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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2010

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 ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 ☒
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 ☒

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	**112,323,950**
(Class)	(Outstanding as of November 4, 2010)

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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)

	September 30, 2010	December 31, 2009
Assets		
Current Assets:		
Cash and cash equivalents	$ 35,967	$ 48,275
Accounts receivable	5,241	2,085
Other current assets	1,106	950
Total Current Assets	42,314	51,310
Property held for sale	1,979	2,372
Property and Equipment, net of accumulated depreciation and amortization of $14,678 and $14,026	2,155	2,466
Patent Costs, net of accumulated amortization of $1,870 and $1,762	4,301	3,759
Other assets	111	120
Total Assets	$ 50,860	$ 60,027
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable	$ 4,945	$ 1,381
Accrued employee compensation	2,223	922
Long-term debt, current portion	80	77
Warrant valuation	33,118	27,609
Deferred revenue	3,335	3,428
Other liabilities	64	90
Total Current Liabilities	43,765	33,507
Commitments and Contingencies	—	—
Long-term debt, non-current portion	1,863	1,924
Other long-term liabilities	1,069	966
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; 112,323,950 and 110,495,587 issued and outstanding	11	11
Additional paid-in capital	304,154	299,088
Deficit accumulated during the development stage	(300,002)	(275,469)
Total Shareholders' Equity	4,163	23,630
Total Liabilities and Shareholders' Equity	$ 50,860	$ 60,027

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

	Three months ended September 30,		Nine months ended September 30,		July 22, 1980 (Inception) through
	2010	2009	2010	2009	September 30, 2010
Revenues from license fees, grants and research contracts	$ 8,702	$ 6,353	$ 13,903	$ 12,448	$ 73,712
Operating expenses:					
Research and development	9,059	7,473	22,080	17,770	252,512
General and administrative	3,440	1,800	11,017	6,226	85,037
Acquired in-process research and development					29,461
Operating loss	(3,797)	(2,920)	(19,194)	(11,548)	(293,298)
Other non-operating (loss) income:					
Interest (expense) income and other, net	82	(132)	170	(147)	8,493
(Increase) decrease on warrant valuation	(3,578)	(5,038)	(5,509)	(16,989)	(2,059)
Realized gain on sale of short-term securities—available-for-sale	—	—	—	—	3,863
Write-down of short-term securities—available-for-sale	—	—	—	—	(17,001)
	(3,496)	(5,170)	(5,339)	(17,136)	(6,704)
Net loss and comprehensive loss	$ (7,293)	$ (8,090)	$ (24,533)	$ (28,684)	$ (300,002)
Net loss per share - basic and diluted	$ (0.07)	$ (0.08)	$ (0.22)	$ (0.33)	
Weighted average number of common shares outstanding for computing basic and diluted loss per share (in thousands)	111,767	95,261	110,863	87,493	—

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Nine months ended September 30,		For the Period July 22, 1980 (Inception) through September 30, 2010
	2010	2009	
Cash flows from operating activities:			
Net loss	$ (24,533)	$ (28,684)	$ (300,002)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	1,053	1,080	18,735
Loss on disposal of assets	274	221	1,579
Realized gain on sale of short-term securities— available-for-sale	—	—	(3,863)
Write-down of short-term securities—available-for-sale	—	—	17,001
Impairment charge on real estate owned	393	128	1,321
Stock-based compensation	2,540	1,592	25,237
Conversion of interest accrued to common stock	—	—	8
Acquired in-process research and development	—	—	29,461
Increase (decrease) on warrant valuation	5,509	16,989	2,059
(Increase) decrease in:			
Accounts receivable and other current assets	(3,297)	(1,026)	(6,197)
Net increase in accounts payable, accrued employee compensation, and other liabilities	4,740	1,957	10,014
Net cash used in operating activities	(13,321)	(7,743)	(204,647)
Cash flows from investing activities:			
Purchase of property and equipment	(628)	(276)	(18,497)
Patent costs	(821)	(751)	(8,064)
Purchase of marketable securities	(5)	113	(112,991)
Sale of marketable securities	—	—	117,724
Acquisition costs	—	—	(2,389)
Net cash used in investing activities	(1,454)	(914)	(24,217)
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	2,525	47,782	265,462
Repayments of long-term debt	(58)	(49)	(245)
Buyback of common stock pursuant to rescission offering	—	—	(289)
Withdrawal of partnership net assets	—	—	(177)
Issuance of convertible debt	—	—	80
Net cash provided by (used in) financing activities	2,467	47,733	264,831
Increase (decrease) in cash and cash equivalents	(12,308)	39,076	35,967
Cash and cash equivalents:			
Beginning of period	48,275	11,192	—
End of period	$ 35,967	$ 50,268	$ 35,967
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the year for interest	$ 70	$ 65	$ 375
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING ACTIVITIES AND FINANCING ACTIVITIES:			
Short-term securities—available-for-sale received in connection with the private offering	$ —	$ —	$ 17,897
Issuance of common stock and warrants in satisfaction of liabilities	$ —	$ —	$ 545
Issuance of common stock for building purchase	$ —	$ —	$ 750
Assumption of long-term debt for building purchase	$ —	$ —	$ 2,200
Issuance of common stock for Ercole assets	$ —	$ —	$ 8,075
Assumption of liabilities for Ercole assets	$ —	$ —	$ 2,124
Issuance of common stock and warrants in satisfaction of employee bonuses	$ —	$ 239	$ —

See accompanying notes to financial statements.

AVI BIOPHARMA, INC.
NOTES TO FINANCIAL STATEMENTS
(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements reflect the accounts of AVI BioPharma, Inc. (the "Company") and its consolidated subsidiaries. The accompanying unaudited condensed consolidated balance sheet data as of December 31, 2009 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 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, 2009. The results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

Reclassifications

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

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.

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, or others. It is impossible to predict with certainty whether any resulting liability would have a material adverse effect on the Company's financial position, results of operations or cash flows.

Note 2. Fair Value Measurements

The Company measures at fair value certain financial assets and liabilities 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:

	Fair Value Measurement as of September 30, 2010			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Cash equivalents	$ 35,967	$ 35,967	—	—
Other current assets	459	—	$ 459	—
Total assets	$ 36,426	$ 35,967	$ 459	$ —

	Fair Value Measurement as of September 30, 2010			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Warrants	$ 33,118	—	—	$ 33,118
Total liabilities	$ 33,118	$ —	$ —	$ 33,118

	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Cash equivalents	$ 48,275	$ 48,275	—	—
Other current assets	455	—	$ 455	—
Total assets	$ 48,730	$ 48,275	$ 455	$ —

	Fair Value Measurement as of December 31, 2009			
	Total	Level 1	Level 2	Level 3
	(in thousands)			
Warrants	$ 27,609	$ —	$ —	$ 27,609
Total liabilities	$ 27,609	$ —	$ —	$ 27,609

A reconciliation of the change in value of the Company's warrants for the three months ended September 30, 2010 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
	(in thousands)
Balance at June 30, 2010	$ 29,540
Change in value of warrants	3,578
Balance at September 30, 2010	$ 33,118

A reconciliation of the change in value of the Company's warrants for the nine months ended September 30, 2010 is as follows:

	Fair Value Measurements Using Significant Unobservable Inputs (Level 3)
	(in thousands)
Balance at December 31, 2009	$ 27,609
Change in value of warrants	5,509
Balance at September 30, 2010	$ 33,118

See Note 6 —"Warrants" for additional information related to the determination of fair value of the warrants. The carrying amounts reported in the balance sheets for cash, accounts receivable, accounts payable, and other current monetary assets and liabilities approximate fair value because of the immediate or short-term maturity of these financial instruments.

Note 3. Property Held for Sale

In 2009, the Company decided to outsource its large scale manufacturing activities listing for sale the industrial property located in Corvallis, Oregon and recorded a $0.1 million impairment charge to reduce carrying value to fair value less estimated costs to sell. The Company recorded an additional impairment charge of $0.4 million in the quarter ended September 30, 2010 to reduce its carrying value to the current appraised value. The Company has used a Level 3 fair value measure with the use of an independent appraisal to estimate value of this property.

Note 4. U.S. Government Contracts

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. 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. As of September 30, 2010, the Company had contracts with the U.S. government pursuant to which it is entitled to receive up to an aggregate of $157.2 million for development of its product candidates, of which $62.2 million had been billed to the U.S. government and $95.0 million of which relates to development that has not yet been completed and has not been billed. The following is a description of such contracts.

January 2006 Agreements (Ebola and Marburg Host Factors, Dengue, Anthrax and Ricin)

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of $11.0 million to fund the Company's ongoing defense-related programs under certain executed contracts. Net of government administrative costs, it is anticipated that the Company will receive up to $9.8 million under this allocation. The Company's technology is expected to be used to continue developing RNA-based drugs against Ebola and Marburg viruses. As of September 30, 2010, the Company has recognized revenue of $9.8 million with respect to these contracts.

December 2006 Agreement (Ebola, Marburg and Junín Viruses)

In December 2006, the Company entered into a two-year research contract with Defense Threat Reduction Agency ("DTRA"), an agency of the U.S. Department of Defense (the "DoD"), pursuant to which the Company was entitled to $28.0 million to fund its development of antisense therapeutics to treat the effects of Ebola, Marburg and Junín hemorrhagic fever viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by $5.9 million to an aggregate of $33.9 million. In June 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional $11.5 million to an aggregate of $45.4 million. In November 2010, the Company and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and be deemed concluded. As of September 30, 2010, the Company had recognized revenue of $38.2 million with respect to this contract and does not expect significant further revenue.

May 2009 Agreement (H1N1/Influenza)

In May 2009, the Company entered into a contract with DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to $4.1 million to the Company for the work involving the application of the Company's proprietary PMO and PMO*plus*™ antisense chemistry and the Company plans to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu®-resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by $4.0 million to an aggregate of $8.1 million. As of September 30, 2010, the Company has recognized revenue of $4.5 million with respect to this contract.

June 2010 Agreement (H1N1/Influenza)

On June 4, 2010, the Company entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by the Company, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the Transformational Medical Technologies program ("TMT") of the DoD. The contract provides for funding of up to $18 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration ("FDA"), the development of an intranasal delivery formulation, and the funding of a Phase 1 clinical program to obtain human safety data to support potential use under an Emergency Use Authorization. As of September 30, 2010, the Company has recognized revenue of $4.6 million with respect to this contract.

July 2010 Agreement (Ebola and Marburg)

On July 14, 2010, the Company was awarded a new contract with the 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, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was instigated to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately $291 million. Activity under the first segment, which began in July 2010, provides for funding to the Company of up to approximately $80 million. Activities under the first segment include Phase 1 studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.

After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to the Company of up to approximately $291 million over a period of approximately six years. Under an earlier contract, the Company completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of September 30, 2010, the Company has recognized revenue of $2.7 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government on the Company's results of operations for the three and nine months ended September 30, 2010 and 2009.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
January 2006 Agreements *(Ebola and Marburg host factor, Dengue, Anthrax and Ricin)*	$ 88	$ 285	$ 556	$ 1,908
December 2006 Agreement *(Ebola, Marburg and Junín Viruses)*	345	4,418	2,953	7,483
May 2009 Agreement *(H1N1)*	1,358	780	2,802	1,136
June 2010 Agreement *(H1N1)*	4,201	—	4,634	—
July 2010 Agreement *(Ebola and Marburg)*	2,716	—	2,716	—
Other Agreements	(6)	870	242	1,921
Total	$ 8,702	$ 6,353	$ 13,903	$ 12,448

Note 5. Stock Compensation

Stock Options

The Company sponsors a 2002 Equity Incentive Plan (the "Plan") pursuant to which it may issue options to purchase its common stock to the Company's employees, directors and service providers. In general, stock options granted under the Plan 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. As of September 30, 2010, 1,721,493 shares of common stock remain available for future grant under the Plan.

A summary of the Company's stock option compensation activity with respect to the nine months ended September 30, 2010 follows:

Stock Options	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2009	8,932,811	$ 2.79		
Granted	3,432,865	1.56		
Exercised	(1,673,128)	1.18		
Canceled or expired	(2,287,491)	4.49		
Outstanding at September 30, 2010	8,405,057	2.14	7.24	$ 2,763,892
Vested at September 30, 2010 and expected to vest	8,193,961	2.16	7.18	2,679,047
Exercisable at September 30, 2010	3,907,316	2.93	5.18	888,655

The weighted-average fair value per share of stock-based awards, including stock options and restricted stock grants, granted to employees during the nine months ended September 30, 2010 and 2009 was $1.10 and $1.07, respectively. During the same periods, the total intrinsic value of stock options exercised was $955,000 and $24,000, respectively, and the total grant date fair value of stock

options that vested was $2,555,000 and $1,450,000, respectively. The total grant date fair value of stock options vested for the three months ended September 30, 2010 and 2009 was $169,000and $446,000, 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. Stock options granted to employees are service-based and typically vest over three years.

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 and Nine Months Ended September 30,	
	2010	2009
Risk-free interest rate	1.39%-2.37%	1.2%-1.60%
Expected dividend yield	0%	0%
Expected lives	5.3-5.5 years	9.0 years
Expected volatility	83.3%-85.2%	92.0%-94.2%

The risk-free interest rate is estimated using an average of treasury bill interest rates that correlate to the prevailing interest rates at the time of grant. 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 of the Company's common stock. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

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

Restricted Stock Awards

In the three months ended June 30, 2010, the Company granted a total of 20,000 shares of restricted stock to members of its Board of Directors. These shares vest over a period of approximately one year. During the three and nine month periods ended September 30, 2010, the Company recognized compensation expense related to these shares of $6,600 and $9,600, respectively.

In the three months ended June 30, 2009, the Company granted 25,000 shares of restricted stock to members of its Board of Directors. These shares vest over a period of one year. During the three and nine months ended September 30, 2009, the Company recognized compensation expense related to these shares of $24,000 and $27,000, respectively.

Also in the three months ended June 30, 2009, the Company granted 100,000 shares of restricted stock to its Chief Business Officer. These shares vest upon the achievement of certain performance milestones. No compensation expense related to these shares has been recognized in 2010 or 2009 as the achievement of the performance milestones was not accomplished and the restricted stock was cancelled.

In the three months ended March 31, 2009, the Company granted 60,000 shares of restricted stock to its Chief Medical Officer. These shares vested over a period of 181 days. During the three and nine months ended September 30, 2009 the Company recognized compensation expense related to these shares of $11,000 and $82,000, respectively.

In the three months ended March 31, 2008, the Company granted 333,000 shares of restricted stock to its former Chief Executive Officer. Of these shares, 100,000 vested immediately and the remaining 233,000 were scheduled to vest over a period of four years. In April 2010, the former Chief Executive Officer tendered his resignation at the request of the Board of Directors and pursuant to the terms of the related separation agreement, 116,500 shares of previously granted restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. During the three months ended September 30, 2010 and 2009, the Company recognized compensation expense related to these shares of $0 and $16,000, respectively. During the nine month periods

ended September 30, 2010 and 2009, the Company recognized compensation expense related to these shares $134,000 and $48,000, respectively.

	Restricted Stock Awards	Weighted-Average Grant Date Fair Value
	(in thousands)	
Balance as of December 31, 2009	300	$ 1.09
Granted	20	1.30
Vested	(200)	1.09
Forfeited or canceled	(100)	1.10
Balance as of September 30, 2010	20	$ 1.30

The weighted-average grant-date fair value of restricted stock awards is based on the market price of the Company's common stock on the date of grant. There were no grants of restricted stock awards in the three months ended September 30, 2010 and the grant-date fair value of the restricted stock award made during the nine months ended September 30, 2010 was $1.30. The grant-date fair value of the restricted stock awards made during the three and nine month periods ended September 30, 2009 was $0 and $1.01, respectively. The total grant-date fair values of restricted stock awards that vested during the nine months ended September 30, 2010 and 2009 were approximately $219,000 and $385,000, respectively.

Stock-based Compensation Expense

The amount of stock-based compensation expense recognized in the three months ended September 30, 2010 and 2009 related to stock options was $509,000 and $511,000, respectively. For the nine months ended September 30, 2010 and 2009, stock-based compensation expense was $2,540,000 and $1,592,000, respectively. A summary of the stock based compensation expense recognized in the statement of operations is as follows:

	Three Months Ended	
	September 30, 2010	September 30, 2009
	(in thousands)	
Research and development	$ 250	$ 205
General and administrative	259	306
Total	$ 509	$ 511

The following are the stock-based compensation expense recognized in the Company's statements of operations for the nine months ended September 30, 2010 and 2009:

	Nine Months Ended	
	September 30, 2010	September 30, 2009
	(in thousands)	
Research and development	$ 665	$ 826
General and administrative	1,875	766
Total	$ 2,540	$ 1,592

As of September 30, 2010, there was $3,570,000 of total unrecognized compensation cost related to non-vested share-based compensation arrangements, including stock options and restricted stock, granted under the Plan. These costs are expected to be recognized over a weighted-average period of 1.99 years.

Pursuant to the terms of the separation agreement between the Company's former Chief Executive Officer and the Company, unvested options previously granted to Dr. Hudson to purchase 1,166,833 shares of common stock and 116,500 shares of restricted stock immediately became fully vested and exercisable at the effective date of the separation agreement. The Company recorded a charge of stock compensation expense of $1,181,292 as a result of the accelerated vesting of these shares in the second quarter of 2010.

