AVI BIOPHARMA INC
Form 10-Q
May 10, 2012
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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, 2012

OR

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

For the transition period from to

Commission file number 001-14895

AVI BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Oregon	**93-0797222**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3450 Monte Villa Parkway, Suite 101, Bothell, Washington	**98021**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No 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 $0.0001 par value	**135,743,787**
(Class)	(Outstanding as of May 1, 2012)

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements.

AVI BIOPHARMA, INC.

(A Development Stage Company)

BALANCE SHEETS

(unaudited)

(in thousands, except per share data)

	March 31, 2012	December 31, 2011
Assets		
Current Assets:		
Cash and cash equivalents	$ 30,573	$ 39,904
Accounts receivable	5,135	3,633
Other current assets	1,924	1,647
Total Current Assets	37,632	45,184
Property and Equipment, net of accumulated depreciation and amortization of $15,982 and $15,765	4,105	4,265
Patent Costs, net of accumulated amortization of $2,298 and $2,199	4,704	4,764
Other assets	206	155
Total Assets	$ 46,647	$ 54,368
Liabilities and Shareholders Equity		
Current Liabilities:		
Accounts payable	$ 8,195	$ 9,396
Accrued employee compensation	1,852	2,244
Long-term debt, current portion	86	85
Warrant valuation	16,372	5,446
Deferred revenue	3,304	3,304
Other liabilities	114	126
Total Current Liabilities	29,923	20,601
Commitments and Contingencies		
Long-term debt, non-current portion	1,735	1,757
Other long-term liabilities	967	993
Shareholders Equity:		
Preferred stock, $.0001 par value, 20,000,000 shares authorized; none issued and outstanding	0	0
Common stock, $.0001 par value, 300,000,000 and 200,000,000 shares authorized; 135,743,787 and 135,743,120 issued and outstanding	13	13
Additional paid-in capital	341,677	340,968
Deficit accumulated during the development stage	(327,668)	(309,964)
Total Shareholders Equity	14,022	31,017

Total Liabilities and Shareholders Equity	$ 46,647	$ 54,368

See accompanying notes to financial statements.

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AVI BIOPHARMA, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS and COMPREHENSIVE INCOME (LOSS)

(unaudited)

(in thousands, except per share amounts)

	Three months ended March 31, 2012	2011	July 22, 1980 (Inception) through March 31, 2012
Revenues from license fees, grants and research contracts	$ 11,212	$ 14,296	$ 147,431
Operating expenses:			
Research and development	14,805	14,801	348,071
General and administrative	3,281	5,026	107,738
Acquired in-process research and development	0	0	29,461
Operating loss	(6,874)	(5,531)	(337,839)
Other income (loss):			
Interest income and other, net	96	90	9,265
Gain (loss) on change in warrant valuation	(10,926)	7,274	14,044
Realized gain on sale of short-term securities - available-for-sale	0	0	3,863
Write-down of short-term securities - available-for-sale	0	0	(17,001)
	(10,830)	7,364	10,171
Net income (loss)	$ (17,704)	$ 1,833	$ (327,668)
Other comprehensive income (loss):			
Write-down of short-term securities - available-for-sale	0	0	17,001
Realized gain on sale of short-term securities - available-for-sale	0	0	(3,863)
Unrealized loss on short-term securities - available-for-sale	0	0	(13,138)
Comprehensive income (loss)	$ (17,704)	$ 1,833	$ (327,668)
Net income (loss) per share - basic	$ (0.13)	$ 0.02	
Net income (loss) per share - diluted	$ (0.13)	$ 0.02	
Weighted average number of common shares outstanding for computing basic income (loss) per share (in thousands)	135,743	112,482	

Weighted average number of common shares outstanding for computing diluted income (loss) per share (in thousands)	135,743	121,285

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, 2012	2011	For the Period July 22, 1980 (Inception) through March 31, 2012
Cash flows from operating activities:			
Net income (loss)	$ (17,704)	$ 1,833	$ (327,668)
Adjustments to reconcile net income (loss) to net cash flows used in operating activities:			
Depreciation and amortization	353	239	20,798
Loss on disposal of assets	65	26	2,336
Realized gain on sale of short-term securities - available-for-sale	0	0	(3,863)
Write-down of short-term securities - available-for-sale	0	0	17,001
Impairment charge on real estate owned	0	0	1,445
Stock-based compensation	708	1,145	29,703
Conversion of interest accrued to common stock	0	0	8
Acquired in-process research and development	0	0	29,461
Increase (decrease) on warrant liability	10,926	(7,274)	(14,044)
(Increase) in accounts receivable, other current assets and other assets	(1,830)	(11,226)	(7,004)
Increase (decrease) in accounts payable, accrued employee compensation, and other liabilities	(1,567)	5,191	12,564
Net cash used in operating activities	(9,049)	(10,066)	(239,263)
Cash flows from investing activities:			
Purchase of property and equipment	(9)	(227)	(19,888)
Patent costs	(253)	(109)	(9,745)
Purchase of marketable securities	0	0	(112,993)
Sale of marketable securities	0	0	117,724
Acquisition costs	0	0	(2,389)
Net cash used in investing activities	(262)	(336)	(27,291)
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	1	116	297,879
Repayments of long-term debt	(21)	(20)	(366)
Buyback of common stock pursuant to rescission offering	0	0	(289)
Withdrawal of partnership net assets	0	0	(177)
Issuance of convertible debt	0	0	80
Net cash provided by (used in) financing activities	(20)	96	297,127
Increase (decrease) in cash and cash equivalents	(9,331)	(10,306)	30,573
Cash and cash equivalents:			
Beginning of period	39,904	33,589	

