with the third quarter of 2007. This increase in compensation was due to a number of factors, including \$630,000 of severance for the Company s former President and Chief Operating Officer, who resigned during the quarter; an increase in stock-based compensation of approximately \$400,000, primarily due to the acceleration of the vesting of the former President and Chief Operating Officer s stock options; and approximately \$195,000 in relocation expenses paid on behalf of certain executive officers. The increase in general and administrative costs for the quarter also reflects an increase in accounting and auditing expenses of \$189,000 and an increase in corporate travel of \$102,000.

For the nine months ended September 30, 2008, operating expenses increased to \$40,342,083 from \$33,238,130 for the comparable period of 2007. This increase was due to \$9,916,271 of acquired in-process research and development associated with the acquisition of Ercole Biotechnology, Inc. (Ercole), partially offset by a decrease in research and development to \$23,572,395 from \$25,358,937 for the first nine months of 2007 and a decrease in general and administrative to \$6,853,417 from \$7,879,193 for the comparable 2007 period.

The decrease in research and development expenses for the nine months ended September 30, 2008 was due primarily to decreases in contracting costs for the production of GMP subunits of approximately \$3,176,000, a decrease in government research contract expenses of approximately \$770,000, a decrease in amortization of leaseholds of approximately

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\$409,000, a decrease in chemical costs of approximately \$312,000, a decrease in the purchases of equipment for government research contracts of approximately \$261,000 and a decrease of \$100,000 in amortization of patent costs. These amounts were partially offset by an increase in net clinical expenses of approximately \$1,949,000, an increase in compensation costs of approximately \$715,000 and an increase in professional consultants of approximately \$576,000. The decrease in general and administrative expenses for the nine months ended September 30, 2008 was due primarily to a decrease in compensation costs of approximately \$843,000. This decrease in compensation reflects year 2007 expenses of approximately \$1,620,000 (including \$562,500 in cash compensation and \$1,057,372 in SFAS 123R expenses) related to the Separation and Release Agreement with the Company s former Chief Executive Officer, partially offset by year 2008 expenses of approximately \$1,012,000 (including \$630,000 in cash compensation and \$382,000 in additional SFAS 123R expenses), pursuant to the resignation of the Company s President and Chief Operating Officer in the third quarter of 2008. General and administrative expenses also includes decreases in legal expenses of approximately \$318,000 and public and investor-relations costs of approximately \$111,000, partially offset by increases in accounting and auditing expenses of \$314,000.

Net interest income decreased to \$60,147 in the third quarter of 2008 from \$182,320 in the third quarter of 2007 and to \$307,949 for the nine months ended September 30, 2008 from \$848,397 for the comparable period in 2007. These declines were due to decreases in average cash, cash equivalents and short-term securities and decreases in average interest rates of the Company s interest-earning investments. The loss on warrant liability was \$168,975 in the third quarter of 2008, compared with a gain of \$1,296,322 in the third quarter of 2007. For the nine months ended September 30, 2008, the gain on warrant liability was \$1,443,800, compared with a gain of \$3,550,330 for the comparable period in 2007. The gain (loss) on warrant liability is primarily a function of the Company s stock price and fluctuates as the market price of the Company s stock fluctuates.

Liquidity and Capital Resources

The Company does not expect any material revenues in the remainder of 2008 or 2009 from its business activities, other than from potential government grants and research contracts. The Company believes it has adequate cash for the next twelve months, subject to its ability to secure additional government awards, collaboration agreements, or capital in the equity markets.

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. Funding under this contract is expected over three years, with approximately \$24.5 million committed through the end of 2008 (including amounts received in 2007). The Company has requested a no-cost extension of this contract, which the Company expects to be granted, the result of which is that the Company anticipates receiving the remaining \$3.5 million during the first five months of 2009. The Company recognized \$4,924,791 and \$13,555,621 in research contract revenues from this contract in the third quarter and first nine months of 2008, respectively, and has recognized \$21,574,010 in total revenues to date from this contract.

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In January 2006, the Company announced that the final version of the 2006 defense appropriations act had been approved, which included an allocation of \$11.0 million to fund the Company s ongoing defense-related programs. Net of government administrative costs, it is anticipated that the Company will receive up to \$9.8 million under this allocation. The Company s NEUGENE technology is expected to be used to continue developing therapeutic agents against Ebola, Marburg and dengue viruses, as well as to continue developing countermeasures for anthrax exposure and antidotes for ricin toxin. The Company has received signed contracts for all four of these projects. The Company expects that funding under these signed contracts will be received over the next 12 months. In the quarter and nine-month period ended September 30, 2008, the Company recognized \$193,391 and \$2,100,106, respectively, in research contract revenues from this contract. As of September 30, 2008, approximately \$5.0 million in additional funding remains available under these contracts.