Note 6. 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. These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

The fair value of these warrants was recorded on the balance sheet at issuance and the warrants are marked to market 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 of the warrants 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 and Nine Months Ended September 30,	
	2010	2009
Risk-free interest rate	0.1%-2.6%	0.2%-2.4%
Expected dividend yield	0%	0%
Expected lives	0.1-4.4 years	0.1-5.0 years
Expected volatility	62.3%-96.68%	83.2%-140.6%
Shares underlying warrants classified as liabilities	29,409,546	30,203,446

	Three and Nine Months Ended September 30,	
	2010	2009
Market value of stock at beginning of year	$ 1.58	$ 0.66
Market value of stock at end of period	1.83	1.72
Weighted average exercise price	1.59	3.40

The risk-free interest rate is estimated using an average of Treasury bill interest rates that correlate to the prevailing interest rates at the time of valuation date. 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 at the valuation date. The expected volatility is estimated using historical volatility of the Company's common stock, taking into account factors such as future events or circumstances that could impact volatility. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these warrants by the holders.

All other warrants issued by the Company other than the warrants issued in connection with its December 2007, January 2009 and August 2009 financings are classified as permanent equity in accordance with GAAP; the fair value of the warrants was recorded as additional paid-in capital and no further adjustments are made. For the three months ended September 30, 2010 and 2009, 255,895 and 2,129,530 shares, respectively, were underlying such warrants.

A summary of the Company's warrant activity with respect to the nine months ended September 30, 2010 is as follows:

Warrants	Shares	Weighted Average Exercisable Price	Weighted Average Remaining Contractual Term
Outstanding at January 1, 2010	32,332,996	$ 3.40	
Granted	—	—	
Exercised	(308,000)	1.78	
Canceled or expired	(2,359,555)	26.50	
Outstanding at September 30, 2010	29,665,441	1.59	3.55

Note 7. Earnings Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares and dilutive common stock equivalent shares outstanding. Given that the Company was in a loss position for each of the periods presented, there is no difference between basic and diluted net loss per share since the effect of common stock equivalents would be anti-dilutive and are therefore excluded from the diluted net loss per share calculation.

	Three Months Ended September 30,	
	2010	2009
	(in thousands, except per-share data)	
Net loss	$ (7,293)	$ (8,090)
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	111,767	95,261
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	111,767	95,261
Net loss per share - basic and diluted	$ (0.07)	$ (0.08)

	Nine Months Ended September 30,	
	2010	2009
	(in thousands, except per-share data)	
Net loss	$ (24,533)	$ (28,684)
Weighted-average number of shares of common stock and common stock equivalents outstanding:		
Weighted-average number of common shares outstanding for computing basic earnings per share	110,863	87,493
Dilutive effect of warrants and stock options after application of the treasury stock method	*	*
Weighted-average number of common shares outstanding for computing diluted earnings per share	110,863	87,493
Net loss per share - basic and diluted	$ (0.22)	$ (0.33)

* Warrants and stock options to purchase 38,070,498 and 41,262,099 shares of common stock as of September 30, 2010 and 2009, respectively, were excluded from the net loss per share calculation as their effect would have been anti-dilutive.

Note 8. Liquidity

Since its inception in 1980 through September 30, 2010 the Company has incurred losses of approximately $300.0 million, substantially all of which resulted from expenditures related to research and development, general and administrative charges and acquired in-process research and development resulting from two acquisitions. The Company has not generated any material revenue from product sales to date, and there can be no assurance that revenue from product sales will be achieved. Moreover, even if the Company does achieve revenue from product sales, the Company expects to incur operating losses over the next several years.

At September 30, 2010, cash, cash equivalents and short-term investments were $36.4 million, compared to $48.7 million at December 31, 2009. The Company's principal sources of liquidity have been revenue from its U.S. government research contracts and equity financings. The Company's principal uses of cash have been research and development expenses, general and administrative expenses and other working capital requirements.

In the periods presented, substantially all of the revenue generated by the Company was derived from research contracts with the U.S. government. As of September 30, 2010, the Company had contracts with the U.S. government pursuant to which its is entitled to receive up to an aggregate of $157.2 million for development of its product candidates, of which $62.2 million had been billed to the U.S. government and $95.0 million of which relates to development that has not yet been completed and has not been billed. See Note 4 — "U.S. Government Contracts" for additional information.

In January and August 2009, the Company sold shares of its common stock and also issued warrants to purchase shares of its common stock in offerings registered under the Securities Act of 1933 (the "Securities Act"). See Note 9 — "Equity Financing" for more information.

Note 9. Equity Financing

In January 2009, the Company sold approximately 14.2 million shares of its common stock and also issued warrants to purchase approximately 14.2 million shares of its common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $15.5 million. The warrants issued to the investors in the offering have an exercise price of $1.16 per share and are exercisable at any time on or before July 30, 2014. In connection with the offering, the Company also issued to the placement agent a warrant to purchase approximately 427,000 shares of the Company's common stock at an exercise price of $1.45 per share. The warrant issued to the placement agent is exercisable on or before January 30, 2014.

In August 2009, the Company sold approximately 24.3 million shares of its common stock and also issued warrants to purchase approximately 9.7 million shares of its common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $32.3 million. The warrants issued to the investors in the offering have an exercise price of $1.78 per share and are exercisable at any time on or before August 25, 2014. The warrants issued in connection with the January and August 2009 offerings are classified as a liability due to their settlement terms. Accordingly, the fair value of the warrants is recorded on the consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in the consolidated statement of operations as described in greater detail in Note 6 — "Warrants". These warrants are non-cash liabilities; the Company is not required to expend any cash to settle these liabilities.

Note 10. Income Taxes

The Company has not recognized any liability for unrecognized tax benefits. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties on its balance sheet at September 30, 2010 or December 31, 2009, and has not recognized interest and/or penalties in the statement of operations for the three and nine months ended September 30, 2010.

At December 31, 2009, the Company had net deferred tax assets of approximately $111 million. The 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, share-based compensation expense and intangibles. Due to uncertainties surrounding its ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset its net deferred tax asset. Additionally, the Internal Revenue Code rules could limit the future use of its net operating loss and research and development credit carryforwards to offset future taxable income based on ownership changes and the value of the Company's stock.

Note 11. Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board ("FASB"), issued guidance to amend the disclosure requirements related to recurring and nonrecurring fair value measurements. The guidance requires new disclosures on the transfers of assets and liabilities between Level 1 (quoted prices in active market for identical assets or liabilities) and Level 2 (significant other observable inputs) of the fair value measurement hierarchy, including the reasons and the timing of the transfers. The guidance became effective for the Company with the reporting period beginning January 1, 2010, except for the disclosure on the roll forward activities for Level 3 fair value measurements, which will become effective for the Company with the reporting period beginning July 1, 2011. Other than requiring additional disclosures, adoption of this new guidance did not have a material impact on the Company's financial statements.

In April 2010, the FASB issued guidance on applying the milestone method of revenue recognition for milestone payments for achieving specific performance measures when those payments are related to uncertain future events. The scope of this guidance is limited to transactions involving research or development. Under the guidance, the milestone method is a valid application of the proportional performance model for revenue recognition if the milestones are substantive and there is substantive uncertainty about whether the milestone will be achieved. The guidance is effective on a prospective basis to milestones achieved in fiscal years, and interim periods within those years, beginning after June 15, 2010, with early adoption permitted. The Company, based on its current revenue contracts, does not believe that this guidance will have a material impact on the Company's financial statements.

Note 12. Subsequent Events

In October 2010, the Company received notification from the Treasury Department that they had been awarded grants totaling approximately $1.2 million under the U.S. Government's Qualifying Therapeutic Discovery Project (QTDP) program. AVI was awarded grants for each of the five project applications submitted for the company's Duchenne muscular dystrophy program and four infectious disease programs.

The QTDP was part of the March 2010 Patient Protection and Affordable Care Act and provides a tax credit or grant equal to 50 percent of eligible costs and expenses for tax years 2009 and 2010. Under the program, a total of $1 billion in grant or tax credits was made available to companies with 250 or fewer employees. The grant received by AVI for each application was approximately $244,000.

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 report and the section contained in our annual report on Form 10-K for the year ended December 31, 2009 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. Forward-looking statements are identified by such words as "believe," "expect," "anticipate" and words of similar import and are based on current expectations that involve risks and uncertainties, such as our plans, objectives, expectations and intentions. 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, expectations regarding future expenses, funding from government and other sources, the results of research and development efforts, the adequacy of funds to support or future operations, 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. 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 report in Part II, Item 1A — "Risk Factors," and elsewhere in this report. These statements, like all statements in this 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 novel RNA-based therapeutics for rare and infectious diseases, as well as other select disease targets. Applying pioneering technologies developed and optimized by AVI, we are able to target a broad range of diseases and disorders through distinct RNA-based mechanisms of action. Unlike other RNA-based approaches, our technologies can be used to directly target both messenger RNA (mRNA) and precursor messenger RNA (pre-mRNA) to either down-regulate (inhibit) or up-regulate (promote) the expression of targeted genes or proteins. We believe that these broad capabilities represent highly competitive RNA-based technology platforms and a strong intellectual property position, both of which are the result of advances across several areas of science, including over 20 years of research and development work in chemistry and biology. Our patent estate includes 205 patents (foreign and domestic) issued to or licensed by us and 186 patent applications (domestic and foreign).

We are leveraging our discovery and development capabilities to build a pipeline of RNA-based therapeutic drug candidates to develop independently and in collaboration with larger pharmaceutical and biotechnology partners. Current applications of our RNA technology platform include genetic diseases (Duchenne Muscular Dystrophy, or DMD), infectious diseases (including Ebola, Marburg and H1N1 Influenza viruses), and other early discovery targets. Several of our antiviral programs, including Ebola, Marburg, Junín and H1N1, have been or are currently funded by the U.S. government as described in greater detail below. Some of our other programs have received funding from non-government sources.

On June 4, 2010, we were awarded a new contract with the U.S. Defense Threat Reduction Agency, or DTRA, an agency of the U.S. Department of Defense, or DoD, to advance the development of AVI-7100 as a medical countermeasure against the pandemic H1N1 influenza virus (swine flu) in cooperation with the Transformational Medical Technologies program, or TMT, of the DoD. The contract provides for funding of up to $18 million to advance the development of AVI-7100, including studies enabling an Investigational New Drug, or IND, application with the U.S. Food and Drug Administration, or FDA, the development of an intranasal delivery formulation and the funding of a Phase 1 clinical program to obtain human safety data to support potential use under an Emergency Use Authorization.

On July 14, 2010, we were awarded a new contract with the 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 therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately $291 million. Activity under the first segment began in July 2010 and provides us funding of up to approximately $80 million. After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to us of up to approximately $291 million. Under an earlier contract, we completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003.

In October 2010, we were awarded five cash grants totaling approximately $1.2 million under the U.S. Government's Qualifying Therapeutic Discovery Project, or QTDP, program. We were awarded grants for each of the five project applications submitted for our DMD program and four infectious disease programs. The QTDP was part of the March 2010 Patient Protection and Affordable Care Act and provides a tax credit or grant equal to 50 percent of eligible costs and expenses for tax years 2009 and 2010. Under the program, a total of $1 billion in grant or tax credits was made available to companies with 250 or fewer employees. The grant we received for each application was approximately $244,000.

On April 20, 2010, our chief executive officer and president, Leslie Hudson, Ph.D., tendered his resignation at the request of our Board of Directors. Pursuant to his separation agreement, Dr. Hudson will receive total cash severance payments of $1,412,170 (comprised of two times the sum of (i) his annual base salary in effect as of the Separation Date ($494,400), (ii) the average of his last two annual bonuses ($188,669), and (iii) the annual cost of Pfizer retiree healthcare coverage for him and his spouse ($23,016). The cash severance payments are paid to Dr. Hudson in 24 equal monthly installments, less required deductions and withholdings following the effective date of the separation agreement. In addition, as of the effective date of the separation agreement, unvested options to purchase 1,166,833 shares of our common stock and 116,500 shares of restricted stock previously granted to Dr. Hudson became fully vested and exercisable, which resulted in a charge to stock compensation expense of $1,181,292 in the second quarter of 2010.

As previously disclosed, on April 20, 2010, we entered into a settlement agreement with a shareholder group that had sought a special meeting of our shareholders to replace certain members of our Board of Directors. Pursuant to such settlement agreement, among other things, (i) our Board of Directors sought Dr. Hudson's resignation and appointed J. David Boyle II, our Chief Financial Officer, as interim Chief Executive Officer and President, (ii) our bylaws were amended to reduce the size of our Board of Directors,

(iii) Dr. Hudson and K. Michael Forrest resigned as directors to facilitate the reduction in the size of the Board of Directors, and (iv) Anthony R. Chase was appointed to fill the vacancy created by Dr. Hudson's resignation. In addition, for a period of one year, the shareholder group agreed not to engage in the solicitation of any proxy relating to the voting of our common stock and not to take certain actions relating to our Board of Directors or the management of our company.

At our 2010 annual meeting of shareholders, Chris Garabedian and Hans Wigzell were elected to our Board of Directors, replacing Christopher Henney and Michael D. Casey who did not stand for reelection.

From our inception in 1980, we have devoted our resources primarily to fund our research and development efforts. As the result of new Influenza, Ebola and Marburg U.S. government research contracts, we expect future revenues and research and development cost to increase. We have been unprofitable since inception and, other than limited interest, license fees, grants and research contracts, we have had no material revenue from the sale of products or other sources, other than from government grants and research contracts, and we do not expect material revenue for the foreseeable future. We expect to continue to incur losses for the foreseeable future as we continue our research and development efforts and seek to enter additional collaborative efforts. As of September 30, 2010, our accumulated deficit was $300.0 million.

Government Contracts

In the periods presented, substantially all of the revenue generated by our company was derived from research contracts with the U.S. government. As of September 30, 2010, we had contracts with the U.S. government pursuant to which we are entitled to receive up to an aggregate of $157.2 million for development of its product candidates, of which $62.2 million had been billed to the U.S. government and $95.0 million of which relates to development that has not yet been completed and has not been billed. The following is a description of such contracts.

January 2006 Agreement (Ebola and Marburg Host Factors, Dengue, Anthrax and Ricin)

In January 2006, the final version of the 2006 defense appropriations act was enacted, which act included an allocation of $11.0 million to fund our ongoing defense-related programs under certain executed contracts. Net of government administrative costs, it is anticipated that we will receive up to $9.8 million under this allocation. Our technology is expected to be used to continue developing RNA based drugs against Ebola and Marburg viruses. We have received signed contracts for all of these projects. As of September 30, 2010, we have recognized revenue of $9.8 million with respect to these contracts and expect to receive the remaining funding under these contracts in 2010.

December 2006 Agreement (Ebola, Marburg and Junín Viruses)

In December 2006, we entered into a two-year research contract with the DTRA pursuant to which we were entitled to $28 million to fund development of our antisense therapeutic candidates Ebola, Marburg and Junín hemorrhagic viruses. In May 2009, this contract was amended to extend the term of the contract until November 2009 and to increase funding by $5.9 million to an aggregate of $33.9 million. In June 2009, the contract was amended again to extend the term of the contract to February 2011 and to increase funding by an additional $11.5 million to an aggregate of $45.4 million. In November 2010, we and DTRA agreed that the key activities under this contract had been completed and that further activities under this contract would cease and this contract would be deemed concluded. As of September 30, 2010, we had recognized revenue of $38.2 million with respect to this contract and does not expect significant further revenue.

May 2009 Agreement (H1N1/Influenza)

In May 2009, we entered into a contract with the DTRA to develop swine flu drugs. Under this contract, DTRA will pay up to $4.1 million to our company for the work involving the application of our proprietary PMO and PMO*plus*™ antisense chemistry and we plan to conduct preclinical development of at least one drug candidate and demonstrate it is effective by testing it on animals. In March 2010, the contract was amended to include testing against additional influenza strains including H5N1 (avian flu), Tamiflu® resistant H1N1 (swine flu) and H3N2 (seasonal flu) and funding increased by $4.0 million to an aggregate of $8.1 million. As of September 30, 2010, we have recognized revenue of $4.5 million with respect to this contract and expect to receive the remaining funding under this contract in 2010.

June 2010 Agreement (H1N1/Influenza)

On June 4, 2010, we entered into a contract with the DTRA to advance the development of AVI-7100, which was previously designated AVI-7367 and which has been renumbered by us, as a medical countermeasure against the pandemic H1N1 influenza virus in cooperation with the TMT. The contract provides for funding of up to $18 million to advance the development of AVI-7100, including studies enabling an IND application with the FDA, the study of an intranasal delivery formulation, and the funding of a Phase 1 clinical trial to obtain human safety data to support potential use under an Emergency Use Authorization. As of September 30, 2010, we have recognized revenue of $4.6 million with respect to this contract and expect to receive the remaining funding under this contract in 2010 and 2011.

July 2010 Agreement (Ebola and Marburg)

On July 14, 2010, we were awarded a new contract with the DoD Chemical and Biological Defense Program through the U.S. Army Space and Missile Defense Command for the advanced development of the our hemorrhagic fever virus therapeutic candidates, AVI-6002 and AVI-6003, for Ebola and Marburg viruses, respectively. The contract is funded as part of the TMT program, which was established to develop innovative platform-based solutions countering biological threats. The contract is structured into four segments with potential funding of up to approximately $291 million. Activity under the first segment began in July 2010and provides for funding to us of up to approximately $80 million. Activities under the first segment include Phase 1 studies in healthy volunteers as well as preclinical studies, and are scheduled over an 18-month period.

After completion of the first segment, and each successive segment, TMT has the option to proceed to the next segment for either or both AVI-6002 and AVI-6003. If TMT exercises its options for all four segments, contract activities would include all clinical and licensure activities necessary to obtain FDA regulatory approval of each therapeutic candidate and would provide for a total funding award to the us of up to approximately $291 million over a period of approximately six years. Under an earlier contract, we completed development activities that culminated in the opening of IND applications for both AVI-6002 and AVI-6003. As of September 30, 2010, we have recognized revenue of $2.7 million with respect to the July 2010 Agreement.