End of period	$ 30,573	$ 23,283	$ 30,573
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for interest	$ 22	$ 23	$ 511
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:			
Short-term securities - available-for-sale received in connection with the private offering	$ 0	$ 0	$ 17,897
Issuance of common stock and warrants in satisfaction of liabilities	$ 0	$ 644	$ 1,188
Issuance of common stock for building purchase	$ 0	$ 0	$ 750
Assumption of long-term debt for building purchase	$ 0	$ 0	$ 2,200
Issuance of common stock for Ercole assets	$ 0	$ 0	$ 8,075
Assumption of liabilities for Ercole assets	$ 0	$ 0	$ 2,124

See accompanying notes to financial statements.

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AVI BIOPHARMA, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

1. ORGANIZATION AND BASIS OF PRESENTATION

AVI BioPharma, Inc. (the Company) is a biopharmaceutical company incorporated in the State of Oregon on July 22, 1980. The Company is focused on the discovery and development of unique RNA-based therapeutics for the treatment of rare and infectious diseases. Applying the Company s proprietary platform technologies, the Company is able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. The Company is focused on rapidly advancing the development of its Duchenne muscular dystrophy drug candidates, including its lead product candidate, eteplirsen. In April 2012, the Company announced results from its Phase IIb placebo controlled trial in eteplirsen. Following completion of this study, the Company initiated an open label extension study with the same participants from the original Phase IIb placebo controlled trial. The Company is also focused on developing therapeutics for the treatment of infectious diseases, including its lead infectious disease programs aimed at the development of drug candidates for the Ebola and Marburg hemorrhagic fever viruses for which the Company has historically received and expects to continue to receive significant financial support from U.S. government research contracts.

The accompanying unaudited condensed consolidated financial statements reflect the accounts of the Company and its consolidated subsidiaries. The accompanying unaudited condensed consolidated balance sheet data as of December 31, 2011 was derived from audited financial statements not included in this report. The accompanying unaudited condensed consolidated financial statements were prepared in conformity with accounting principles generally accepted in the United States of America (GAAP) and the rules and regulations of the U.S. Securities and Exchange Commission (SEC) pertaining to interim financial statements. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements.

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

The accompanying unaudited condensed consolidated financial statements reflect all adjustments that are, in the opinion of management, necessary for a fair presentation of the financial position, results of operations and cash flows for the interim periods. The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the financial statements and the notes thereto included in the Company s annual report on Form 10-K for the year ended December 31, 2011. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

Since its inception in 1980, the Company has incurred losses of approximately $327.7 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenues from product sales will be achieved. Moreover, even if the Company does achieve revenue from product sales, the Company expects to incur operating losses over the next several years.

In the periods presented, nearly all of the revenue generated by the Company was derived from research contracts and grants with the U.S. government. As of March 31, 2012, the Company had had substantially completed all of its contracts with the U.S. government except for the July 2010 agreement for the development of therapeutics against Ebola and Marburg. Pursuant to this agreement, as of March 31, 2012, the Company is currently entitled to receive up to an aggregate of $126.5 million for development of its product candidates, of which $63.9 million has been recognized as revenue and $62.6 million relates to development that has not yet been completed and has not been billed or recognized as revenue. In addition, if the U.S. government elects to exercise all its options under the agreement, an additional $161.5 million in funding is available. See Note 6 U.S. Government Contracts for additional information.

At March 31, 2012, cash and cash equivalents were $30.6 million. The Company s principal sources of liquidity have been equity financings and revenue from its U.S. government research contracts. The Company s principal uses of cash have been research and development expenses, general and administrative expenses and other working capital requirements.

The Company believes it has sufficient cash to fund operations at least through the following 12 months. The Company anticipates receiving continued funding from the U.S. government to pursue the development of its therapeutics against Ebola and

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Marburg, and has assumed certain revenues from these awards in providing this guidance. Should the Company s funding from the U.S. government cease or be delayed, it would have a significant negative impact on the Company s financial condition and on this guidance and the Company would likely be forced to significantly curtail its research and development efforts unless additional funding was obtained. The Company is also likely to pursue additional funding through public or private financings and cash generated from establishing collaborations or licensing its technology to other companies.

Estimates and Uncertainties

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the valuation of liability classified warrants and stock-based awards, long lived asset impairment, and revenue recognition.

Commitments and Contingencies

As of the date of this report, the Company is not a party to any material legal proceedings with respect to itself, its subsidiaries, or any of its material properties. In the normal course of business, the Company may from time to time be named as a party to various legal claims, actions and complaints, including matters involving employment, intellectual property, effects from the use of therapeutics utilizing its technology, professional services 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.

Reclassifications

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

2. NET INCOME (LOSS) PER SHARE

Basic net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares outstanding. Diluted net income (loss) per share is computed by dividing net income (loss) by the weighted-average number of common shares and dilutive common stock equivalent shares outstanding.