The Company s cash, cash equivalents and short-term securities totaled \$14,360,741 at September 30, 2008, compared with \$25,074,413 at December 31, 2007. The decrease of \$10,713,672 was due primarily to \$9,864,598 used in operations and \$782,649 used for purchases of property and equipment and patent related costs. This decrease also included approximately \$900,000 paid to Ercole for its use in retiring certain of its debts prior to closing of the Ercole asset purchase.

The Company s short-term securities may include certificates of deposit, commercial paper and other highly liquid investments with original maturities in excess of 90 days at the time of purchase and less than one year from the balance sheet date. The Company classifies its investment securities as available-for-sale and, accordingly, such investment securities are stated on the balance sheet at their fair market value with unrealized gains (losses) recorded as a separate component of shareholders—equity and comprehensive income (loss).

The Company s future expenditures and capital requirements depend on numerous factors, most of which are difficult to project beyond the short term, including, without limitation, the progress of its research and development programs, the progress of its pre-clinical and clinical trials, the time and costs involved in obtaining regulatory approvals, the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights, competing technological and market developments, its ability to establish collaborative arrangements and the terms of any such arrangements, and the costs associated with commercialization of its products. The Company s cash requirements are expected to continue to increase each year as the Company expands its activities and operations. There can be no assurance, however, that the Company will ever be able to generate product revenues or achieve or sustain profitability.

The Company expects to continue to incur losses as it continues its research and development activities and related regulatory work and collaborative efforts. For 2008, the Company expects expenditures for operations, net of government funding, including collaborative efforts, and GMP facilities to be approximately \$14 to \$16 million. Expenditures for 2008 could increase if the Company undertakes additional collaborative efforts.

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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 disclosures 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 9).

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 2007 Annual Report on Form 10-K.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

As of September 30, 2008, 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 as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on this review of its disclosure controls and procedures pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934, 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 changes in the Company s internal controls over financial reporting identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 that have materially affected, or are reasonably likely to materially affect, the Company s internal controls over financial reporting.

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PART II - OTHER INFORMATION
Item 1. Legal Proceedings.
None
Item 1A. Risk Factors.
There have been no substantial changes in the Company s Risk Factors contained in our Annual Report on Form 10-K as filed with the SEC for the year ended December 31, 2007.
The Company will need additional funds to continue operations at current levels.
As noted previously, the Company s net cash use through the end of 2008 is expected to be approximately \$4 to \$6 million, assuming no material change in the Company s operations, including clinical trials and research and development activities. As of September 30, 2008, the Company had cash, cash equivalents and short-term securities of \$14 million. Thus, assuming no receipt of any material amounts of cash or cash equivalents and assuming no change in the Company s net cash use rates, the Company expects to have cash available for operations of approximately \$8 to \$10 million at December 31, 2008. Based on historical net cash use rates, the amount expected to be available at December 31, 2008 would satisfy the Company s net cash needs only through the end of the second quarter in 2009, thereby requiring the Company to secure additional funds through additional government funding awards, the issuance of debt or equity securities or through collaboration efforts. The recent credit crisis and retrenchment of the capital markets is likely to make the Company s fund raising efforts more difficult than was the case earlier in 2008.
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.
N.T.	
None	
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Item 6. Exhibits

			Incorporated by Reference to Filings Indicated Filing			Filed
Exhibit No	Exhibit Description	Form	File No.	Exhibit	Date	Herewith
3.1	Third Restated Articles of Incorporation of AntiVirals Inc.	SB-2	333-20513	3.1	5/29/97	
3.2	First Restated Bylaws of AVI BioPharma, Inc.	8-K	1-14895	3.5	2/7/08	
3.3	First Amendment to Third Restated Articles of Incorporation	8-K	0-22613	3.3	9/30/98	
3.4	Amendment to Article 2 of the Company s Third Restated Articles of Incorporation	DEF 14A	1-14895	N/A	4/11/02	
10.65+	Employment Agreement dated July 24, 2008 by and between AVI BioPharma, Inc. and J. David Boyle II					X
10.66+	Amendment No. 1 to Employment Agreement dated August 1, 2008 by and between AVI BioPharma, Inc. and J. David Boyle II					X
31.1	Certification of the Company s Chief Executive Officer, Leslie Hudson, Ph.D, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32	Certification of the Company s Chief Executive Officer, Leslie Hudson, Ph.D, and Chief Financial Officer, J. David Boyle II, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

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

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date:November 10, 2008

AVI BIOPHARMA, INC.

By: /s/ LESLIE HUDSON, Ph.D.

Leslie Hudson, Ph.D. Chief Executive Officer (Principal Executive Officer)

By: /s/ J. DAVID BOYLE II

J. David Boyle II Chief Financial Officer

(Principal Financial and Accounting Officer)

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