The following table sets forth the impact on revenue of each of the contracts with the U.S. government on our results of operations for the three and nine months ended September 30, 2010 and 2009.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2010	2009	2010	2009
	(in thousands)		(in thousands)	
January 2006 Agreements *(Ebola and Marburg host factor, Dengue, Anthrax and Ricin)*	$ 88	$ 285	$ 556	$ 1,908
December 2006 Agreement *(Ebola, Marburg and Junin Viruses)*	345	4,418	2,953	7,483
May 2009 Agreement *(H1N1)*	1,358	780	2,802	1,136
June 2010 Agreement *(H1N1)*	4,201	—	4,634	—
July 2010 Agreement *(Ebola and Marburg)*	2,716	—	2,716	—
Other Agreements	(6)	870	242	1,921
Total	$ 8,702	$ 6,353	$ 13,903	$ 12,448

Key Financial Metrics

Revenue

Government Research Contract Revenue. In the periods presented, we have generated substantially all of our revenue from U.S. government research 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.

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

We defer recognition of non-refundable upfront fees if we have 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 our company performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement. As of September 30, 2010, we had deferred revenue of $3.3 million, which represents up-front fees received from third parties pursuant to certain contractual arrangements and will be recognized as performance obligations are satisfied.

As the result of recent new government research contracts for H1N1/Influenza, Ebola and Marburg, we expect future revenues to increase in the near term.

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. As the result of recent new government research contracts for H1N1/Influenza, Ebola and Marburg, we expect future research and development cost to increase.

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, and 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, 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 and other income or expense, net, consists of interest on our cash, cash equivalents and short-term investments and rental income and other income. Our cash equivalents consist of money market investments and our short term investments consist of certificates of deposit which are included in other current assets. Interest expense includes interest paid on our mortgage loan related to the Corvallis property held for sale. Other income includes rental income on sublease 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. These warrants are non-cash liabilities; we are not required to expend any cash to settle these liabilities. 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 for the inputs used in the model. For more information, see Note 6—"Warrants" of the unaudited condensed consolidated 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 condensed consolidated 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, revenue 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 consolidated financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

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

- revenue recognition;
- impairment of long-lived assets;
- 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 16, 2010 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2010 and filed with the SEC on August 9, 2010.

Warrant Liability

In December 2007 and January and August of 2009, we issued warrants to purchase an aggregate of 29.7 million shares of our common stock in connection with a registered direct offering of our common stock and warrants. These warrants are classified as a liability due to their settlement terms. These warrants are non-cash liabilities; we are not required to expend any cash to settle these liabilities.

The fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting period with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option pricing model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. If, for example, the market value of our common stock or its volatility at December 31, 2009 were 10% higher or lower than used in the valuation of such warrants, our valuation of the warrants would have increased by up to $4.4 million or decreased up to $4.3 million, respectively, with such difference reflected in our statement of operations.

Results of Operations for the Three and Nine Months Ended September 30, 2010 and 2009

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

	Three Months Ended September 30,		%	Nine Months Ended September 30,		%
	2010	2009	Change	2010	2009	Change
	(In thousands, except per share amounts)			(In thousands, except per share amounts)		
Revenue:	$ 8,702	$ 6,353	37%	$ 13,903	$ 12,448	12%
Expenses:						
Research and development	9,059	7,473	21%	22,080	17,770	24%
General and administrative	3,440	1,800	91%	11,017	6,226	77%
Operating loss	(3,797)	(2,920)		(19,194)	(11,548)	
Other income (loss):						
Interest(expense) income and other, net	82	(132)	+	170	(147)	+
(Increase) decrease on warrant valuation	(3,578)	(5,038)	+	(5,509)	(16,989)	+
Net loss	$ (7,293)	$ (8,090)		$ (24,533)	$ (28,684)	
Basic and diluted loss per share	$ (0.07)	$ (0.08)		$ (0.22)	$ (0.33)	

\+ Not meaningful

Revenue

Revenue for the three months ended September 30, 2010 increased by $2.3 million, or 37%, compared to the three months ended September 30, 2009 due to a $3.3 million increase in revenue from U.S. government research contracts offset, in part, from lower revenue associated with the Children's National Medical Center contract related to DMD.

Revenue for the nine months ended September 30, 2010 increased by $1.4 million, or 12%, compared to the nine months ended September 30, 2009 due to a $3.2 million increase in government research contracts as detailed in the table above, partially offset by a $1.7 million decrease in revenue from the Children's National Medical Center.

Research and Development Expenses

Research and development expenses for the three months ended September 30, 2010 increased by $1.6 million, or 21%, compared to the three months ended September 30, 2009 due primarily to $1.1 million for upfront payments to a contract research organization primarily related to our H1N1 program and $0.5 million in increased salaries and employee costs from new staff additions.

Research and development expenses for the nine months ended September 30, 2010 increased by $4.3 million, or 24%, compared to the nine months ended September 30, 2009 due primarily to $1.4 million in costs for active investigational therapeutic components, $1.1 million for contract research organizations costs for the H1N1 program, $1.1 million for toxicology studies for the Junin and H1N1 programs and $0.9 million in increased salaries and employee costs from the addition of new staff.

General and Administrative Expenses

General and administrative expenses for the three months ended September 30, 2010 increased by $1.6 million, or 91%, compared to the three months ended September 30, 2009. The significant increase in the three months ended September 30, 2010 is primarily due to $0.5 million in salaries related to increased staff and $0.5 million increase in professional consulting and legal costs. In addition, there was a $0.4 million reduction in the fair value of property held for sale in Corvallis, Oregon, investor relations costs increased by $0.2 million and technology costs increased $0.1 million.

General and administrative expenses for the nine months ended September, 2010 increased by $4.8 million, or 77%, compared to the nine months ended September 30, 2009 primarily due to $2.6 million in severance costs and stock compensation related to the departure, in April 2010, of our former chief executive officer. Other increases include legal costs of $0.6, salary costs related to additional staff of $0.5 million, rent expense of $0.4 million for the addition of our new Bothell, Washington facility, $0.4 million impairment charge for property held for sale in Corvallis, Oregon, $0.2 million of investor relations costs and $0.1 million for technology costs.

Interest Income (Expense) and Other, Net

The increase in interest income (expense) and other, net for the three and nine months ended September 30, 2010 compared to the three and nine months ended September 30, 2009 was attributable to increased rental income from the sublease of excess space in our Corvallis, Oregon facility.

Change in Fair Value of Warrant Liability

The significant changes in fair value of warrant liability for the three and nine months ended September 30, 2010 compared to the three month and nine month periods ended September 30, 2009 was attributable to changes in our stock price. See "—Key Financial Metrics—Change in Fair Value of Warrants," "—Critical Accounting Policies—Warrant Liability," and Note 6 to the financial statements included elsewhere in this report.

Net loss

The decrease in net loss of $0.8 million for the three months ended September 30, 2010 compared to the prior year period was attributable primarily to the change in warrant liability. The decrease in net loss of $4.2 million for the nine months ended September 30, 2010 compared to the prior year period was primarily attributable to a decrease in warrant liability partially offset by an increase in operating expenses.

Liquidity and Capital Resources

At September 30, 2010, cash, cash equivalents and short-term investments were $36.4 million, compared to $48.7 million at December 31, 2009. Our principal sources of liquidity are revenue from our U.S. government research contracts and equity financings. 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, cash equivalents and short-term investments, exclusive of receipt of future proceeds pursuant to our contracts with the U.S. government, 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 could 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.

In January 2009, we sold approximately 14.2 million shares of our common stock and also issued warrants to purchase approximately 14.2 million shares of our common stock in an offering registered under the Securities Act of 1933, or the Securities Act. The offering generated net proceeds of approximately $15.5 million. The warrants issued to the investors in the offering have an exercise price of $1.16 per share and are exercisable at any time on or before July 30, 2014. In connection with the offering, we also issued to the placement agent a warrant to purchase approximately 427,000 shares of our common stock at an exercise price of $1.45 per share. The warrant issued to the placement agent is exercisable on or before January 30, 2014.

In August 2009, we sold approximately 24.3 million shares of our common stock and also issued warrants to purchase approximately 9.7 million shares of our common stock in an offering registered under the Securities Act. The offering generated net proceeds of approximately $32.3 million. The warrants issued to the investors in the offering have an exercise price of $1.78 per share and are exercisable at any time on or before August 25, 2014.

We will require additional capital from time to time in the future in order to 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 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 material commercial revenue from the sale of our non-governmental 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 $300.0 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

	Nine Months Ended September 30,	
	2010	2009
	(in thousands)	
Cash provided by (used in):		
Operating activities	$ (13,321)	$ (7,743)
Investing activities	(1,454)	(914)
Financing activities	2,467	47,733
Increase (decrease) in cash and equivalents	$ (12,308)	$ 39,076

Operating Activities. We used $13.3 million of cash in operating activities for the nine months ended September 30, 2010, an increase of $5.6 million compared to $7.7 million of cash used in operating activities for the nine months ended September 30, 2009. The increase net cash used in operating activities during the comparative periods was primarily attributable to increased research and development costs, higher general and administrative expenses and the increase in accounts receivable.

Investing Activities. We used $1.5 million of cash in investing activities for the nine months ended September 30, 2010, an increase of $0.6 million compared to $0.9 million of cash used in investing activities for the nine months ended September 30, 2009. The increase of cash used for investing activities was attributable to increased spending on patents and fixed assets, and no liquidation of certificate of deposit in 2010 as occurred in 2009.

Financing Activities. We had financing activities of $2.5 million that consisted of stock option and warrant exercises and debt repayment for the nine months ended September 30, 2010. The $47.7 million of cash generated by financing activities for the nine months ended September 30, 2009 was attributable to our January and August 2009 equity financings.

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 contractual obligations arising from these arrangements as of September 30, 2010:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating leases — premises	$ 17,304	$ 1,881	$ 3,922	$ 3,545	$ 7,956
Royalty payments	634	80	160	160	234

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 11 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, cash equivalents, and short-term investments of $36.4 million and $48.7 million at September 30, 2010 and December 31, 2009, respectively. We do not enter into investments for trading or speculative purposes; our cash equivalents are invested in money market accounts and our short-term investments consisted of short-term certificates of deposit. 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, cash equivalents, and short-term investments. 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.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation as of the end of period covered by this report, under the supervision and with the participation of our management, including our interim chief executive officer and our chief 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 interim chief executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding required disclosure. Based on that evaluation, management has concluded that as of September 30, 2010, 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 September 30, 2010 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, AVI-4658 is in clinical trials, we have open INDs for AVI-6002 in Ebola and AVI-6003 in Marburg, and the rest of our product candidates are in preclinical development. We expect that much of our effort and many of our expenditures over the next few years will be devoted to development activities associated with AVI-4658 in Duchenne Muscular Dystrophy, or DMD, AVI-6002 in Ebola, AVI-6003 in Marburg and AVI-7100 in influenza. 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 AVI-4658, depends on first receiving required regulatory approvals, and it is possible that we may never receive regulatory approval for any of our product candidates. However, in July 2010 we received notification from the U.S. Food and Drug Administration, or FDA, that our Investigational New Drug, or IND, application, required to start clinical testing in the United States, had been allowed. Even if a product candidate receives regulatory approval, the resulting product may not gain market acceptance among physicians, patients, healthcare payers 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;
- cost-effectiveness of the product;
- the product's potential advantage over alternative treatment methods;
- whether the product can be produced in commercial quantities at acceptable costs; and
- marketing and distribution support for the product.

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 not able 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, which regulations differ 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. We have no experience in preparing and 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 not be sufficient to support approval by the FDA or any other foreign regulatory authority. In addition, the FDA or their advisors may disagree with our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may approve a product candidate for fewer conditions than requested or may grant approval subject to the performance of post-approval studies for a product candidate. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards, or IRBs, for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Due to these and other factors, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than we expect or may never gain regulatory approval, which could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

If we receive regulatory approval for our product candidates, we will also be subject to ongoing FDA obligations and oversight, including adverse event reporting requirements, marketing restrictions and potential other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. The FDA's policies may also change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States, or abroad. If we are not able to maintain regulatory compliance, we may be subject to civil and criminal penalties, we may not be permitted to market our products and our business could suffer. Any delay in, or failure to, receive or maintain regulatory approval for any of our product candidates could harm our business and prevent us from ever generating meaningful revenues or achieving profitability. We will need to obtain regulatory approval from authorities in foreign countries to market our product candidates in those countries. We have not filed for regulatory approval to market our product candidates in any foreign jurisdiction. Approval by one regulatory authority does not ensure approval by regulatory authorities in other jurisdictions. If we fail to obtain approvals from foreign jurisdictions, the geographic market for our product candidates would be limited.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of our product candidates, which could prevent or significantly delay their regulatory approval.

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate, through extensive preclinical and clinical studies; that the product candidate is safe and effective in humans. Ongoing and future clinical trials

of our product candidates may not show sufficient safety or efficacy to obtain regulatory approvals. We expect to develop the therapeutic product candidates to treat Ebola and Marburg viruses under defined regulatory pathways using the Animal Rule mechanism. This mechanism has become available only relatively recently and has been infrequently used. This process has yet to be well tested and is currently under evaluation by the FDA. This may present challenges for gaining final regulatory approval for these product candidates.

Phase 1 clinical trials generally are not designed to test the efficacy of a product candidate but rather are designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the product candidate's side effects at various doses and dosing schedules in healthy volunteers. Delays in establishing the appropriate dosage levels can lead to delays in the overall clinical development of a product candidate. As of the date of this report, we do not believe that we have identified a consistently effective dose in DMD patients for AVI-4658. We are expeditiously moving to start a U.S.-based clinical trial for AVI-4658 at higher doses to further explore and identify a more consistently effective dose that may be more appropriate for future clinical trials and that can serve as a basis for approval by governmental regulatory authorities; however, we can not assure you that these efforts will be successful. If a consistently effective dose is found in the U.S. based clinical trial we will expect to engage in discussions with regulatory authorities about the design and subsequent execution of any further studies required. This might include an open label "extension study" for all patients who have previously received AVI-4658, as well as other patients (e.g., non-ambulant patients) and any additional placebo-controlled "pivotal" study or studies.

Furthermore, success in preclinical and early clinical trials does not ensure that later large-scale trials will be successful nor does it predict final results. Acceptable results in early trials may not be reproduced in later trials. For example, pivotal trials for AVI-4658 and AVI-7100 will likely involve a larger number of patients to achieve statistical significance, will be expensive and will take a substantial amount of time to complete. As a result, we may conduct lengthy and expensive clinical trials of our product candidates, only to learn that the product candidate is not an effective treatment or is not superior to existing approved therapies, or has an unacceptable safety profile, which could prevent or significantly delay regulatory approval for such product candidate.

We rely on U.S. government contracts to support several important research and development programs and substantially all of our revenue. If the U.S. government fails to fund such programs on a timely basis or at all, or such contracts are terminated, the results of our operations would be materially and adversely affected.

We rely on U.S. government contracts and awards to fund several of our development programs, including those for the Ebola, Marburg, Junín and H1N1 viruses and for all of our current revenue.

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

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

The termination of one or more of these contracts, whether due to lack of funding, for convenience, or otherwise, or the occurrence of delays or product failures in connection with one or more of these contracts, could negatively impact our financial condition. Furthermore, we can give no assurance that we would be able to procure new U.S. government contracts to offset the revenue lost as a result of termination of any of our contracts.

Our U.S. government contracts may be terminated and we may be liable for penalties under a variety of procurement rules and regulations and changes in government regulations or practices could adversely affect our profitability, cash balances or growth prospects.

We must comply with laws and regulations relating to the formation, administration and performance of U.S. government contracts, which affect how we do business with our customers. Such laws and regulations may potentially impose added costs on our business and our failure to comply with them may lead to penalties and the termination of our U.S. government contracts. Some significant regulations that affect us include:

- the Federal Acquisition Regulation and supplements, which regulate the formation, administration and performance of U.S. Government contracts;
- the Truth in Negotiations Act, which requires certification and disclosure of cost and pricing data in connection with contract negotiations; and
- the Cost Accounting Standards, which impose accounting requirements that govern our right to reimbursement under certain cost-based government contracts.

Our contracts with the U.S. government are subject to periodic review and investigation. If such a review or investigation identifies improper or illegal activities, we may be subject to civil or criminal penalties or administrative sanctions, including the termination of contracts, forfeiture of profits, the triggering of price reduction clauses, suspension of payments, fines and suspension or debarment from doing business with U.S. government agencies. We could also suffer harm to our reputation if allegations of impropriety were made against us, which would impair our ability to win awards of contracts in the future or receive renewals of existing contracts.

In addition, U.S. government agencies routinely audit and review their contractors' performance on contracts, cost structure, pricing practices and compliance with applicable laws, regulations and standards. They also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Such audits may result in adjustments to our contract costs, and any costs found to be improperly allocated will not be reimbursed. We have recorded contract revenues for the periods presented in this report based upon costs we expect to realize upon final audit; however, we do not know the outcome of any future audits and adjustments and, if future audit adjustments exceed our estimates, our results of operations could be adversely affected. Additionally, we may be required to enter into agreements and subcontracts with third parties, including suppliers, consultants and other third party contractors in order to satisfy our contractual obligations pursuant to our agreements with the U.S. government. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement. Any such agreement also has to be compliant with the terms of our government grants. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our grants, may result in violations of our contracts with the U.S. government.

Clinical trials for our product candidates are expensive and time consuming, may take longer than we expect or may not be completed at all, and their outcome is uncertain.