	Three Months Ended March 31,	
	2012	2011
	(in thousands, except per share data)	
Net income (loss)	$ (17,704)	$ 1,833
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	135,743	112,482
Dilutive effect of warrants and stock options after application of the treasury stock method*		8,803
Weighted-average number of common shares outstanding for computing diluted earnings per share	135,743	121,282
Net income (loss) per share - basic	$ (0.13)	$ 0.02
Net income (loss) per share - dilutive	$ (0.13)	$ 0.02

* Warrants and stock options to purchase 42,953,909 and 12,572,964 shares of common stock as of March 31, 2012 and 2011, respectively, were excluded from the net income (loss) per share calculation as their effect would have been anti-dilutive.

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3. FAIR VALUE MEASUREMENTS

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

Level 1 quoted prices for identical instruments in active markets;

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

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

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

	00000000	00000000	00000000	00000000
	Fair Value Measurement as of March 31, 2012			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Cash and cash equivalents	$ 30,573	$ 30,573	$	$
Total assets	$ 30,573	$ 30,573	$	$

	00000000	00000000	00000000	00000000
	Fair Value Measurement as of March 31, 2012			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Warrants*	$ 16,372	$	$	$ 16,372
Total liabilities	$ 16,372	$	$	$ 16,372

	00000000	00000000	00000000	00000000
	Fair Value Measurement as of December 31, 2011			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Cash and cash equivalents	$ 39,904	$ 39,904	$	$
Total assets	$ 39,904	$ 39,904	$	$

	00000000	00000000	00000000	00000000
	Fair Value Measurement as of December 31, 2011			
	Total	Level 1	Level 2	Level 3

			(in thousands)	
Warrants*	$ 5,446	$	$	$ 5,446
Total liabilities	$ 5,446	$	$	$ 5,446

* See Note 5 Warrants for additional information related to the determination of fair value of the warrants and a reconciliation of changes in fair value.

The carrying amounts reported in the balance sheets for 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.

4. ACCOUNTS RECEIVABLE

Accounts receivable are stated at invoiced amount and do not bear interest. Because all accounts receivable are from the U.S. government and historically no amounts have been written off, an allowance for doubtful accounts receivable is not considered necessary. The accounts receivable balance included $2,623,000 and $2,093,000 of U.S. government receivables that were unbilled at March 31, 2012 and December 31, 2011, respectively.

5. WARRANTS

Warrants issued in connection with the Company s December 2007, January 2009 and August 2009 financings are classified as liabilities, as opposed to equity, due to their settlement terms which require settlement in registered shares. Additionally, the settlement terms may result in cash settlement upon the occurrence of certain specified transactions set forth in the warrant agreements. Warrants classified as liabilities are adjusted to fair value each reporting period with the fair value adjustment recorded in the statement of operations. All other warrants issued by the Company were recorded as additional paid-in capital and no further adjustments are made.

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

	Three Months Ended March 31,	
	2012	2011
Risk-free interest rate	0.2%-0.3%	0.8%-1.3%
Expected dividend yield	0%	0%
Expected lives	0.7-2.4 years	1.7-3.4 years
Expected volatility	65.1%-82.4 %	71.4%-88.5%
Shares underlying warrants classified as liabilities	28,948,962	28,948,962
Market value of stock at beginning of period	$ 0.75	$ 2.12
Market value of stock at end of period	$ 1.54	$ 1.86

A reconciliation of the change in value of such warrants for the three months ended March 31, 2012 is as follows:

(in thousands)	
Balance at December 31, 2011	$ 5,446
Change in value of warrants	10,926
Reclassification to shareholders equity upon exercise of warrants	
Balance at March 31, 2012	$ 16,372

The following table summarizes information about warrants outstanding at March 31, 2012.

Exercise Price	Outstanding Warrants at March 31, 2012	Weighted Average Remaining Contractual Life (Years)	Exercisable Warrants
$0.0003	16,667	No expiration date	16,667
0.1679	238,228	0.6	238,228
1.14	1,000	No expiration date	1,000
1.16	14,124,202	2.3	14,124,202
1.45	66,142	1.8	66,142
1.78	9,410,310	2.4	9,410,310
2.45	5,348,308	0.7	5,348,308
	29,204,857		29,204,857

6. U.S. GOVERNMENT CONTRACTS

The Company recognizes revenues from U.S. government research contracts during the period in which the related expenditures are incurred and presents these revenues and related expenses gross in the consolidated financial statements. In the periods presented, all of the revenue generated by the Company was derived from research contracts with and grants from the U.S. government. As of March 31, 2012, the Company had completed all of its contracts with the U.S. government except for the July 2010 agreement for the development of therapeutics against Ebola and Marburg.

July 2010 Agreement (Ebola and Marburg)

On July 14, 2010, the Company was awarded a contract with the U.S. Department of Defense, or DoD, Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the Company s hemorrhagic fever virus

therapeutic candidates, AVI-6002 and AVI-6003, against the Ebola and Marburg viruses, respectively. In February 2012, the Company announced that it received approval from the FDA to proceed with a single oligomer from AVI-6003, AVI-7288, as the lead product candidate against Marburg virus infection. The contract is structured into four segments for each therapeutic candidate and has an aggregate period of performance spanning approximately six years if DoD exercises its options for

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all segments. Activities under the first segment began in July 2010 and include Phase I studies in healthy volunteers as well as preclinical studies which are scheduled to be completed in the second quarter of 2013. The aggregate available funding for the current segments is approximately $126.5 million of which $63.9 million has been recognized to date.