We recently completed a Phase1b/2 clinical trial for AVI-4658 in the UK and are currently completing the analysis and reporting of data from this study. We expect to commence additional trials of AVI-4658 and other product candidates in the future. Each of our clinical trials requires the investment of substantial expense and time and the timing of the commencement, continuation and completion of these clinical trials may be subject to significant delays relating to various causes, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay or failure to obtain IRB approval to conduct a clinical trial at a prospective site, unexpected adverse events and shortages of available drug supply. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the existence of competing clinical trials and the availability of alternative or new treatments. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with Good Clinical Practice, or GCP, and to the extent they fail to enroll patients for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of our trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, we conduct clinical trials in foreign countries which may subject us to further delays and expenses as a result of increased drug shipment costs, additional regulatory requirements and the engagement of foreign CROs, as well as expose us to risks associated with less experienced clinical investigators who are unknown to the FDA, and different standards of medical care. Foreign currency transactions insofar as changes in the relative value of the U.S. dollar to the foreign currency where the trial is being conducted may impact our actual costs. In addition, for some programs (e.g., DMD and, Ebola and Marburg infections) there are currently no approved drugs to compare against and an agreement about how to measure efficacy has yet to be reached with the FDA and then demonstrated.

Clinical trials must be conducted in accordance with FDA or other applicable foreign government guidelines and are subject to oversight by the FDA, other foreign governmental agencies and IRBs at the medical institutions where the clinical trials are

conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under GMP and other requirements in foreign countries, and may require large numbers of test patients. We, the FDA or other foreign governmental agencies could delay, suspend or halt our clinical trials of a product candidate for numerous reasons, including:

- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold;
- the product candidate may have unforeseen adverse side effects, including fatalities, or a determination may be made that a clinical trial presents unacceptable health risks;
- the time required to determine whether the product candidate is effective may be longer than expected;
- fatalities or other adverse events arising during a clinical trial that may not be related to clinical trial treatments;
- the product candidate may appear to be no more effective than current therapies;
- the quality or stability of the product candidate may fall below acceptable standards;
- our inability to produce or obtain sufficient quantities of the product candidate to complete the trials;
- our inability to reach agreement on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our inability to obtain IRB approval to conduct a clinical trial at a prospective site;
- lack of adequate funding to continue the clinical trial, including the occurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties;
- our inability to recruit and enroll patients to participate in clinical trials for reasons including competition from other clinical trial programs for the same or similar indications; or
- our inability to retain patients who have initiated a clinical trial but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up.

In addition, we may experience significant setbacks in advanced clinical trials, even after promising results in earlier trials, such as unexpected adverse events that occur when our product candidates are combined with other therapies, which often occur in later-stage clinical trials. In addition, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Also, patient advocacy groups may demand additional clinical trials even if our interpretation of clinical results received thus far leads us to determine that additional clinical trials are unwarranted. Any disagreement with patient advocacy groups may require management's time and attention and may result in legal proceedings being instituted against us, which could be expensive, time-consuming and distracting. Negative or inconclusive results or adverse medical events, including patient fatalities that may be attributable to our product candidates, during a clinical trial may necessitate it to be redesigned, repeated or terminated. Further, some of our clinical trials may be overseen by an independent data safety monitoring board, (DSMB), and the DSMB may determine to delay or suspend one or more of these trials due to safety or futility findings based on events occurring during a clinical trial.

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

We incurred a net loss of $24.5 million for the nine months ended September 30, 2010 and $25.2 million for the year ended December 31, 2009. As of September 30, 2010, our accumulated deficit was $300.0 million. Our losses have resulted principally from expenses incurred in research and development of our technology and products and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval of our products. Our ability to achieve profitability depends on our ability to raise additional capital, partner one or more programs, complete development of our products, obtain regulatory approvals and market our products. It is uncertain when, if ever, we will become profitable.

We will need additional funds to conduct our planned research and development efforts. If we fail to continue to attract significant capital or fail to enter into strategic relationships, we may be unable to continue to develop our product candidates.

We expect that we will require additional capital from time to time in the future in order to continue the development of product candidates in our pipeline and to expand our product portfolio. The actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include the success of our research and development efforts, the status of our pre-clinical and clinical testing, costs relating to securing regulatory approvals and the costs and timing of obtaining new patent rights, regulatory changes, competitive and technological developments in the market. An unforeseen change in these factors, or others, might increase our need for additional capital. We may need funds sooner than currently anticipated.

We would expect to seek additional financing from the sale and issuance of equity or debt securities or the entry into strategic relationships, and we cannot predict that financing will be available when and as we need financing or that, if available, the financing terms will be commercially reasonable. If we are unable to obtain additional financing when and if we require, or on commercially reasonable terms, 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.

Further, we plan to enter into relationships with pharmaceutical or biotechnology companies to conduct clinical trials and to market our products. We currently do not have a strategic relationship with a third party to assist us in funding the continued development and commercialization of AVI-4658. If we are unable to enter into partnerships or strategic relationships with respect to AVI-4658 or our other product candidates on favorable terms it may impede our ability to develop and commercialize our product candidates.

We currently rely on third-party manufacturers and other third parties for production of our drug products and our dependence on these manufacturers may impair the development of our product candidates.

We do not currently have the internal ability to manufacture the drug products that we need to conduct our clinical trials and we rely upon a limited number of manufacturers to supply our drug products. In addition, we rely on other third parties to perform additional steps in the manufacturing process, including filling and labeling of vials and storage of our product candidates. For the foreseeable future, we expect to continue to rely on contract manufacturers and other third parties to produce, fill vials and store sufficient quantities of our product candidates for use in our clinical trials. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or to develop our own manufacturing capabilities, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our product candidates. In addition, we depend on outside vendors for the supply of raw materials used to produce our product candidates. If the third-party suppliers were to cease production or otherwise fail to supply us with quality raw materials and we are unable to contract on acceptable terms for these raw materials with alternative suppliers, our ability to have our product candidates manufactured and to conduct preclinical testing and clinical trials of our product candidates would be adversely affected.

We do not yet have all of the agreements necessary for the supply of our product candidates in quantities sufficient for commercial sale and we may not be able to establish or maintain sufficient commercial manufacturing arrangements on commercially reasonable terms. Securing commercial quantities of our product candidates from contract manufacturers will require us to commit significant capital and resources. We may also be required to enter into long-term manufacturing agreements that contain exclusivity provisions and/or substantial termination penalties. In addition, contract manufacturers have a limited number of facilities in which our product candidates can be produced and any interruption of the operation of those facilities due to events such as equipment malfunction or failure or damage to the facility by natural disasters could result in the cancellation of shipments, loss of product in the manufacturing process or a shortfall in available product candidates.

Our contract manufacturers are required to produce our clinical product candidates under current Good Manufacturing Practice, or cGMP, conditions in order to meet acceptable standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our product candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our product candidates. We and our contract manufacturers are subject to periodic unannounced inspection by the FDA and corresponding state and foreign authorities to ensure strict compliance with GMP and other applicable government regulations and corresponding foreign standards. We do not have control over a third-party manufacturer's compliance with these regulations and standards. Any difficulties or delays in our contractors' manufacturing and supply of product candidates or any failure of our contractors to maintain compliance with the applicable regulations and standards could increase our costs, cause us to lose revenue, make us postpone or cancel clinical trials, prevent or delay regulatory approval by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our product candidates, or cause our products to be recalled or withdrawn.

We rely on third parties to provide services in connection with our preclinical and clinical development programs. The inadequate performance by or loss of any of these service providers could affect our product candidate development.

Several third parties provide services in connection with our preclinical and clinical development programs, including *in vitro* and *in vivo* studies, assay and reagent development, immunohistochemistry, toxicology, pharmacokinetics, clinical assessments, data monitoring and management and statistical analysis and other outsourced activities. If these service providers do not adequately perform the services for which we have contracted or cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our product candidates, our development programs may be delayed.

Our RNA-based, or antisense, technology has not been incorporated into a commercial product and is still at a relatively early stage of development.

Our RNA-based platform, utilizing proprietary antisense technology, has not been incorporated into a commercial product and is still at a relatively early stage of development. This antisense technology is used in all of our therapeutic candidates, including AVI-4658. We are conducting toxicology, pharmacology, pharmacokinetics and other preclinical studies and, although we have initiated clinical trials for AVI-4658, additional preclinical studies may be required for AVI-4658 and before other product candidates enter human clinical trials. For example, we noted unexpected toxicology findings in the kidney as part of our series of preclinical studies for AVI-5038, our preclinical PPMO drug candidate for DMD that is based on a different chemistry, derived from the PMO chemistry used in AVI-4658. Based on those findings, we are conducting additional preclinical work to help clarify the therapeutic index of AVI-5038, which will guide decision making on continued development of this candidate. In addition, preclinical models to study patient toxicity and activity of compounds are not necessarily predictive of toxicity or efficacy of these compounds in the treatment of human disease and there may be substantially different results in clinical trials from the results obtained in preclinical studies. Any failures or setbacks utilizing our antisense technology, including adverse effects resulting from the use of this technology in humans, could have a detrimental impact on our internal product candidate pipeline and our ability to maintain and/or enter into new corporate collaborations regarding these technologies, which would negatively affect our business and financial position.

We intend to increase the size of our workforce and if we fail to manage our growth effectively, our growth prospects and operating results could be adversely affected.

Our ability to perform our U.S. government contracts, growth prospects and operating results depend on highly-skilled personnel to conduct product development and we intend to recruit, hire and retain significant numbers of additional personnel in the near term. Competition for qualified personnel in our industry, particularly those with experience with the infectious diseases we are target, is intense. In addition, we expect to meet some of our short-term personnel needs by engaging contractors who may be difficult to retain if they are offered permanent positions with other companies that guarantee a wider range of employee benefits not typically offered to contractors. If we are unable to attract, assimilate or retain such personnel or manage our growth effectively, our continued growth, expansion and ability to perform our U.S. government contracts would be adversely affected.

We rely on highly skilled personnel, and if we are unable to retain or motivate key personnel or hire qualified personnel, our operations may be adversely affected.

Our operations and our ability to execute our business strategy are highly dependent on the efforts of our executive management team. In April 2010, our chief executive officer and president resigned in connection with the settlement with a group of our shareholders. Following his departure, our board of directors appointed J. David Boyle II, our chief financial officer, to serve as interim chief executive officer and president, and we have hired an executive to assist Mr. Boyle with his responsibilities as chief financial officer. We are conducting a nationwide search for a new chief executive officer, but the departure of our chief executive officer and president and the circumstances surrounding his departure could have a disruptive effect on our ability to attract and retain qualified team members and execute our strategic plan. An extended period of time without a permanent chief executive officer could materially and adversely affect our business, financial condition or operating results. In the event we are unable to effect a smooth transition from our interim chief executive officer to a permanent chief executive officer, or if a new chief executive officer should unexpectedly prove to be unsuitable, the resulting disruption could negatively affect our operations and impede our ability to execute our strategic plan. In addition, although the members of our senior management team have employment agreements with us, these agreements may not provide sufficient incentives for these officers to continue employment with us. The loss of one or more of the members of our senior management team could adversely affect our operations.

Recent changes in our executive leadership and board of directors and any similar changes in the future my serve as a significant distraction for our management.

As previously disclosed on April 20, 2010, we entered into a settlement agreement with a shareholder group that had sought a special meeting of our shareholders to replace certain members of our board of directors. In connection with such settlement

agreement, among other things, we experienced the change in our executive leadership described above and our board of directors underwent significant change. Such changes may disrupt our operations as our company adjusts to the reallocation of responsibilities and assimilate new leadership and, potentially, differing perspectives on our strategic direction. The dispute with the shareholder group required the expenditure of significant time and resources by us and if we are involved in a similar dispute in the future, we may incur significant additional expenditures and it may be a significant distraction for our management and employees.

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

Our success will depend in significant part on our existing patents and licenses 205 patents (domestic and foreign) issued or licensed to us and 186 (domestic and foreign) pending patent applications) and our ability to obtain additional patents in the future. We license patents from other parties for certain complementary technologies.

We cannot be certain that pending patent applications will result in patents being issued in the United States or foreign countries. In addition, the patents that have been or will be issued may not afford meaningful protection for our technology and products. Competitors may develop products similar to ours that do not conflict with our patents. Pharmaceutical research and development is highly competitive; others may file patents first that cover our products or technology. We are aware of a European patent to which Prosensa has rights that may provide the basis for Prosensa or other parties that have rights to patent to assert that our drug AVI-4658 infringes on such patent. We are currently opposing this patent in the Opposition Division of the European Patent Office and believe that we may be able to invalidate some or all of the claims covered by this patent and non-U.S. foreign equivalents. Final resolution of this opposition proceeding may take a number of years. In any case, we have freedom to operate with respect to our ongoing clinical trials for this drug candidate.

Our success will also depend partly on our ability to operate without infringing upon the proprietary rights of others as well as our ability to prevent others from infringing on our proprietary rights. We may be required at times to take legal action to protect our proprietary rights and, despite our best efforts, we may be sued for infringing on the patent rights of others. We have not received any communications or other indications from owners of related patents or others that such persons believe our products or technology may infringe on their patents. Patent litigation is costly and, even if we prevail, the cost of such litigation could adversely affect our financial condition. If we do not prevail, in addition to any damages we might have to pay, we could be required to stop the infringing activity or obtain a license. If any patent related to our products or technology issues, and if our activities are determined to be covered by such a patent, we cannot assure you that we will be able to obtain or maintain a license, which could have a material adverse effect on our business, financial condition, operating results and ability to obtain and/or maintain our strategic business relationships.

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

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

Our research collaborators may publish data and information to which we have rights. If we cannot maintain the confidentiality of our technology and other confidential information in connection with our collaborations, then our ability to receive patent protection or protect our proprietary information may be impaired.

We face intense competition and rapid technological change, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. We are aware of many pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antisense technology or that are developing alternative approaches to or therapeutics for the disease indications on which we are focused. Some of these competitors are developing or testing product candidates that do now, or may in the future, compete

directly with our product candidates. For example, we believe that companies including Alnylam Pharmaceuticals, Isis Pharmaceuticals, and Santaris share a focus on RNA-based drug discovery and development. Competitors with respect to our exon skipping DMD program, or AVI-4658, include Prosensa and GlaxoSmithKline, or GSK, and other companies such as BioMarin Pharmaceuticals and Acceleron have also been working on DMD programs. A European based clinical trial evaluating the systemic administration of the Prosensa/GSK lead DMD drug candidate started several months before the start of our similar clinical trial, although the full biological results from this trial have yet to be made publically available. The Prosensa/GSK drug candidate may, or may not, prove to be safer or more efficacious than our product candidate and it could gain marketing approval before our product candidate. This might affect our ability to successfully complete a clinical development program or market for AVI-4658 once approved. This competition may also extend to other exon skipping drugs for DMD limiting our ability to gain market share. We also face significant competition with respect to our influenza program from many different companies, including large biopharmaceutical companies that have both marketed products like Tamiflu® and other products in various stages of development.

Other potential competitors include large, fully integrated pharmaceutical companies and more established biotechnology companies that have significant greater resources and expertise in research and development, manufacturing, testing, obtaining regulatory approvals and marketing. Also, academic institutions, government agencies and other public and private research organizations conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing. It is possible that these competitors will succeed in developing technologies that are more effective than our product candidates or that would render our technology obsolete or noncompetitive. Our competitors may, among other things:

- develop safer or more effective products;
- implement more effective approaches to sales and marketing;
- develop less costly products;
- obtain quicker regulatory approval;
- have access to more manufacturing capacity;
- develop products that are more convenient and easier to administer;
- form more advantageous strategic alliances; or
- establish superior proprietary positions.

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

We currently have no products that have been approved for commercial sale; however, the current and future use of our product candidates by us and our corporate collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made directly by consumers or healthcare providers or indirectly by pharmaceutical companies, our corporate collaborators or others selling such products. We may experience financial losses in the future due to product liability claims. We have obtained limited general commercial liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against all losses. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Our operations involve the use of hazardous materials, and we must comply with environmental laws, which can be expensive, and may affect our business and operating results.

Our research and development activities involve the use of hazardous materials, including organic and inorganic solvents and reagents. Accordingly, we are subject to federal, state, and local laws and regulations governing the use, storage, handling, manufacturing, exposure to, and disposal of these hazardous materials. In addition, we are subject to environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens, and the handling of biohazardous materials. Although we believe that our activities conform in all material respects with such environmental laws, there can be no assurance that violations of these laws will not occur in the future as a result of human error, accident, equipment failure, or other causes. Liability under environmental, health and safety laws can be joint and several and without regard to fault or negligence. The failure to comply with past, present, or future laws could result in the imposition of substantial fines and penalties,

remediation costs, property damage and personal injury claims, loss of permits or a cessation of operations, and any of these events could harm our business and financial conditions. We expect that our operations will be affected by other new environmental and health and workplace safety laws on an ongoing basis, and although we cannot predict the ultimate impact of any such new laws, they may impose greater compliance costs or result in increased risks or penalties, which could harm our business.

Risks Related to Our Common Stock

Provisions of our articles of incorporation, bylaws and Oregon corporate law might deter acquisition bids for us that might be considered favorable and prevent or frustrate any attempt to replace or remove the then current management and board of directors.

Certain provisions of our articles of incorporation and bylaws may make it more difficult for a third party to acquire control of us or effect a change in our board of directors and management. These provisions include:

- classification of our board of directors into two classes, with one class elected each year;
- prohibit cumulative voting of shares in the election of directors;
- prohibit shareholder actions by less than unanimous written consent;
- provide that the board of directors is expressly authorized to make, alter or repeal our bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by shareholders at shareholder meetings; and
- the ability of our board of directors to authorize the issuance of undesignated preferred stock, the terms and rights of which may be established and shares of which may be issued without shareholder approval, including rights superior to the rights of the holders of common stock.