After completion of the first segment, and each successive segment, DoD has the option to proceed to the next segment for either or both AVI-6002 and AVI-7288. If DoD exercises its options for all four segments for both AVI-6002 and AVI-7288 , contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval for each therapeutic candidate and would provide for a total funding award to the Company of up to $288.0 million over a period of six years, of which $161.5 million remains to be funded.

June 2010 Agreement (H1N1/Influenza)

On June 4, 2010, the Company entered into a contract with the Defense Threat Reduction Agency to advance the development of AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program of DoD. The period of performance for this contract ended on June 3, 2011 and, as of December 31, 2011, the Company has recognized revenue of $12.3 million and does not expect to receive any additional revenue.

The following table sets forth the revenue for each of the contracts with the U.S. government for the three months ended March 31, 2012 and 2011.

	Three Months Ended March 31,	
	2012	2011
	(in thousands)	
July 2010 Agreement *(Ebola and Marburg)*	$ 11,163	$ 11,905
June 2010 Agreement *(H1N1)*		2,324
Other Agreements	49	67
Total	$ 11,212	$ 14,296

7. STOCK COMPENSATION

Stock Options

In general, stock options granted prior to December 31, 2010 vest over a three year period, with one-third of the underlying shares vesting on each anniversary of grant, and have a ten year term. Beginning in January 2011, stock options granted generally vest over a four year period, with one-fourth of the underlying shares vesting on the first anniversary of the grant and 1/48th of the underlying shares vesting monthly thereafter, such that the underlying shares will be fully vested on the fourth anniversary of the grant. As of March 31, 2012, 13,040,676 shares of common stock remain available for future grant.

A summary of the Company s stock option activity with respect to the three months ended March 31, 2012 follows:

Stock Options	Underlying Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2011	14,505,857	$ 1.86		
Granted	653,000	1.40		
Exercised	(667)	0.92		
Canceled or expired	(1,409,138)	1.42		

Outstanding at March 31, 2012	13,749,052	$ 1.89	7.39	$ 2,626,000
Vested at March 31, 2012 and expected to vest	13,202,433	$ 1.91	7.31	$ 2,477,000
Exercisable at March 31, 2012	5,149,551	$ 2.54	4.33	$ 609,000

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The weighted-average fair value per share of stock-based awards granted to employees during the three months ended March 31, 2012 and 2011 was $0.91 and $1.54, respectively. During the three months ended March 31, 2012 and 2011, the total intrinsic value of stock options exercised was $280 and $0 respectively, and the total grant date fair value of stock options that vested was $1,942,000 and $1,089,000, respectively.

Valuation Assumptions

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

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

	Three Months Ended March 31,	
	2012	2011
Risk-free interest rate	1.1%	2.4%
Expected dividend yield	0%	0%
Expected lives	5.3 years	5.4 years
Expected volatility	79.7%	81.6%

Stock-based Compensation Expense

A summary of the stock-based compensation expense recognized in the statements of operations is as follows:

	Three Months Ended March 31,	
	2012	2011
	(in thousands)	
Research and development	$ 253	$ 373
General and administrative	455	772
Total	$ 708	$ 1,145

As of March 31, 2012, there was $7,526,000 of unrecognized compensation cost related to non-vested share-based compensation arrangements granted, including stock options and restricted stock. These costs are expected to be recognized over a weighted-average period of 3.1 years.

8. INCOME TAXES

At December 31, 2011, the Company had net deferred tax assets of approximately $116.8 million. The net deferred tax assets are primarily composed of U.S. federal and state tax net operating loss carryforwards, U.S. federal and state research and development credit carryforwards and share-based compensation expense. Due to uncertainties surrounding the Company s ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules could limit the future use of its net operating loss and research and development credit carryforwards to offset future taxable income based on ownership changes and the value of the Company s stock.

9. RESTRUCTURING

In December 2011, the Company restructured its operations by reducing its workforce by 28%. Restructuring charges totaling $1,145,000 were recorded in 2011 and included severance and related costs. The charge included $548,000 to research and development expense and $597,000 to general and administrative expense. The restructuring was completed by January 31, 2012 and all severance costs are expected to be paid by July 31, 2012.

Changes in the accrued employee compensation liability and the balance related to the December 2011 restructuring plan are as follows:

	Three months ending March 31, 2012 (in thousands)
Balance at January 1, 2012	$ 828
Restructuring charge for severance	
Severance payments	(86)
Balance at March 31, 2012	$ 742

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10. RECENT ACCOUNTING PRONOUNCEMENTS

In April 2011, the Financial Accounting Standards Board (FASB) issued guidance to achieve common fair value measurement and disclosure requirements between GAAP and International Financial Reporting Standards. This guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. The guidance is effective for fiscal years and interim periods beginning after December 15, 2011. The adoption of this new guidance did not have a material impact on the Company s financial statements.

In June 2011, the FASB issued guidance regarding presentation of other comprehensive income in the financial statements. This guidance eliminated the option under GAAP to present other comprehensive income in the statement of changes in equity. Under the guidance, the Company had the option to present the components of net income and comprehensive income in either one or two consecutive financial statements. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of this new guidance did not have a material impact on the Company s financial statements.

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

This section should be read in conjunction with our condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and the section contained in our Annual Report on Form 10-K for the year ended December 31, 2011 under the caption Part II-Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations . This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Exchange Act. 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 and are sometimes identified by such words as believe, expect, anticipate, may, will, should, could, would, plan, estimate, project, predict, and potential, and words of similar import. These forward-lo include, but are not limited to, statements regarding:

our expectations regarding the development and clinical benefits of our product candidates;

the results of our research and development efforts and the efficacy of our PMO-based chemistries and other RNA-based technology;

our expectations regarding our ability to become a leading developer and marketer of RNA-based therapeutics;

the efficacy, potency and utility of our product candidates in the treatment of rare and infectious diseases, and their potential to treat a broad number of human diseases;

our expectations regarding the results of preclinical and clinical testing of our product candidates;

our ability to release results by the fourth quarter of 2012 from our Phase IIb extension study for eteplirsen and initiate a pivotal Phase III clinical trial for eteplirsen in 2013;

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our expectations regarding the timing, completion and receipt of results from our ongoing development programs;

the receipt of any required approval from the U.S. Food and Drug Administration, or FDA, or other regulatory approval for our products;

the effect of regulation by FDA and other agencies;

our expectations regarding the markets for our products;

acceptance of our products, if introduced, in the marketplace;

the impact of competitive products, product development, commercialization and technological difficulties;

our expectations regarding partnering opportunities and other strategic transactions;

the extent of protection that our patents provide and our pending patent applications may provide, if patents issue from such applications, to our technologies and programs;

our plans to file additional patent applications to enhance and protect our existing intellectual property portfolio;

our ability to invalidate some or all of the claims covered by patents issued to competitors;

our estimates regarding our future revenues, research and development expenses, other expenses, payments to third parties and changes in staffing levels;

our estimates regarding how long our currently available cash and cash equivalents, exclusive of the U.S. government exercising its options under the 2010 Ebola and Marburg agreement, will be sufficient to finance our operations and statements about our future capital needs; and

our expectations about funding from the government and other sources.

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

Overview

We are a biopharmaceutical company focused on the discovery and development of unique RNA-based therapeutics for the treatment of rare and infectious diseases. Applying our proprietary, highly-differentiated and innovative platform technologies, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. We are primarily focused on rapidly advancing the development of

our potentially disease-modifying Duchenne muscular dystrophy drug candidates, including our lead product candidate, eteplirsen. We are also focused on developing therapeutics for the treatment of infectious diseases, including our lead infectious disease programs aimed at the development of drug candidates for the Ebola and Marburg hemorrhagic fever viruses. By building our infectious disease programs funded by the U.S. government and leveraging our highly-differentiated, proprietary technology platforms, we are seeking to further develop our research and development competencies and identify additional product candidates.

Our highly-differentiated RNA-based technologies work at the most fundamental level of biology and potentially could have a meaningful impact across a broad range of human diseases and disorders. Our lead program focuses on the development of disease-modifying therapeutic candidates for Duchenne muscular dystrophy, or DMD, a rare genetic muscle-wasting disease caused by the

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absence of dystrophin, a protein necessary for muscle function. Currently, there are no disease-modifying therapies available for DMD. Eteplirsen is our lead therapeutic candidate for DMD and if we are successful in our development efforts, eteplirsen will address a severe unmet medical need. We recently completed a U.S.-based Phase IIb clinical trial for eteplirsen that was initiated in August 2011 and announced results from this trial in April 2012.

In April 2012, we announced that treatment with eteplirsen met the primary efficacy endpoint in the Phase IIb study. Eteplirsen administered once weekly at 30mg/kg over 24 weeks resulted in a statistically significant (p £ 0.002) increase in novel dystrophin (22.5% dystrophin-positive fibers as a percentage of normal) compared to no increase in the placebo group. Restoration of dystrophin expression and dystrophin positive fibers is believed to be critical for successful disease-modifying treatment of individuals with DMD. In the study, a shorter duration of eteplirsen treatment, 12 weeks, did not show a significant increase in novel dystrophin (0.79% dystrophin-positive fibers as a percentage of normal; p-value NS), despite administration of the drug at a higher dose (50mg/kg once weekly). This finding suggests that a longer duration of dosing is required before meaningful levels of dystrophin are produced. Eteplirsen was well tolerated at both dose levels through 24 weeks of treatment and there were no treatment-related adverse events, no serious adverse events, and no treatment discontinuations related to eteplirsen. No significant improvements in clinical outcomes in the treated groups were observed compared to placebo, suggesting that a longer period of observation will be required to demonstrate clinical effects of eteplirsen versus a placebo control. Following completion of this study, we initiated an open label extension study with the same participants from the original Phase IIb placebo controlled trial. We anticipate releasing results from the open label extension study in the fourth quarter of 2012 and initiating a pivotal Phase III trial in 2013.