In addition, the Oregon Control Share Act and Business Combination Act may limit parties that acquire a significant amount of voting shares from exercising control over us for specific periods of time. These provisions could discourage, delay or prevent a transaction involving a change of control, even if doing so would benefit our shareholders. These provisions also could discourage proxy contests and make it more difficult for shareholders to elect directors of their choosing or cause us to take other corporate actions, such as replacing or removing management or members of our board of directors.

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

The market prices for, and trading volumes of, securities of biotechnology companies, including our securities, have been historically volatile. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common stock may fluctuate significantly due to a variety of factors, including:

- positive or negative results of testing and clinical trials by ourselves, strategic partners, or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to our company;
- technological innovations or commercial product introductions by ourselves or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our products;
- financing or other corporate transactions;
- comments by securities analysts;

- the perception that shares of our common stock may be delisted from The NASDAQ Stock Market; or
- general market conditions in our industry or in the economy as a whole.

In addition, the stock market has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may seriously affect the market price of companies' stock, including ours, regardless of actual operating performance. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often been instigated against these companies. This litigation, if instigated against us, could result in substantial costs and a diversion of our management's attention and resources.

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

Our common stock is listed on The NASDAQ Global Market. The NASDAQ Global Market has several quantitative and qualitative requirements with which companies must comply in order to maintain this listing, including a $1.00 minimum bid price per share and $50 million minimum value of listed securities. In the past our stock price has traded near, and at times below, the $1.00 minimum bid price required for continued listing on NASDAQ. For example, the trading price for our common stock was $0.99 as recently as May 11, 2009. Although NASDAQ in the past has provided relief from the $1.00 minimum bid price requirement as a result of the recent weakness in the stock market, it may not do so in the future. If we fail to maintain compliance with NASDAQ's listing standards, and our common stock becomes ineligible for listing on The NASDAQ Stock Market the liquidity and price of our common stock would be adversely affected.

If our common stock was delisted, the price of our stock and the ability of our shareholders to trade in our stock would be adversely affected. In addition, we would be subject to a number of restrictions regarding the registration of our stock under U.S. federal securities laws, and we would not be able to allow our employees to exercise their outstanding options, which could adversely affect our business and results of operations. If we are delisted in the future from The NASDAQ Global Market, there may be other negative implications, including the potential loss of confidence by actual or potential collaboration partners, suppliers and employees and the loss of institutional investor interest in our company.

We expect that we will seek to raise additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing shareholders would experience further dilution.

We expect that we will seek to raise additional capital from time to time in the future. For example, in connection with our December 2007, January 2009 and August 2009 financings, we sold an aggregate of 29.7 million shares of our common stock and issued warrants to purchase an additional 29.7 million shares of our common stock. Future financings may involve the issuance of debt, equity and/or securities convertible into or exercisable or exchangeable for our equity securities. These financings may not be available to us on reasonable terms or at all when and as we require funding. If we are able to consummate such financings, the trading price of our common stock could be adversely affected and/or the terms of such financings may adversely affect the interests of our existing shareholders. Any failure to obtain additional working capital when required would have a material adverse effect on our business and financial condition and would be expected to result in a decline in our stock price. Any issuances of our common stock, preferred stock, or securities such as warrants or notes that are convertible into, exercisable or exchangeable for, our capital stock, would have a dilutive effect on the voting and economic interest of our existing shareholders.

We expect our quarterly operating results to fluctuate in future periods, which may cause our stock price to fluctuate or decline.

Our quarterly operating results have fluctuated in the past, and we believe they will continue to do so in the future. Some of these fluctuations may be more pronounced than they were in the past as a result of the issuance of warrants to purchase 29.7 million shares of our common stock by us in December 2007 and January and August 2009. Each of these warrants is classified as a derivative liability. Accordingly, the fair value of the warrants is recorded on our consolidated balance sheet as a liability, and such fair value is adjusted at each financial reporting date with the adjustment to fair value reflected in our consolidated statement of operations. The fair value of the warrants is determined using the Black-Scholes option valuation model. Fluctuations in the assumptions and factors used in the Black-Scholes model can result in adjustments to the fair value of the warrants reflected on our balance sheet and, therefore, our statement of operations. Due to the classification of such warrants and other factors, quarterly results of operations are difficult to forecast, and period-to-period comparisons of our operating results may not be predictive of future performance. In one or more future quarters, our results of operations may fall below the expectations of securities analysts and investors. In that event, the

market price of our common stock could decline. In addition, the market price of our common stock may fluctuate or decline regardless of our operating performance.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. (Removed and Reserved).

Item 5. Other Information.

None.

Item 6. Exhibits.

		Incorporated by Reference to Filings Indicated				
Exhibit No	Exhibit Description	Form	File No.	Exhibit	Filing Date	Filed Herewith
10.85	AVI BioPharma, Inc. Non-Employee Director Compensation Policy	8-K	1-14895	10.85	10/1/10	
10.86*	Contract Number W9113M-10-C-0056 between U.S. Army Space and Missile Defense Command and the Company dated July 14, 2010					X
31.1	Certification of the Company's Interim President and Chief Executive Officer and Chief Financial Officer, J. David Boyle II, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of the Company's Controller and Chief Accounting Officer, Melinda K. Miles, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	Certification of the Company's Interim President and Chief Executive Officer, and Senior Vice President and Chief Financial Officer, J. David Boyle II, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X

* Confidential treatment has been requested for portions of this exhibit. These portions are omitted from this Quarterly Report on Form 10-Q and have been filed separately with the Securities and Exchange Commission.

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 9, 2010

AVI BIOPHARMA, INC.

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

By: /s/ MELINDA K. MILES
Melinda K. Miles
Chief Accounting Officer

(Principal Accounting Officer)

EXHIBIT INDEX

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Exhibit 10.86

AWARD/CONTRACT	1 THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING DO C9	PAGE OF PAGES 1 I 29
2. CONTRACT *(Proc. Inst. Indent.)* NO. W9113M-10-C-0056	3. EFFECTIVE DATE 14 July 2010	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. SEE SCHEDULE	

5. ISSUED BY CODE W9113M

USASMDC/ARSTRAT
SMDC-RDC-EB
64 THOMAS JOHNSON DRIVE
FREDERICK MD 21702

6. ADMINISTERED BY *(If other than Item 5)* CODE S4801A

DCM SEATTLE
CORPORATE CAMPUS EAST III
3009 112TH AVE., NE, SUITE 200
BELLEVUE WA 98004-8019

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*

AVIBIOPHARMA, INC.
4575 SW RESEARCH WAY STE 200
CORVALLIS OR 97333-1299

8. DELIVERY

☐ FOB ORIGIN ☒ OTHER *(See below)*

9. DISCOUNT FOR PROMPT PAYMENT

10. SUBMIT INVOICES *(4 copies unless otherwise specified)* TO THE ADDRESS SHOWN IN ITEM G

CODE 49WU1 FACILITY CODE

11. SHIP TO/MARK FOR CODE
See Schedule

12. PAYMENT WILL BE MADE BY CODE HQ0339

DFAS-COLUMBUS CETER
DFAS-CO/WEST ENTITLEMENT OPERATION
PO BOX 182381 COLUMBUS OH 43218-2381

13, AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:

10 U.S.C. 2304(c) ( ) I 141 U.S.C. 253(c) ( )

14. ACCOUNTING AND APPROPRIATION DATA

SEE SCHEDULE

15A. ITEM NO.	1513, SUPPLIES/SERVICES	15C. QUANTITY	15D.UNIT	15E. UNIT PRICE	15F. AMOUNT
	SEE SCHEDULE				

15G. TOTAL AMOUNT OF CONTRACT $ 80396827.30

16. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
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X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	3-10			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
X	C	DESCRIPTION/SPECS./WORK STATEMENT	11	X	J	LIST OF ATTACHMENTS	28
X	D	PACKAGING AND MARKING	12			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
X	E	INSPECTION AND ACCEPTANCE	13		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	14		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return 1 copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)

18. ☐ AWARD *(Contractor is not required to sign this document.) Your offer* on Solicitation Number W9113M-09-R-0008, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the terms listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary,

19A. NAME AND TITLE OF SIGNER (Type *or Print)*

J. David Boyle II
Interim President & CEO, SVP & CFO

20A. NAME OF CONTRACTING OFFICER

LYNN M. SELFRIDGE

19A. NAME OF CONTRACTOR 19C. DATE SIGNED

20B. UNITED STATES OF AMERICA 20 DATE SIGNED

BY: */s/ J. David Boyle II* July 13, 2010
(Signature of person authorized to sign)

BY: */s/ Lynn M. Selfridge* July 14 2010
(Signature of Contracting Officer)

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is usable

STANDARD FORM 26 (REV. 4/2008)
Prescribed by GSA — FAR (48 CFR) 53.214(a)

+ DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Section A - Solicitation/Contract Form

SECTION A
CONTINUATION OF FORM 26

Award is hereby made for the Advanced Development through licensure of a Hemorrhagic Fever Virus Therapeutic.

The AVI Biopharma Inc. proposal dated 1/30/2010 and as revised on 3/11/2010 and 4/30/2010, is incorporated into contract No. W9113M-10-C-0056 in its entirety with the following revisions:

1. Section G has been revised to include local WAWF clause to include the type and codes required for payment purposes.

2. Section H has been revised to include paragraphs H. 6, requirements from the RFP at Section M.3.4 Post-Award Evaluations of Contractors' Performance and Down-Select Criteria.

3. The following clauses are hereby added to Section I by reference:

52.215-16 Facilities Capital Cost of Money (June 2003)

252.204-7008 Export Controlled Items (April 2010)

4. The following clauses are hereby deleted from Section I:

52.232-25 Prompt Payment OCT 2008

5. The following clause in Section I is hereby revised to remove the last sentence: 52.217-7 Option for Increased quantity — Separately Priced Line Item (MAR 1989)

6. The AVI proposed IMS dates take precedence over any inconsistencies contained within the SOW Attached in Section J, Attachments 1 and 2.

7. CLINs 0001 through 0004 referenced in AVI SOW, Section J. Attachment 2, are revised to read CLIN 0005 through 0008, respectively.

8. As noted in Government Statement of Objectives Section 5.7, as a condition of submitting a proposal under the solicitation W9113M-09-R-0008, AVI agrees to the no cost termination, under FAR 52.249-6 of their current Government contract, HDTRA1-07-C-0010, CLINs 000301, 000302, and 000303 only for the performing efforts related to any or both of these products as a condition of the award of this contract.

+ DESIGNATES PORTIONS OF THIS DOCUMENT THAT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT FILED SEPARATELY WITH THE COMMISSION

Section B - Supplies or Services and Prices

ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0001		Lot		$[+]
	Advanced Development of Hemorrhagic			
	CPIF			
	Fever virus Therapeutic - Ebola Virus. Delivery of the developmental therapeutic end item that has successfully achieved all activities associated with completing FDA [+] Clinical Trials exclusive of those required to achieve Technology Readiness Level 4, to include Pre-IND, IND, and Phase 1 [+] Clinical Studies, including Management, Regulatory Affairs, all FDA submissions and official program reporting requirements (to include [+] if required) in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 1 of Section J. (Note: maturity level of candidate receiving award will determine the specific activities awarded.) Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
000101				$[+]
	Funding for CLIN 0001			
	CPIF			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	
			SHARE RATIO BELOW TARGET	
	ACRN AA			$[+]
	CIN: 00000000000000000000000000000			

ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0002		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Ebola Virus. Delivery of the developmental therapeutic end item that has successfully achieved [+]. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required) in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 1 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0003		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Ebola Virus. Delivery of the developmental therapeutic end item that has successfully achieved [+] Clinical Studies. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required). in accordance with the Contractor's Statement of Work (SOW), dated (insert upon award), Attachment 1 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0004		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Ebola Virus. New Drug Application and delivery of FDA licensed developmental therapeutic end item to include all New Drug Application and Licensure activities resulting in the delivery of at least [+] of an FDA approved therapeutic. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required), in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 1 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0005		Lot		$[+]
	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Marburg Virus. Delivery of the developmental therapeutic end item that has successfully achieved all activities associated with completing FDA [+] Clinical Trials exclusive of those required to achieve Technology Readiness Level 4, to include Pre-IND, IND, and Phase 1 [+] Clinical Studies, including Management, Regulatory Affairs, all FDA submissions and official program reporting requirements (to include [+] if required) in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 2 of Section J. (Note: maturity level of candidate receiving award will determine the specific activities awarded.) Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
000501		Lot		$[+]
	Funding for CLIN 0005			
	CPIF			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	
			SHARE RATIO BELOW TARGET	
	ACRN AB			$[+]
	CIN: 00000000000000000000000000000000			

ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0006		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Marburg Virus. Delivery of the developmental therapeutic end item that has successfully achieved [+]. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required). in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 2 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0007		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Marburg Virus. Delivery of the developmental therapeutic end item that has successfully achieved [+] Clinical Studies. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required). in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 2 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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ITEM NO	SUPPLIES/SERVICES QUANTITY	UNIT	UNIT PRICE	AMOUNT
0008		Lot		$[+]
OPTION	Advanced Development of Hemorrhagic			
	CPIF			
	Fever Virus Therapeutic - Marburg Virus. New Drug Application and delivery of FDA licensed developmental therapeutic end item to include all New Drug Application and Licensure activities resulting in the delivery of at least [+] of an FDA approved therapeutic. This line item includes all associated Management, Regulatory Affairs, FDA submissions and Official program reporting requirements (to include [+] if required), in accordance with the Contractor's Statement of Work (SOW), dated 3/11/10, Attachment 2 of Section J. Reporting requirements are delineated in Contract Data Requirements List DD Form 1423, attached as Exhibits A001 through A006 in Section J.			
	FOB: Destination			
			TARGET COST	$[+]
			TARGET FEE	$[+]
			TOTAL TGT COST + FEE	$[+]
			MINIMUM FEE	$[+]
			MAXIMUM FEE	$[+]
			SHARE RATIO ABOVE TARGET	[+]
			SHARE RATIO BELOW TARGET	[+]

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SECTION C
Contractor's Statement of Work, dated 3/11/10, Attachment 1 and 2, Section J.

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SECTION D

Packaging and Marking shall be in accordance with FDA regulations as described in Contractor's Statement of Work, dated 3/11/10, Attachment 1and 2 in Section J.

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Section E - Inspection and Acceptance

INSPECTION AND ACCEPTANCE TERMS

Supplies/services will be inspected/accepted at:

CLIN	INSPECT AT	INSPECT BY	ACCEPT AT	ACCEPT BY
0001	Destination	Government	Destination	Government
000101	N/A	N/A	N/A	Government
0002	Destination	Government	Destination	Government
0003	Destination	Government	Destination	Government
0004	Destination	Government	Destination	Government
0005	Destination	Government	Destination	Government
000501	N/A	N/A	N/A	Government
0006	Destination	Government	Destination	Government
0007	Destination	Government	Destination	Government
0008	Destination	Government	Destination	Government

CLAUSES INCORPORATED BY REFERENCE

52.246-8	Inspection Of Research And Development Cost Reimbursement	MAY 2001
52.246-16	Responsibility For Supplies	APR 1984

CLAUSES INCORPORATED BY FULL TEXT

52.246-11 HIGHER-LEVEL CONTRACT QUALITY (FEB 1999)

The Contractor shall comply with the higher-level quality standard selected below. (If more than one standard is listed, the offeror shall indicate its selection by checking the appropriate block.)

Title	Number	Date	Tailoring

ISO 9001/2000 or higher;
X Quality System in compliance with FDA quality requirements

(End of clause)

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Section F - Deliveries or Performance

DELIVERY INFORMATION

CLIN	DELIVERY DATE	QUANTITY	SHIP TO ADDRESS	UIC
0001	25-MAR-2012	Lot	Transformational Medical Technologies Initiative Defense Threat Reduction Agency 8725 John J. Kingman Road, stop 6201 Fort Belvoir, VA, 22060-6201 FOB: Destination	HDTRA1
000101	N/A	N/A	N/A	
0002	09-FEB-2015	Lot	Same As Above FOB: Destination	HDTRA1
0003	08-NOV-2015	Lot	Same As Above FOB: Destination	HDTRA1
0004	07-SEP-2016	Lot	Same As Above FOB: Destination	HDTRA1
0005	01-APR-2012	Lot	Same As Above FOB: Destination	HDTRA1
000501	N/A	N/A	N/A	
0006	09-FEB-2015	Lot	Same As Above FOB: Destination	HDTRA1
0007	08-NOV-2015	Lot	Same As Above FOB: Destination	HDTRA1
0008	07-SEP-2016	Lot	Same As Above FOB: Destination	HDTRA1

CLAUSES INCORPORATED BY REFERENCE

52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.247-34	F.O.B. Destination	NOV 1991

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Section G - Contract Administration Data

SECTION G
PAYMENTS:

Detailed Copies of all payment requests will be provided electronically to the Government points of contact listed below at the same time of submission to WAWF:

Contracting Office:

USASMDC
Attn: SMDC-RDC-EB/S. O'Connell 64 Thomas Johnson Drive
Frederick, MD 21702
Telephone: 301-619-2895
Fax: 301-619-5069
Email: sandra.oconnell@us.army.mil

Contracting Officers Representative (COR):

CLINS 0001-0004
John Anderson
8725 John J. Kingman Road, stop 6201
Fort Belvoir, VA 22060-6201
Telephone: (703)767-2908
Email: John.anderson@dtra.mil

CLINS 0005-0008
Adekunle Famodu
8725 John J. Kingman Road, stop 6201
Fort Belvoir, VA 22060-6201
Telephone: (703)767-7935
Email: Adekunle.famodu@dtra.mil

ACCOUNTING AND APPROPRIATION DATA

AA: 970040026TM5YTMW61D255999BD33800000S49012 DODAAC: HD1115
AMOUNT: $[+]
CIN 000000000000000000000000000000: $[+]

ACCOUNTING AND APPROPRIATION DATA

AB: 970040026TM5YTMW61D255999BD337801000S49012 DODAAC: HD1115
AMOUNT: $[+]
CIN 000000000000000000000000000000: $[+]

CLAUSES INCORPORATED BY REFERENCE

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252.201-7000 Contracting Officer's Representative DEC 1991

CLAUSES INCORPORATED BY FULL TEXT

INVOICING INSTRUCTIONS

a. The contractor shall submit payment request electronically in accordance with DFARS 252.232-7003 utilizing Wide Area Work Flow (WAWF). The WAWF application allows DOD vendors to submit and track invoices and receipt/acceptance documents electronically. The contractor shall register with WAWF at https://wawf.eb.mil and ensure an electronic business point of contract (POC) is designated in the Central Contractor Registration site at http://www.ccr.gov within ten (10) days after award of this contract. Payments made under this contract shall be via Electronic Funds Transfer (EFT) and shall be based on the EFT information contained in the Central Contractor Registration (CCR) database. The contractor shall ensure that its EFT information in the CCR database remains current and correct.

b. Multiple pricing structures may be utilized for this contract or, if a task ordering contract, for individual task orders issued thereunder. In order to ensure the successful flow of WAWF documents, the type of payment request submitted shall be based on the following as applicable:

☐ **Invoice and Receiving Report (COMBO)**: applicable to Firm-Fixed-Price (FFP) contracts/task orders that include the delivery of supplies/hardware.