We are also leveraging the capabilities of our RNA-based technology platforms to develop therapeutics for the treatment of infectious diseases. The U.S. Department of Defense, or DoD, has provided significant financial support for the development of therapeutics against Ebola, Marburg, and influenza viruses, as described in greater detail below under the heading Government Contracts .

Since our inception in 1980, we have incurred losses of approximately $327.7 million and substantially all of our revenue has been derived from research and development contracts with the U.S. government. We have not yet generated any material revenue from product sales and we have incurred expenses related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. We expect to continue to incur losses in the future as we continue our research and development efforts and seek approval from various regulatory agencies for our product candidates, but there can be no assurance that we will obtain approval for our product candidates and achieve revenues from product sales.

As of March 31, 2012, we had cash and cash equivalents of $30.6 million and we anticipate receiving continued funding from the U.S. government to pursue the development of our therapeutics against Ebola and Marburg. Combined together, we believe these sources provide us with sufficient cash to fund operations at least through the following 12 months. In addition, we are likely to pursue additional funding through public or private financings and cash generated from establishing collaborations or licensing our technology to other companies. Should our funding from the U.S. government cease or be delayed, it would have a significant negative impact on our financial condition and on this guidance and we would likely be forced to significantly curtail our research and development efforts.

The likelihood of our long-term success 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, the risks associated with U.S. government-sponsored programs, and the complex regulatory environment in which we operate. There can be no assurance that we will ever achieve significant revenues or profitable operations.

Government Contracts

We recognize revenues from U.S. government research contracts during the period in which the related expenditures are incurred and present these revenues and related expenses gross in the consolidated financial statements. In the periods presented, all of the revenue generated by us was derived from research contracts with and grants from the U.S. government. As of March 31, 2012, we had completed all of our significant contracts with the U.S. government except for the July 2010 agreement for the development of therapeutics against Ebola and Marburg.

July 2010 Agreement (Ebola and Marburg)

On July 14, 2010, we were awarded a contract with the U.S. Department of Defense, or DoD, Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of our hemorrhagic fever virus

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therapeutic candidates, AVI-6002 and AVI-6003 against the Ebola and Marburg viruses, respectively. In February 2012, we announced that we received approval from the FDA to proceed with a single oligomer from AVI-6003, AVI-7288, as the lead product candidate against Marburg virus infection. The contract is structured into four segments for each therapeutic candidate and has an aggregate period of performance spanning approximately six years if DoD exercises its options for all segments. Activities under the first segment began in July 2010 and include Phase I studies in healthy volunteers as well as preclinical studies which are scheduled to be completed in the second quarter of 2013. The aggregate available funding for the current segments is approximately $126.5 million of which $63.9 million has been recognized to date.

After completion of the first segment, and each successive segment, DoD has the option to proceed to the next segment for either or both AVI-6002 and AVI-7288. If DoD exercises its options for all four segments for both AVI-6002 and AVI-7288, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval for each therapeutic candidate and would provide for a total funding award to us of up to $288.0 million over a period of six years, of which $161.5 million remains to be funded.

June 2010 Agreement (H1N1/Influenza)

On June 4, 2010, we entered into a contract with the Defense Threat Reduction Agency to advance the development of AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program of DoD. The period of performance for this contract ended on June 3, 2011 and, as of December 31, 2011, we have recognized revenue of $12.3 million and do not expect to receive any additional revenue.

The following table sets forth the revenue for each of the contracts with the U.S. government for the three months ended March 31, 2012 and 2011.

	Three Months Ended March 31,	
	2012	2011
	(in thousands)	
July 2010 Agreement *(Ebola and Marburg)*	$ 11,163	$ 11,905
June 2010 Agreement *(H1N1)*		2,324
Other Agreements	49	67
Total	$ 11,212	$ 14,296

Key Financial Metrics

Revenue

Government Research Contract and Grant Revenue. Substantially all of our revenue is generated from U.S. government research contracts and grants. See Note 6 U.S. Government Contracts of the financial statements included elsewhere in this report. We recognize revenue from U.S. government research contracts and grants during the period in which the related expenses are incurred and present such revenues and related expenses gross in the consolidated financial statements. Government contract revenue is highly dependent on the timing of various activities performed by us and our third party vendors. Changes in the timing of activities performed in support of this contract have, and may in the future, result in unexpected fluctuations in our revenue from period to period. We expect that future revenue generated under our government contracts will continue to be variable as a result of these factors.

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

We defer recognition of non-refundable upfront fees if we have continuing performance obligations when 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 our performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because of our know-how or because the services can only be performed by us, then such upfront fees are deferred and recognized over the period of continuing involvement. As of March 31, 2012, we had deferred revenue of $3.3 million, which represents upfront fees which we will recognize as revenue as we satisfy the outstanding performance obligations.

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Expenses

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

Direct research and development expenses associated with our programs include clinical trial site costs, clinical manufacturing costs, costs incurred for consultants and other outside services, such as data management and statistical analysis support, and materials and supplies used in support of the clinical programs. Indirect costs of our clinical program include salaries, stock based compensation, and an allocation of our facility costs.

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

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

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

Interest Income (Expense) and Other, Net. Interest income (expense) and other, net, consists of interest on our cash and cash equivalents, rental income and other income. Our cash equivalents consist of money market investments. Interest expense includes interest paid on our mortgage loan related to the Corvallis property. Other income includes rental income from subleasing excess space in some of our facilities.