☐ **Invoice as 2-in-1**: applicable to Labor Hour and FFP contracts/task orders for services only.

☒ **Cost Voucher**: applicable to Time and Material (T&M) and Cost-Reimbursement type contracts/task orders.

☐ **Construction Invoice**: applicable to contracts/task orders for construction.

c. WAWF requires the following data for each payment request: *(To be provided by the Government. If a task ordering contract, each awarded task order shall identify this information)*

Contract/Task Order Data

Contractor CAGE Code: 49WU1
Issue by DODAAC: W9113M
Admin by DODAAC: S4801A
Inspect by DODAAC: S4801A
Accept by DODAAC: S4801A
Ship to DODAAC: HD1115
Payment by DODAAC: HQ0339

Email Points of Contact Listing

Inspector: TBD
Acceptor: TBD
Contracting Specialist: sandra.oconnell@us.army.mil
Contracting Officer:
Contracting Officer's Technical Representative: John.anderson@dtra.mil (CLINs 1-4)
Adekunle.famodu@dtra.mil (CLINs 5-8)

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d. Questions concerning payments shall be directed to the Defense Finance and Accounting Service (DFAS). The appropriate DFAS office is indentified in the "PAYMENT WILL BE MADE BY" block on the contract award coversheet. Please have your contract and, if applicable, task order number ready when calling about payments. Payment and receipt information may be accessed using the DFAS web site MyInvoice. MyInvoice is a web-based application developed specifically for contractors/vendors and Government/ Military employees to obtain invoice status. It is an interactive web-based system, accessible 24/7. Users must allow pop-up messages within this system. Your contract and, if applicable, task order number or invoice number will be required to inquire about the status of your payment. For additional information, see the MyInvoice website at https://myinvoice.csd.disa.mil/ or visit http://www.dfas.mil/contractorpay/ electroniccommerce/myinvoice.html.

e. The contractor may submit requests for payment through WAWF not more frequently than monthly (or bi-weekly if a small business).

f. For Labor Hour and T&M contracts/task orders, payment requests for labor shall be based on the total labor hours/DPPH expended thereunder for the applicable billing period. These labor charges shall be derived by applying the total hours expended for each labor category multiplied by the applicable fixed-labor rates specified in the contract/task order. Labor charges for cost-reimbursement contracts/task orders shall be based on the total hours expended for each labor category multiplied by actual direct labor rates plus applicable indirect burdens and fee. Travel and ODC/material under T&M and Cost-Reimbursement type contracts/task orders shall be billed at actual costs. For each payment request, the contractor shall attach/upload into WAWF sufficient documentation as to how the billed amounts were derived/calculated.

g. For Firm-Fixed-Price contracts/task orders, payments on the total contract price (excluding any unexercised options) may be requested in equal monthly (or bi-weekly if a small business) amounts calculated over the life of the contract/task order unless alternative payment schedules (e.g., performance-based payments) are specified elsewhere in the contract, or if applicable, in individual task orders.

h. For each payment request, the contractor shall maintain sufficient documentation to substantiate the submitted charges. Such documentation shall include evidence of actual expenditures/payment such as individual daily job timecards, subcontractor/vendor invoices and payment receipts, or other substantiation specified by the Contracting Officer. Such data shall be maintained and readily available for audit purposes, but shall not be included with the WAWF submission. The contractor shall provide such documentation within 7 days of request by the Procuring Contracting Officer, Administrative Contracting Officer, or DCAA auditor.

i. The contractor shall ensure that each payment request submitted in WAWF denotes that the Contracting Officer and Contract Specialist will receive a copy of the payment request notice.

j. Except for FFP contracts/task orders, the contractor and each assignee under an assignment entered into under this contract or, if applicable, an individual task order and in effect at the time of final payment on this contract or, if applicable, an individual task order issued under this contract, shall execute and deliver, at the time of and as a condition precedent to, any final payment thereunder, a release discharging the Government, its officers, agents, and employees, of and from all liabilities, obligations, and claims arising out of, or under, the specific contract/task order. These closing documents shall be submitted with the final payment request.

k. The contractor shall submit final payment requests for Labor Hour and FFP contracts/task orders within 120 days (or longer if approved in writing by the Contracting Officer) after contract/order completion. For T&M or Cost-Reimbursement type contracts/task orders, the contractor shall prepare a final payment request within 120 days (or longer if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates to reflect the settled amounts and rates for the performance period covered. The cognizant DCAA shall perform a final audit on the contractor's final payment request to determine allowable costs. The Administrative Contracting Officer may utilize the cumulative allowable worksheets included with the DCAA incurred cost audit reports in lieu of

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requesting DCAA to perform the final closeout audit to determine the final costs on the cost reimbursable portions of the contract/task order.

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SECTION H

H. 1 SECURITY CONSIDERATIONS

At this time, there are no anticipated classified materials or performance required for this acquisition. However, if mandated by a program and/or contractual requirements in the future, the selected contractor(s) may need to have a Facility Security Clearance and Personnel Security Clearances to maintain a safeguarding capability through SECRET clearance level in accordance with the Industrial Security Regulation, DoD 5220.22-R and the National Industrial Security Program Operating Manual, DoD 5220.22-M. Following contract award, should classified information be required, it will be safeguarded in accordance with these documents, including submission of a DD Form 254 and Government generation of a Security Classification Guide. The contractor(s) will receive routine Government audits of their industrial security management system to ensure adequate security safeguards have been established and maintained. The Government's assigned Industrial Security Representative will determine the frequency of such formal reviews, but a review will normally be conducted on an annual basis.

Although not anticipated at this time, should performance of the contract(s) require physical access to a Federally-controlled facility, the contractor(s) shall comply with the Office of Management and Budget Guidance M-05-24, dated August 5, 2005, Implementation of Homeland Security Presidential Directive 12-Policy for a Common Identification Standard for Federal Employees and Contractors. The Government will coordinate all actions necessary for access to a Federally-controlled facility to ensure proper and only essential access is provided to the contractor(s).

Ebola and Marburg viruses are category A select agents as classified by the CDC and require BSL-4 containment facilities. Therefore, this contract will involve access to Biological Select Agents and Toxins (BSAT). The Contractors will be required to certify they are registered in accordance with Federal, State, and local regulations, including with the CDC and the Animal and Plant Health Inspection Service. The Contractor will be required to comply with DoD Directive 5210.88, Safeguarding Biological Select Agents and Toxins; DoDI 5210.89, Minimum Security Standards for Safeguarding Biological Select Agents and Toxins; Army Regulation (AR) 50-1, Biological Surety; and AR 190-17, Biological Select Agents and Toxins Security Program; and AR 190-51, Army Physical Security Program.

The HFV Class will not generate or require the use of classified information or classified material of any kind. The data generated in the projects would be considered "unclassified controlled information" at best. The Contractor must meet the requirements for working with unclassified controlled information set forth by DoDD 5200.1.

The Contractor will comply with DoDD 5200.1 Appendix C in the marking of all documents and media items, safeguarding of all information, accessing of all information, storage of all project data, reproduction and disposal of all information, handling and transport of all information, management of the Information Security Program, and limited control and distribution of some project documents.

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H.2 TEST AND EVALUATION

The HFV Class of Therapeutics will be developed in full accordance with FDA regulations and guidelines established by CFR 21, the Pure Food and Drug Act. The FDA mandates test and evaluation processes that follow a series of phases that establish the effectiveness and safety of new drugs. The FDA issues extensive mandatory guidance and requires submission of substantive evidence for FDA review. Only after FDA approval can work proceed from one phase to the next. The FDA process is mandatory for licensure. The Government will utilize the Contractor's validated information and FDA process documentation in evaluating progress and conformance with TPP Guidelines.

H.3. PROHIBITION OF USE OF LABORATORY ANIMALS
Information and guidance is provided at the following web site:
https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro

https://mrmc.amedd.army.mil/rodorpaurd.asp

**** PROHIBITION — READ FURTHER FOR DETAILS ****

Notwithstanding any other provisions contained in this award or incorporated by reference herein, the recipient is expressly forbidden to use or subcontract for the use of laboratory animals in any manner whatsoever without the express written approval of the US Army Medical Research and Materiel Command, Animal Care and Use Office. You will receive written approval to begin research under the applicable protocol proposed for this award from the US Army Medical Research and Materiel Command, Animal Care and Use Office under separate letter to the recipient and Principal Investigator. A copy of this approval will be provided to the US Army Space and Missile Defense Command for the official file. Non-compliance with any provision of this clause may result in the termination of the award.

H.4. PROHIBITION OF USE OF HUMAN SUBJECTS
Information and guidance is provided at the following web site:

https://mrmc.amedd.army.mil/rodorphrpo.asp

**** PROHIBITION — READ FURTHER FOR DETAILS ****

Research under this award involving the use of human subjects may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human subjects under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to the US Army Space and Missile Defense Command for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

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H.5. PROHIBITION OF USE OF HUMAN ANATOMICAL SUBSTANCES
Information and guidance is provided at the following web site:

https://mrmc.amedd.army.mil/rodorphrpo.asp

**** PROHIBITION — READ FURTHER FOR DETAILS****

Research at funded institutions using human anatomical substances may not begin until the U.S. Army Medical Research and Materiel Command's Office of Research Protections, Human Research Protections Office (HRPO) approves the protocol. Written approval to begin research or subcontract for the use of human anatomical substances under the applicable protocol proposed for this award will be issued from the US Army Medical Research and Materiel Command, HRPO, under separate letter to the funded institution and the Principal Investigator. A copy of this approval will be provided to the US Army Space and Missile Defense Command for the official file. Non-compliance with any provision of this clause may result in withholding of funds and or the termination of the award.

H.6 Post-Award Evaluations of Contractors' Performance and Down-Select Criteria

H.6.1 This acquisition provides that Contractors with products that fail in development or in default of contract requirements will not be continued by option exercise (if not defaulted sooner).

H.6.2 All other performing Contractors will not be denied the opportunity to continue performance under an option clause by the Government's decision to exercise or not exercise an option, or otherwise, absent a best value comparative evaluation using established RFP evaluation criteria. The criteria shall include, but not be limited to, post-award performance, the Government's preference to avoid therapeutics addressing duplicative indications and the Anti-Viral TPP Guidelines. Trade-offs can be considered at down-select points in the evaluation of each candidate against the evaluation criteria. The Government's right to unilaterally decide not to exercise all options and to discontinue the development of all HFV therapeutics is paramount.

H.6.3 In the event a best value comparative evaluation becomes necessary or is desired at a down-select point, selection shall be based on evaluation of the contractors' actual post-award contract performance against evaluation criteria established in the RFP to include the Anti-Viral TPP Guidelines and the Government's preference to avoid therapeutics addressing duplicative indications.

CLAUSES INCORPORATED BY REFERENCE

252.234-7002	Earned Value Management System	APR 2008

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Section I - Contract Clauses

CLAUSES INCORPORATED BY REFERENCE

52.202-1	Definitions	JUL 2004
52.203-3	Gratuities	APR 1984
52.203-5	Covenant Against Contingent Fees	APR 1984
52.203-6	Restrictions On Subcontractor Sales To The Government	SEP 2006
52.203-7	Anti-Kickback Procedures	JUL 1995
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	JAN 1997
52.203-10	Price Or Fee Adjustment For Illegal Or Improper Activity	JAN 1997
52.203-12	Limitation On Payments To Influence Certain Federal Transactions	SEP 2007
52.203-14	Display of Hotline Poster(s)	DEC 2007
52.204-4	Printed or Copied Double-Sided on Recycled Paper	AUG 2000
52.204-7	Central Contractor Registration	APR 2008
52.204-10	Reporting Subcontract Awards	SEP 2007
52.209-6	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	SEP 2006
52.211-5	Material Requirements	AUG 2000
52.215-2	Audit and Records—Negotiation	MAR 2009
52.215-2 Alt I	Audit and Records—Negotiation (Mar 2009) Alternate I	MAR 2009
52.215-8	Order of Precedence—Uniform Contract Format	OCT 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	OCT 1997
52.215-11	Price Reduction for Defective Cost or Pricing Data—Modifications	OCT 1997
52.215-12	Subcontractor Cost or Pricing Data	OCT 1997
52.215-13	Subcontractor Cost or Pricing Data—Modifications	OCT 1997
52.215-15	Pension Adjustments and Asset Reversions	OCT 2004
52.215-16	Facilities Capital Cost of Money	JUN 2003
52.215-19	Notification of Ownership Changes	OCT 1997
52.215-23	Limitations on Pass-Through Charges	OCT 2009
52.216-7	Allowable Cost And Payment	DEC 2002
52.219-6	Notice Of Total Small Business Set-Aside	JUN 2003
52.219-8	Utilization of Small Business Concerns	MAY 2004
52.219-14	Limitations On Subcontracting	DEC 1996
52.222-19	Child Labor — Cooperation with Authorities and Remedies	AUG 2009
52.222-20	Walsh-Healey Public Contracts Act	DEC 1996
52.222-21	Prohibition Of Segregated Facilities	FEB 1999
52.222-26	Equal Opportunity	MAR 2007
52.222-35	Equal Opportunity For Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-36	Affirmative Action For Workers With Disabilities	JUN 1998
52.222-37	Employment Reports On Special Disabled Veterans, Veterans Of The Vietnam Era, and Other Eligible Veterans	SEP 2006
52.222-39	Notification of Employee Rights Concerning Payment of Union Dues or Fees	DEC 2004
52.222-50	Combating Trafficking in Persons	FEB 2009
52.223-3	Hazardous Material Identification And Material Safety Data	JAN 1997
52.223-6	Drug-Free Workplace	MAY 2001
52.223-14	Toxic Chemical Release Reporting	AUG 2003

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52.225-13	Restrictions on Certain Foreign Purchases	JUN 2008
52.227-1	Authorization and Consent	DEC 2007
52.227-2	Notice And Assistance Regarding Patent And Copyright Infringement	DEC 2007
52.227-11	Patent Rights—Ownership By The Contractor	DEC 2007
52.227-14	Rights in Data—General	DEC 2007
52.227-23	Rights to Proposal Data (Technical)	JUN 1987
52.228-7	Insurance—Liability To Third Persons	MAR 1996
52.232-1	Payments	APR 1984
52.232-17	Interest	OCT 2008
52.232-20	Limitation Of Cost	APR 1984
52.232-22	Limitation Of Funds	APR 1984
52.232-23	Assignment Of Claims	JAN 1986
52.232-33	Payment by Electronic Funds Transfer—Central Contractor Registration	OCT 2003
52.233-1	Disputes	JUL 2002
52.233-3 Alt I	Protest After Award (Aug 1996) - Alternate I	JUN 1985
52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
52.242-1	Notice of Intent to Disallow Costs	APR 1984
52.242-3	Penalties for Unallowable Costs	MAY 2001
52.242-4	Certification of Final Indirect Costs	JAN 1997
52.242-13	Bankruptcy	JUL 1995
52.242-15 Alt I	Stop-Work Order (Aug 1989) - Alternate I	APR 1984
52.242-17	Government Delay Of Work	APR 1984
52.243-2	Changes—Cost-Reimbursement	AUG 1987
52.243-2 Alt V	Changes—Cost-Reimbursement (Aug 1987) - Alternate V	APR 1984
52.244-2	Subcontracts	JUN 2007
52.244-5	Competition In Subcontracting	DEC 1996
52.244-6	Subcontracts for Commercial Items	AUG 2009
52.249-6	Termination (Cost Reimbursement)	MAY 2004
52.249-14	Excusable Delays	APR 1984
52.253-1	Computer Generated Forms	JAN 1991
252.203-7000	Requirements Relating to Compensation of Former DoD Officials	JAN 2009
252.203-7001	Prohibition On Persons Convicted of Fraud or Other Defense- Contract-Related Felonies	DEC 2008
252.204-7004 Alt A	Central Contractor Registration (52.204-7) Alternate A	SEP 2007
252.204-7006	Billing Instructions	OCT 2005
252.204-7008	Export-Controlled Items	APR 2010
252.205-7000	Provision Of Information To Cooperative Agreement Holders	DEC 1991
252.209-7004	Subcontracting With Firms That Are Owned or Controlled By The Government of a Terrorist Country	DEC 2006
252.211-7003	Item Identification and Valuation	AUG 2008
252.215-7000	Pricing Adjustments	DEC 1991
252.215-7004	Excessive Pass-Through Charges	MAY 2008
252.223-7001	Hazard Warning Labels	DEC 1991
252.225-7004	Report of Contract Performance Outside the United States and Canada—Submission after Award	MAY 2007
252.225-7006	Quarterly Reporting of Actual Contract Performance Outside the United States	MAY 2007
252.225-7012	Preference For Certain Domestic Commodities	DEC 2008
252.227-7039	Patents—Reporting Of Subject Inventions	APR 1990

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252.232-7003	Electronic Submission of Payment Requests and Receiving Reports	MAR 2008
252.232-7010	Levies on Contract Payments	DEC 2006
252.235-7002	Animal Welfare	DEC 1991
252.235-7004	Protection of Human Subjects	JUL 2009
252.243-7002	Requests for Equitable Adjustment	MAR 1998
252.244-7000	Subcontracts for Commercial Items and Commercial Components (DoD Contracts)	AUG 2009
252.247-7023	Transportation of Supplies by Sea	MAY 2002
252.247-7024	Notification Of Transportation Of Supplies By Sea	MAR 2000

CLAUSES INCORPORATED BY FULL TEXT

52.216-10 INCENTIVE FEE (MAR 1997)

(a) General. The Government shall pay the Contractor for performing this contract a fee determined as provided in this contract.