Change in Fair Value of Warrants. Warrants issued in connection with our December 2007 and January and August 2009 financings are classified as liabilities, as opposed to equity, due to their settlement terms which require settlement in registered shares. The fair market value of these warrants was recorded on the balance sheet at issuance and the warrants are marked to market each financial reporting period, with changes in the fair value recorded as a gain or loss in our statement of operations. The fair value of the warrants is determined using the Black-Scholes option-pricing model, which requires the use of significant judgment and estimates related to the inputs used in the model and can result in significant swings in the fair market valuation primarily due to changes in our stock price. For more information, see Note 5 Warrants of the financial statements included elsewhere in this report.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our financial statements included elsewhere in this report. The preparation of our financial statements in accordance with accounting principles generally accepted in the United States, or GAAP, requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities for the periods presented. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

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

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

Our critical accounting policies and significant estimates are detailed in our annual report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 13, 2012.

Results of Operations for the Three Months Ended March 31, 2012 and 2011

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

	Three Months Ended March 31,		%
	2012	2011	Change
	(in thousands, except per share amounts)		
Revenue	$ 11,212	$ 14,296	(22)%
Expenses:			
Research and development	14,805	14,801	%
General and administrative	3,281	5,026	(35)%
Operating loss	(6,874)	(5,531)	24%
Other income (loss):			
Interest income and other, net	96	90	7%
Gain (loss) on change in warrant valuation	(10,926)	7,274	(250)%
Net income (loss)	$ (17,704)	$ 1,833	(1,066)%
Basic income (loss) per share	$ (0.13)	$ 0.02	
Diluted income (loss) per share	$ (0.13)	$ 0.02	

Revenue

Revenue for the three months ended March 31, 2012 decreased by $3.1 million, or 22%, compared to the three months ended March 31, 2011. The decrease was due to a $2.4 million decrease in revenue associated with the H1N1 U.S. government research contract which was completed in June 2011 and a $0.7 million decrease in revenue associated with the ongoing Ebola and Marburg U.S. government research contract.

Research and Development Expenses

Total research and development expense for the three months ended March 31, 2012 was comparable to the three months ended March 31, 2011. During the current quarter as compared to the prior year quarter, spending on DMD increased by $1.8 million primarily due to the Phase IIb trial for eteplirsen and a $0.4 million increase in spending on other proprietary research. These increases were offset by a $1.2 million reduction in spending on the H1N1 U.S. government contract which was completed in June 2011, a $0.6 million reduction in spending on the ongoing Ebola

and Marburg U.S. government contract and a $0.4 million reduction in personnel related costs.

General and Administrative Expenses

General and administrative expenses for the three months ended March 31, 2012 decreased by $1.7 million, or 35%, compared to the three months ended March 31, 2011. The decrease is primarily due to a $1.1 million decrease in personnel costs resulting from the December 2011 reorganization and an executive severance package recorded in the first quarter of 2011. Legal and professional service fees also decreased $0.5 million.

Gain (Loss) on Change in Warrant Valuation

The $18.2 million change in fair value of our warrant liability for the three months ended March 31, 2012 compared to the three months ended March 31, 2011 was primarily attributable to increases in our stock price. See Key Financial Metrics Change in Fair Value of Warrants, Critical Accounting Policies and Estimates Warrant Liability, and Note 5 to the unaudited condensed consolidated financial statements included elsewhere in this report.

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Net Income (Loss)

Net loss for the three months ended March 31, 2012 was $17.7 million, compared to net income of $1.8 million for the three months ended March 31, 2011, a change of $19.5 million. The increase in the net loss for the three months ended March 31, 2012 was due primarily to the $18.2 million incremental expense associated with the increase in warrant liability and a $1.3 million increase in operating losses.

Liquidity and Capital Resources

At March 31, 2012, cash and cash equivalents were $30.6 million, compared to $39.9 million at December 31, 2011. Our principal sources of liquidity are equity financings and revenue from our U.S. government research contracts. Our principal uses of cash are research and development expenses, general and administrative expenses and other working capital requirements. Based on the factors described below, we believe that our currently available cash and cash equivalents, exclusive of the U.S. government exercising its options under the 2010 Ebola and Marburg agreement, are sufficient to finance our operations for at least the next 12 months.

Sources of Funds

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

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

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

Uses of Funds

From inception in 1980 through the date of this report, our accumulated deficit is $327.7 million. Our principal uses of cash have been research and development expenses, general and administrative expenses, costs associated with the acquisition of in-process research and development and other working capital requirements.

Historical Trends

	Three Months Ended March 31,	
	2012	2011
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (9,049)	$ (10,066)
Investing activities	(262)	(336)
Financing activities	(20)	96
Decrease in cash and equivalents	$ (9,331)	$ (10,306)

Operating Activities. We used $9.0 million of cash in operating activities for the three months ended March 31, 2012, a decrease of $1.0 million, compared to $10.1 million of cash used in operating activities for the three months ended March 31, 2011. The decrease in net cash used in operations during the comparative periods was primarily attributable to a $2.6 million increase in cash provided from changes in working capital

partially offset by a $1.3 million increase in net loss, excluding the noncash loss associated with the periodic revaluation of our warrants to fair market value.

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Investing Activities. We used $0.3 million of cash in investing activities for the three months ended March 31, 2012, which is comparable to the $0.3 million of cash used in investing activities for the three months ended March 31, 2011.

Financing Activities. Financing activities for the three months ended March 31, 2012 were due to repayment of debt compared to the three months ended March 31, 2011 which included cash provided by exercise of warrants partially offset by debt repayment.

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

Contractual Obligations and Contingencies

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and acquisition of technology access rights, among others. The following table presents noncancelable contractual obligations arising from these arrangements as of March 31, 2012:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(in thousands)		
Long-term debt	$ 1,821	$ 86	$ 184	$ 203	$ 1,348
Operating leases	15,301	2,428	5,337	4,530	3,006
Purchase obligations(1)	828	745	83		
Total	$ 17,950	$ 3,259	$ 5,604	$ 4,733	$ 4,354

(1) Purchase obligations include agreements to purchase goods or services that are enforceable and legally binding to the Company and that specify all significant terms. Purchase obligations relate primarily to our DMD development program.

Off Balance Sheet Arrangements

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

Recent Accounting Pronouncements

See Note 10 to the unaudited condensed consolidated financial statements contained in Part I, Item 1 of this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Sensitivity

We had cash and cash equivalents of $30.6 million and $39.9 million at March 31, 2012 and December 31, 2011, respectively. We do not enter into investments for trading or speculative purposes; our cash equivalents are invested in money market accounts. We believe that we do not have any material exposure to changes in the fair value of these assets in the near term due to extremely low rates of investment interest and to the short term nature of our cash and cash equivalents. Future declines in interest rates, however, would reduce investment income, but are not likely to be a material source of revenue to our company in the foreseeable future. A 0.1% decline in interest rates, occurring January 1, 2012

and sustained throughout the period ended March 31, 2012, would be inconsequential.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of the end of the period covered by this report, under the supervision and with the participation of our management, including (1) our chief executive officer and principal financial officer and (2) our principal accounting officer, of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the Securities and Exchange Commission, or SEC, under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and (ii) accumulated and communicated to our management, including our chief executive officer and principal financial officer and our principal accounting officer, as appropriate, to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of March 31, 2012, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended March 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Set forth below and elsewhere in this report and in other documents we file with the SEC are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial also affect our results of operations and financial condition.

Risks Relating to Our Business

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

Our product candidates are in relatively early stages of development. These product candidates will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Currently, eteplirsen in DMD, AVI-6002 in Ebola and AVI-7288 in Marburg are in active clinical development. The clinical development of AVI-7100 in influenza is currently paused and the rest of our product candidates are in preclinical development. We

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expect that much of our effort and many of our expenditures over the next several years will be devoted to development activities associated with eteplirsen and other exon-skipping candidates as part of our larger pan-exon strategy in DMD and our antiviral candidates. With current resources, we may be restricted or delayed in our ability to develop other clinical and preclinical product candidates.

Our ability to commercialize any of our product candidates, including eteplirsen, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval (including any accelerated approval by the U.S. Food and Drug Administration (the FDA) under Subpart H Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses) for any of our product candidates based on an inability to adequately demonstrate the safety and effectiveness of our product candidates, lack of funding, changes in the regulatory landscape or other reasons. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Assuming that any of our product candidates receives the required regulatory approvals, commercial success will depend on a number of factors, including:

- establishment and demonstration of clinical efficacy and safety and acceptance of the same by the medical community;
- cost-effectiveness of the product;
- the availability of adequate reimbursement by third parties, including governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers;
- the product s potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs;
- marketing and distribution support for the product; and
- any exclusivities applicable to the product.

Although to date we have been granted orphan status for two of our product candidates in DMD and are seeking orphan status for AVI-6002 and AVI-7288, we are not guaranteed to receive orphan exclusivity based on that status and would not enjoy such exclusivity in the event that another entity could get approval of the same product for the same indication before we receive market approval. Further, application of the orphan drug regulations in the United States and Europe is uncertain and we cannot predict how the respective regulatory bodies will interpret and apply the regulations to our or our competitors product candidates. If another product receives orphan drug status for an indication that we are targeting, and such product is approved for commercial sales before our product, regulators may interpret our product to be the same drug as the competing product and could prevent us from selling our product in the applicable territories. Furthermore, pediatric exclusivity only applies if another product with exclusivity has not received regulatory approval, so if another regulatory exclusivity or patent protection exists for the product once it is approved, we would not receive the benefit of any pediatric exclusivity.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA in the United States, and other regulatory authorities in other countries, with regulations differing from country to country. Marketing of our product candidates in the United States or foreign countries is not permitted until we obtain marketing approval from the FDA or other foreign regulatory authorities, and we may never receive regulatory approval for the commercial sale of any of our product candidates.

Obtaining marketing approval is a lengthy, expensive and uncertain process and approval is never assured. As of the date of this report, we have not progressed to the point of preparing or filing the applications necessary to gain regulatory approvals. Further, the FDA and other foreign regulatory agencies have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate we develop. In this regard, even if we believe the data collected from clinical trials of our product candidates are promising, such data may n