(b) Target cost and target fee. The target cost and target fee specified in the Schedule are subject to adjustment if the contract is modified in accordance with paragraph (d) below.

(1) "Target cost," as used in this contract, means the estimated cost of this contract as initially negotiated, adjusted in accordance with paragraph (d) below.

(2) "Target fee," as used in this contract, means the fee initially negotiated on the assumption that this contract would be performed for a cost equal to the estimated cost initially negotiated, adjusted in accordance with paragraph (d) below.

(c) Withholding of payment. Normally, the Government shall pay the fee to the Contractor as specified in the Schedule. However, when the Contracting Officer considers that performance or cost indicates that the Contractor will not achieve target, the Government shall pay on the basis of an appropriate lesser fee. When the Contractor demonstrates that performance or cost clearly indicates that the Contractor will earn a fee significantly above the target fee, the Government may, at the sole discretion of the Contracting Officer, pay on the basis of an appropriate higher fee. After payment of 85 percent of the applicable fee, the Contracting Officer may withhold further payment of fee until a reserve is set aside in an amount that the Contracting Officer considers necessary to protect the Government's interest. This reserve shall not exceed 15 percent of the applicable fee or $100,000, whichever is less. The Contracting Officer shall release 75 percent of all fee withholds under this contract after receipt of the certified final indirect cost rate proposal covering the year of physical completion of this contract, provided the Contractor has satisfied all other contract terms and conditions, including the submission of the final patent and royalty reports, and is not delinquent in submitting final vouchers on prior years' settlements. The Contracting Officer may release up to 90 percent of the fee withholds under this contract based on the Contractor's past performance related to the submission and settlement of final indirect cost rate proposals.

(d) Equitable adjustments. When the work under this contract is increased or decreased by a modification to this contract or when any equitable adjustment in the target cost is authorized under any other clause, equitable adjustments in the target cost, target fee, minimum fee, and maximum fee, as appropriate, shall be stated in a supplemental agreement to this contract.

(e) Fee payable. (1) The fee payable under this contract shall be the target fee increased by [+] [Contracting Officer insert Contractor's participation] cents for every dollar that the total allowable cost is less than the target cost or decreased by [+] [Contracting Officer insert Contractor's participation] cents for every dollar that the total allowable

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cost exceeds the target cost. In no event shall the fee be greater than [+][Contracting Officer insert percentage] percent or less than . . . .[+] . . . . . [Contracting Officer insert percentage] percent of the target cost.

(2) The fee shall be subject to adjustment, to the extent provided in paragraph (d) above, and within the minimum and maximum fee limitations in subparagraph (1) above, when the total allowable cost is increased or decreased as a consequence of (i) payments made under assignments or (ii) claims excepted from the release as required by paragraph (h)(2) of the Allowable Cost and Payment clause.

(3) If this contract is terminated in its entirety, the portion of the target fee payable shall not be subject to an increase or decrease as provided in this paragraph. The termination shall be accomplished in accordance with other applicable clauses of this contract.

(4) For the purpose of fee adjustment, "total allowable cost" shall not include allowable costs arising out of—

(i) Any of the causes covered by the Excusable Delays clause to the extent that they are beyond the control and without the fault or negligence of the Contractor or any subcontractor;

(ii) The taking effect, after negotiating the target cost, of a statute, court decision, written ruling, or regulation that results in the Contractor's being required to pay or bear the burden of any tax or duty or rate increase in a tax or duty;

(iii) Any direct cost attributed to the Contractor's involvement in litigation as required by the Contracting Officer pursuant to a clause of this contract, including furnishing evidence and information requested pursuant to the Notice and Assistance Regarding Patent and Copyright Infringement clause;

(iv) The purchase and maintenance of additional insurance not in the target cost and required by the Contracting Officer, or claims for reimbursement for liabilities to third persons pursuant to the Insurance Liability to Third Persons clause;

(v) Any claim, loss, or damage resulting from a risk for which the Contractor has been relieved of liability by the Government Property clause; or

(vi) Any claim, loss, or damage resulting from a risk defined in the contract as unusually hazardous or as a nuclear risk and against which the Government has expressly agreed to indemnify the Contractor.

(5) All other allowable costs are included in "total allowable cost" for fee adjustment in accordance with this paragraph (e), unless otherwise specifically provided in this contract.

(f) Contract modification. The total allowable cost and the adjusted fee determined as provided in this clause shall be evidenced by a modification to this contract signed by the Contractor and Contracting Officer.

(g) Inconsistencies. In the event of any language inconsistencies between this clause and provisioning documents or Government options under this contract, compensation for spare parts or other supplies and services ordered under such documents shall be determined in accordance with this clause.

(End of clause)

52.217-7 OPTION FOR INCREASED QUANTITY—SEPARATELY PRICED LINE ITEM (MAR 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. In Accordance with Section H.6.

(End of clause)

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52.219-28 POST-AWARD SMALL BUSINESS PROGRAM REREPRESENTATION (APR 2009)

(a) Definitions. As used in this clause—

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts—

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at http://www.sba.gov/services/contractingopportunities/sizestandardstopics/.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

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(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ( ) is, ( ) is not a small business concern under NAICS Code 541711- assigned to contract number .

(Contractor to sign and date and insert authorized signer's name and title).

(End of clause)

52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http://farsite.hill.af.mil

(End of clause)

252.204-7000 DISCLOSURE OF INFORMATION (DEC 1991)

(a) The Contractor shall not release to anyone outside the Contractor's organization any unclassified information, regardless of medium (e.g., film, tape, document), pertaining to any part of this contract or any program related to this contract, unless—

(1) The Contracting Officer has given prior written approval; or

(2) The information is otherwise in the public domain before the date of release.

(b) Requests for approval shall identify the specific information to be released, the medium to be used, and the purpose for the release. The Contractor shall submit its request to the Contracting Officer at least 45 days before the proposed date for release.

(c) The Contractor agrees to include a similar requirement in each subcontract under this contract. Subcontractors shall submit requests for authorization to release through the prime contractor to the Contracting Officer.

(End of clause)

252.235-7010 Acknowledgment of Support and Disclaimer. (MAY 1995)

(a) The Contractor shall include an acknowledgment of the Government's support in the publication of any material

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based on or developed under this contract, stated in the following terms: This material is based upon work supported by the US Army Space and Missile Defense Command under Contract No. [Insert upon award]

(b) All material, except scientific articles or papers published in scientific journals, must, in addition to any notices or disclaimers by the Contractor, also contain the following disclaimer: Any opinions, findings and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the [name of contracting agency(ies)].

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SECTION J
LIST OF ATTACHMENTS

Attachment No.	Description	Date	Number of Pages
1	Contractor's Statement of Work — Ebola Virus	3/11/10	57
2	Contractor's Statement of Work — Marburg Virus	3/11/10	57

Exhibit No.
A001 Contract Work Breakdown Structure (CWBS)
A002 Contractor's Progress, Status, & Management Report
A003 Contract Funds Status Report, DD Form 1586
A004 Integrated Master Schedule
A005 Contract Performance Report
A006 In Process Review

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Appendix B: Revised Statement of Work

3.0 CONTRACT

AVI BioPharma (AVI) Statement of Work for AVI-6002 as an effective therapeutic for ebolavirus:

3.2 CLIN0001 Technology Development (Part 1): AVI will deliver the developmental therapeutic end item that has completed [+] clinical trials, with all the associated preclinical and regulatory requirements sufficient and in place to support its delivery. This will comprise all those activities necessary for our candidate drug product to complete the US GOVERNMENT (USG) Statement of Objectives for CLIN0001. We will complete the planning (including assessment and mitigation of risk) for manufacturing the drug supply, and execute process development to enable scale up from the current [+] batch GLP material, through a [+] batch cGMP engineering development scale, in anticipation of an ultimate [+] modular manufacturing scale; includes analytical methods development and validation ([+], drug substance) and method qualification (drug product), and development of specifications for lot release.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Drug product on which [+] clinical trials have been completed.

3.2.2 [+] Process Development and Qualification: AVI will prepare drug substance for use in subsequent [+] studies (includes the use of previously manufactured components outside this RFP to prepare drug substance). The [+] development program will improve process reproducibility and prepare for manufacturing at larger scales. AVI will investigate several steps that have shown variability [+], and examine steps that have challenges in scale-up [+]. The overall goal of drug substance development is to design a [+] process that is highly reproducible, and that can be demonstrated at [+] scale, and usable in the final manufacturing [+] scale. [+]. A stable, [+] form of the drug substance will be produced.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Design scalable processes for [+] and drug substance.

3.2.2.1 [+] Process Development and Qualification: The [+] development program is aimed at improving reproducibility and scalability, and ensuring the quality of the product. The overall goal is to design [+] process that is highly reproducible and easily scalable.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Finalization of a highly reproducible and easily scalable [+] process in preparation for manufacturing at larger scales.

3.2.2.1.1 Synthesis and Characterization of Authentics: This project will help ensure a consistent quality of product. [+]. These authentics will be used as markers in the analytical method validation to check the resolution of the methods.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Preparation of authentic impurity markers

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3.2.2.1.2 [+] Process Development: The [+] development program is aimed at improving reproducibility and scalability. It will investigate several steps that have shown [+]. The overall goal is to design a [+] process that is highly reproducible and easily scalable.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Improvement of specific steps and finalization of a highly reproducible and easily scalable [+] process.

3.2.2.1.3 Project Management, Operations and Oversight: Project management will oversee the CROs that are performing [+] process development and will also manage the in-house development effort

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.2.2 Drug Substance [+] Process Development: The drug substance [+] process development program will involve optimization of the [+] components of the manufacturing process. The overall goal is to design a highly reproducible and scalable [+] drug substance manufacturing process that can be demonstrated at an [+] and is usable in the final manufacturing [+] scale.

Period of Work: Approximately [+] days from time of award (e.g. [+].

Deliverable: Demonstration of a reproducible and scalable manufacturing process for drug substance.

3.2.2.2.1 Drug Substance [+] Process Development: Development activities are to include optimization of [+] to produce a scalable synthesis process as well as optimization of current [+] process to increase efficiency of [+]. Investigation of alternative [+] methods [+] will also be conducted.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Optimization of the synthesis and [+] components of the manufacturing process.

3.2.2.2.2 Project Management, Operations and Oversight: This element entails oversight and guidance of the development activities, as well as management of technical personnel.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.3 Manufacturing for Nonclinical Studies: [+]** production will occur at [+], and will supply all the [+] needed for CLIN0001 drug substance manufacture, plus a contingency plan for any drug substance batch needing to be repeated (this is essential to ensureconcordance with the timeline). Any excess [+] will be used during the scale up in CLIN0002. The current [+] drug substance process will be transferred to a contract manufacturing organization (CMO) accomplished in the [+] manufacture of oligomeric therapeutic drugs. The CMO will perform scaling of process to [+], plus process development and Reduction to Practice (RtP) run(s). Material for toxicology studies will be made.

**Drug Product for the [+] clinical trial has already been manufactured and is currently stored awaiting final preparations for the start of the study.

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Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Produce drug substance for [+] studies using [+] scale drug substance process.

3.2.3.1 Manufacture [+]: This production is planned to occur at [+]. It will produce all the [+] needed for CLIN0001 drug substance manufacture plus a contingency if a drug substance batch needs to be repeated. Any excess [+] will be used during the scale up in CLIN0002.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Timely supply of [+] to support CLIN0001 drug substance development and manufacture.

3.2.3.1.1 Contract Negotiation, Material Acquisition: Finalize and sign contracts for production. Order long lead time and custom reagents to support upcoming campaign.

Period of Work: Approximately [+] month from time of award (e.g. [+]).

Deliverable: Contract and materials in place for [+] manufacture.

3.2.3.1.2 Manufacture [+]: Produce all the [+] needed for CLIN0001 drug substance development and manufacture.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Timely supply of [+] to support CLIN0001 drug substance development and manufacture.

3.2.3.1.3 Quality Audits and Review: Quality audits are managed by the Director of QA and scheduled in accordance with the Audit Master Schedule. Automatic audit reminders are issued by the EDMS. Auditors schedule travel to and from audits, write audit reports, provide lists of findings and make recommendations. The Director of QA oversees all operational aspects of audits, procedures connected with audits and audit reports. Audit findings, recommendations and responses are reviewed by the Director of QA, the VP of Regulatory Affairs and QA. Non-compliance issues are brought to the attention of the Chief Executive Officer (CEO), personally, by the Director of QA on a biweekly basis. In addition, a QA Unit and Compliance Report is written monthly by the Director of QA and presented to the CEO in a 1:1 meeting. Functional management and staffing of the QA Unit is the responsibility of, and managed by, the VP of Regulatory Affairs and QA.

Quality Audits include non-cGMP, non-GLP, cGMP or GLP audits, depending on the process step and may include audits of non-regulated facilities (non-cGMP and non-GLP facilities) or audits of facilities that are required to comply with cGMP or GLP. These are Direct Impact audits of Contract Manufacturing Organizations (CMOs), quality control testing , storage and distribution facilities connected with the manufacture of [+] and activated tails. Audit documentation includes a list of questions directly suited to the service provided by the CMO and an ICH Q7-compliant audit checklist. All CMOs must be audited and approved by QA and, when applicable, readiness for Pre-Approval Inspection (PAI) by the FDA or other regulatory agency is evaluated at an appropriate time during an audit. Audit records have limited, controlled review access for authorized departmental and senior management staff, and are

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reviewed through and archived using the EDMS.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: QA approved CMO (vendor) and release of manufactured [+] for AVI-6002 program. Audit report completed and satisfactory resolution of responses to findings for CMO providing [+]. Lot release of [+] for drug substance manufacturing program in accordance with QA-approved specifications using analytical methods.

3.2.3.1.4 Project Management, Operations and Oversight: Project management will oversee the CMO that is doing the CLIN0001 production.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.3.2 Manufacture Drug Substance: Select CMO experienced in [+] synthesis of [+] drugs. Tech transfer of [+] scale process for drug substance; scale-up of process to [+], process development and RtP run(s); determine stable [+] form for drug substance.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Achieve [+] scale drug substance process and produce material for [+] studies.

3.2.3.2.1 Select and Contract CMO: CMOs capable of performing [+] synthesis have been reviewed for suitability for the API manufacture, [+], and isolation. Site visits will be performed followed by quality audits, contract negotiations, technical transfer, and Quality agreement execution.

Period of Work: Approximately [+] months from time of award (e.g. [+])

Deliverable: Selection and completion of contracts with a suitable CMO for API manufacture.

3.2.3.2.2 Manufacturing Tech Transfer at 8L: Production will be introduced at the current [+] scale to allow comparability of previous lots and to transfer knowledge to the new CMO. Each API will be made and purified at this scale with the objective being to produce material suitable for toxicological studies.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Demonstration of successful tech transfer of current [+] sale and production of material suitable for [+] studies.

3.2.3.2.3 Process Development, Reduction to Practice at [+]: After the [+] tech transfer campaigns, the process size will be adapted to a [+] size as part of normal development in order to produce more material suitable for [+] studies. At this point process changes may be introduced to make the process more efficient as long as the impurity profiles remain unchanged.

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: Demonstration of scalability of manufacturing process to [+] scale by successful completion of RtP run(s).

3.2.3.2.4 Project Management, Operations and Oversight: As part of the normal course of outsourcing production, regular team meetings will be held and updates provided. Production oversight from site visits and data review will be shared and discussed. Regular conference calls with the CMO will be established to review progress and results.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget

3.2.4 Develop and Validate Analytical Assays and Lot Release Specifications: Existing analytical methods will be refined and validated for each [+]. Methods for drug substance will be developed and validated to meet characterization criteria set with the FDA for release. For the drug product assays, development will utilize synergies with drug substance methods to reduce time and cost of method qualification. For both drug substance and drug product, AVI will qualify vendors, facilities and conduct audits.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Validated assays for [+] and drug substance, qualification of the drug product assays, and development of lot release specifications for [+], drug substance and drug product.

3.2.4.1 [+] Analytical Method Development and Validation: Existing analytical methods will be refined and validated for each [+].

Period of Work: Approximately [+] days from time of award (e.g. [+])

Deliverable: Audited report for validated analytical methods for each [+].

3.2.4.1.1 Method Development and Validation: Methods confirming process consistency will be developed by a qualified subcontractor. Methods for assay and impurity profile will be validated to established criteria for cGMP starting materials.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audited report for validated analytical methods for each [+].

3.2.4.1.2 Identify Impurities above ID Threshold: Process-critical impurities will be synthesized and included in the validation process. Markers for known impurities will be synthesized as part of the impurity profile. Chromatograms of historic lots will be generated using the refined analytical methods. A team of chemists will work on identifying and synthesizing all impurities that occur [+].

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Identification and preparation of markers for all impurities that occur above the [+].

3.2.4.1.3 Develop (Assess and Refine) Lot Release Specifications: To ensure consistent quality, a team will assess and refine all the [+] lot release specifications.

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Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Preparation of a lot release specification for each [+].

3.2.4.1.4 cGMP Audits: See section 3.2.3.1.3 Quality Audits and Review for general description of Quality Audits. cGMP audits are performed by experienced auditors for the Contract Manufacturing Organizations (CMOs), quality control testing and storage and distribution facilities. Audits employ a checklist approach, based on regulatory requirements and ICH Q7 guidelines, which are customized to comply with requirements for each subcontractor site and circumstance. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of cGMP and GLP subcontractors is also evaluated. Under the Quality System, batch release specifications, test methods and quality control test results, protocols for stability studies and analytical methods and study reports or data are reviewed for compliance with regulations and guidelines and approved by the Director of QA.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audit report completed and satisfactory resolution of responses to findings by subcontract laboratories testing [+] for drug substance for subsequent clinical use.

3.2.4.1.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.4.2 Drug Substance (DS) Analytical Method Development and Validation: Drug substance analytical methods will be developed and validated to meet characterization criteria set forth by regulatory agency for release. Impurities will be isolated and identified. Subcontractors will be qualified, and audits performed, by AVI QA Unit.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Audited report for validated analytical methods for drug substance release.

3.2.4.2.1 Method Development and Validation: Methods, compliant with regulatory expectations, will be developed for impurity profile, assay, identity and description. Method validation will be performed by qualified vendor.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Methods for impurity profile, assay, identity and description, validated and audited report as appropriate.

3.2.4.2.2 Identify Impurities above [+]: Impurities will be identified and the identity verified by synthesis of authentic compounds. Detection level of impurities will be established.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Establish identity and detection levels of impurities.

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3.2.4.2.3 Develop (Assess and Refine) Lot Release Specifications: Release specifications will be established that ensure consistency between production lots. RTP batches will be used to refine release specifications and assess the analytical method capability to meet the specification threshold according to ICH Q6A recommendations. Director of QA participates in review and approval of specifications that are compliant with cGMP and compendial requirements.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: cGMP-compliant lot release specifications are approved for drug substance for subsequent clinical use.

3.2.4.2.4 Quality Audits and review: Documentation for drug substance (DS) analytical method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, reports are completed and satisfactory responses are received to audit findings. Director of QA reviews and approves validation protocols and validation reports for the analytical methods.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audits occur, audit reports are completed audit findings are resolved and validated analytical tests and methods are approved for drug substance.

3.2.4.2.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.4.3 Drug Product (DP) Analytical Method Development and Qualification: Drug product analytical method development and qualification will characterize phosphate buffered saline filled drug product. Method development will utilize synergies with drug substance methods to reduce time and cost of method qualification. Includes subcontractor qualification and audits by AVI QA Unit.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Qualified analytical test methods (validated assay method) that comply with the FDA's quality and regulatory requirements for release of drug product.

3.2.4.3.1 Method Development and Qualification: Methods, compliant with regulatory expectations, will be developed for impurity profile, assay, identity, and description. Method qualification will be performed by qualified vendor. A contract analytical development laboratory will be chosen, and methods for drug product analysis and release will be developed that comply with the FDA's quality and regulatory requirements.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audited reports for qualified methods for impurity profile, identity, and description and validated method for assay

3.2.4.3.2 Identify Impurities above ID Threshold: Impurities will be identified and the identity verified by synthesis of authentic compounds. Detection level of impurities will be established.

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Period of Work: Approximately [+] months (e.g. [+])

Deliverable: Establish identity and detection levels of impurities.

3.2.4.3.3 Develop (Assess and Refine) Lot Release Specifications: Release specifications will be established that ensure consistency between production lots. RTP batches will be used to refine release specifications and assess the analytical method capability to meet the specification threshold according to ICH Q6A recommendations.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Lot release specification in compliance with the FDA's quality and regulatory requirements for drug product for subsequent clinical use.

3.2.4.3.4 cGMP Audits: Documentation for drug product (DP) analytical method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.4.1.4 above. Audit occurs, report completed and satisfactory resolution of responses to findings by subcontract testing laboratories developing analytical methods and testing drug product for subsequent clinical use. Lot release will occur using QA-approved validated analytical methods and specifications compliant with compendia and other regulatory requirement.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Completed and QA reviewed validation reports. Audit report completed and satisfactory resolution of responses to findings by subcontract testing laboratories. Lot release tests and specifications that comply with the FDA's quality and regulatory requirements are approved by the Director of QA.

3.2.4.3.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.5 Nonclinical Toxicology: AVI will conduct [+] studies [+]. A new assay will be used for the determination of drug levels in biological matrices, and each component of the study drug will be assayed independently. The method will be validated (GLP) in plasma as is required for study protocols for pharmacokinetic analysis. An existing [+] will be transferred and validated (GLP) for the analysis of dosing solutions, over a [+]. The single dose [+] will evaluate the effect of a single dose on target organs observed. Quality Audits will be conducted on the contract research organization (CRO) and the audit records maintained by the AVI EDMS.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Completed GLP-compliant non-clinical toxicology study reports for studies in [+], including [+] reports.

3.2.5.1 [+] Method Validation: Feasibility studies have proven a [+] method acceptable for the determination of drug levels in biological matrices. Each component of the study drug is assayed

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independently. The method will be validated (GLP) in matrices corresponding to samples specified by study protocols for pharmacokinetic analysis [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report on validated [+] method for detection of drug levels in biological matrices.

3.2.5.2 Analytical Method Validation for Determination of Dose Solution Concentration: An existing [+] method will be transferred and validated (GLP) for the analysis of dosing solutions. The method will be validated over a concentration range suitable for determination of concentration, homogeneity, and stability of the dose formulations for the non-clinical toxicology studies.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Audited final report on validated method for concentration of drug levels.

3.2.5.3 [+]: The single dose [+] study will evaluate the effect of a [+]. The results will have an impact on the dosages and escalation in the [+] trial. This study requires validation of the analytical method.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.4 [+]: This study provides supportive data for the repeat dose study [+] that has been completed. Allow correlation of observed effects with exposure.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.5 [+]: In vitro study to assess the effects of the test article on [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.6 [+]: To investigate the actions of the test article/vehicle on action potential [+] methods. This study will identify potential risk of [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.7 [+] with Long Recovery: [+]. This study will determine [+] in multidose clinical trial

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] Study with Long Recovery.

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3.2.5.8 cGLP Audits: Quality Audits conducted in this arena are Direct Impact audits of our Contract Research Organizations (CRO). Audits include a list of questions directly suited to the CRO and a GLP/cGMP [+] checklist. All CROs (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. See section 3.2.3.1.3 for general description of Quality Audits. Audits of [+] facilities, [+] laboratories, and related study data will be conducted by experienced auditors from the Quality Unit. Audits employ a checklist approach, based on regulatory requirements (21 CFR Part 58 for GLP compliance) and ICH guidelines. The checklists are customized to comply with requirements applicable for each subcontractor facility and type of testing. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of GLP subcontractors is also evaluated.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audit and audit report completed and acceptable responses to findings received from subcontract [+] facilities and [+] laboratories testing AVI-6002 for [+]. GLP studies will occur using QA-approved protocols that meet regulatory and IUCAC and USG requirements and validated [+] methods are used.

3.2.5.9 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.6 Pilot [+] Studies: [+].

** [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Complete [+] studies.

3.2.6.1 [+]: [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, conduct and receive report for single vs combination agent AVI-6002 study.

3.2.6.2 GLP Audits: Quality Audits conducted in this arena are Direct Impact audits of our Contract Research Organizations (CRO). Audits include a list of questions directly suited to the CRO and a GLP/GMP (animal) checklist. All CROs (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. See section 3.2.5.8 above. See section 3.2.3.1.3 for general description of Quality Audits. Audits of animal testing facilities, bioanalytical laboratories, and related study data will be conducted by experienced auditors from the Quality Unit. Audits employ a checklist approach, based on regulatory requirements (21 CFR Part 58 for GLP compliance) and ICH guidelines. the checklists are customized to comply with requirements applicable for each subcontractor facility and type of testing. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of GLP subcontractors is also evaluated.

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Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable:. Audit and report completed and satisfactory responses to audit findings received from [+] facilities and [+] testing drug product for nonclinical studies. GLP studies will occur using QA-approved protocols that meet regulatory and IUCAC and USG requirements and validated bioanalytical methods are used

3.2.6.3 Project Management, Operations and Oversight: The antiviral team will meet regularly to review the protocol, monitor progress of the studies and evaluate observations. In addition, weekly conference calls with [+] will provide coordination of effort and timing.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.7 Contract Program Management:** AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall study are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

**Work will continue during period [+] on this program — namely [+] and regulatory to prepare for [+] clinical study. Program management will be required to oversee those tasks.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.2.7.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.2.7.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.2.7.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.2.7.4 EDMS Installation, Validation, Implementation, Training and QA: AVI will implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21CFR Part 11 compliant EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system will have been selected, installed and fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.3 CLIN0001 Technology Development — [+] Clinical Study (Part 2): Using the currently filed IND, and [+] data obtained subsequently, AVI will establish agreement with the FDA for the acceptable protocol** [+], such as [+] review and approval. AVI will conduct and report the [+] clinical study in healthy [+].

**Discussions with the FDA are planned for [+] which will cover the [+] and additional input to the proposed [+] study may be requested.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Final study report for [+] clinical study agreed upon by the government.

3.3.1 Support [+] Submission: An [+] cannot be granted until the appropriate legislative order has been given by Congress, however, AVI will submit a Request for Consideration for an [+] and briefing document (per Section 564(c) of the FD&C Act), amendments under Project Bioshield Act of 2004, and draft FDA Guideline of June 2005. The Request for Consideration will contain data from all available research and nonclinical studies together with draft protocol synopses for the [+] studies and the first clinical study. The FDA will be asked to provide advice on the additional requirements to achieve an [+].

As requested by the FDA in the meeting, AVI will continue to submit additional scientific, [+] and [+] study data in final study reports as [+] when the final reports are available with the intention of fulfilling all requirements for an [+] before such use is required.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Letter to the FDA requesting a meeting to discuss the Request for Consideration as an [+] and Briefing Document submitted as an [+]. In addition, after the meeting with the FDA the company's notes of the meeting with the FDA will be submitted as an [+].

3.3.1.1 Support [+] Submission, Meeting with FDA and USG: AVI's regulatory affairs staff will prepare the Meeting Request Letter and Briefing Document for the Request for Consideration as an [+] Meeting with the FDA and submit them as [+]. After the Meeting with the FDA, AVI's regulatory affairs staff will prepare notes of the meeting and submit them as an [+].

The Request for Consideration as an [+] submissions will be planned, prepared and managed by AVI's regulatory affairs staff, using FDA compliant electronic templates, e-publishing techniques and the EDMS. Meeting arrangements and follow-up Meeting Minutes will also be prepared and managed by RA. Oversight will be provided by AVI's senior management.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Letter to the FDA requesting a meeting to discuss a Request for Consideration as an [+] and Briefing Document submitted as an [+]. After the meeting with the FDA the company's notes of the [+] with the FDA will be submitted as an [+].

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3.3.1.2 Project Management, Operations and Oversight: Consideration as an [+] request managed by AVI regulatory affairs, using FDA compliant electronic templates, electronic document management and e-submission. Meeting arrangements and follow-up meeting minutes also managed by RA. Oversight is provided by AVI's senior management.

Period of Work: Approximately [+] month from meeting date being offered with FDA (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones to timeline and budget.

3.3.2 [+] Clinical Study: The [+] will be conducted with [+] to this award. The timeline will not allow AVI to wait for full manufacturing scale [+] cGMP drug product material, however the drug product used will be comparable and the assay method validated. The study and discussions with the FDA will be based on the IND already opened for drug product. Dosing will start at the [+]. Based on the pharmacokinetics, safety and general tolerability, [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] clinical study report; study conducted with research scale cGMP drug product.

3.3.2.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at an audited, selected [+] Clinical Research Facility with support from a fully CLIA accredited laboratory. From initiation onward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

Final report describing [+] clinical study conducted with research scale cGMP drug product manufactured at a cGMP-compliant facility.

3.3.2.1.1 Contracts and Budget: Contract and budget will be negotiated and agreed with the [+] CRO and supporting laboratories.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All contracts (site and laboratories) to permit study to be executed are agreed and signed.

3.3.2.1.2 Final Protocol to FDA; [+] submissions: Final [+] protocol submitted to FDA, [+]; feedback received and incorporated prior to study initiation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All approvals received before initiation of clinical study.

3.3.2.1.3 Site Activities: First Subject In to Last Subject Out: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with site will be documented. Regular site monitoring will be planned and documented to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical

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team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] clinical study conducted under cGCP and completed on schedule, within budget.

3.3.2.1.4 Site Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.3.2.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirming that subcontractors are trained to the study and ready to perform services.

3.3.2.2.1 [+] Method Validation: Feasibility studies have proven a [+] method acceptable for the determination of drug levels in [+] matrices. Each component of the study drug is assayed independently. The method will be validated (GLP) in matrices corresponding to samples specified by the clinical study protocol for pharmacokinetic analysis [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Validated [+] assay for drug levels in [+] matrices.

3.3.2.2.2 Clinical Research Organization and Data Management: The CRO is key to study success. Their team along with AVI personnel is responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.3.2.2.3 Central Laboratory Services and Data Transfer: Exploratory [+] accessioning and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: Laboratory data report.

3.3.2.2.4 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] charter will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed sessions. Members of the [+] will be available to review safety data and confirm or reject dose escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decision to dose escalate; continue or stop study as documented in meeting minutes.

3.3.2.2.5 Provide Electronic Data Management with Access to US Government: Enable [+] web portal with secure access to assigned study, company, vendor and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure EDC portal access.

3.3.2.2.6 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.3.2.3 Study Documents for Clinical Sites and Final Study Report: The Clinical Research Organization (CRO) is responsible for preparing and providing to AVI for review all appropriate study specific documents, except the clinical protocol. Upon AVI authorization the CRO will send these documents to the sites in preparation for study start. Additionally, should any unexpected or serious safety events be reported, the CRO will document, discuss with AVI medical monitor, and complete the appropriate forms. At the study end, the CRO will prepare the tables, listings and figures and draft the final study report which will then be finalized with AVI input.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.3.2.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], safety reporting, and Good Clinical Practice regulations.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, eCRF completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.3.2.3.2 Final Study Report: Prepare compliant and complete final clinical study report

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submission ready final clinical study report.

3.3.2.4 Regulatory Submissions and Templates: The near final draft clinical protocol, FDA Form 1571, FDA Form 3674, FDA Form 1572, information on the investigators (including a copy of the CV of the Principal Investigator), study facility, and [+] will be submitted as an [+] for review by the FDA. An electronic template that is compliant with electronic submission requirements will be used for the protocol. Other "Essential Documents" specified by the ICH guideline on Good Clinical Practice and 21 CFR will be collected and reviewed for compliance. The clinical study will be registered on www.Clinicaltrials.gov or an equivalent public access database.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: FDA Letter confirming that it is "Safe to Proceed" with the clinical study.

3.3.2.5 GCP Audits: Clinical data and document quality checks are carried out by clinical monitors during routine monitoring of each clinical study, as required under GCP. See section 3.2.1.3 for general description of quality Audits and Review. Quality Audits performed by experienced auditors from the QA Unit at clinical investigational sites (hospitals, etc.) are Direct Impact audits that will be specifically designed to verify compliance with GCP requirements and local and international regulatory regulations and guidelines. Audits will include contractor site selection audit, study audits during the study and an end of study audit. Audit documentation will be managed and archived in the EDMS

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audit and audit report are completed and satisfactory responses to audit findings are received from CRO's clinical facilities and [+] laboratories testing drug product in clinical studies. GCP-compliant clinical studies will occur using QA-approved protocols that meet regulatory and Institutional Review Board, HIPAA and USG requirements. Validated [+] methods are used for testing clinical samples.

3.3.2.6 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress as part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.3 Store Drug Product from Clinical Lot for 2 Years Past End of Study: Samples from the drug product batches used in the [+] clinical study will be stored under specified controlled storage conditions for 2 years past the completion of the study.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Store samples of drug product used in [+] clinical study.

3.3.3.1 Initiate Drug Product Storage at Drug Distributor Warehouse: Drug product from the clinical trial will be retained for at least 2 years past the end of the clinical study end. These samples will be held at the recommended storage temperature in a secured refrigerated unit that is calibrated and monitored.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Store samples of drug product used in [+] clinical study.

3.3.3.2 cGMP Audits: See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the subcontract facility storing and distributing AVI-6002 drug product for subsequent clinical use. Release and shipping of clinical supplies to clinical facilities will occur using QA-approved procedures that are compliant with GCP and local and international regulatory requirements.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audit and audit report are completed and satisfactory responses to audit findings are received from the CMO drug product storage facility and conditions are acceptable for drug product lots for subsequent distribution for clinical use.

3.3.3.3 Project Management, Operations and Oversight: Oversight of warehouse storage of drug product will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.4. Stability Studies: Samples from the [+] (drug substance and drug product) and [+] scale (drug substance), will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. A final stability report will be written by the Contract organization that performs the stability studies.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Samples of drug substance and drug product set up for [+] stability studies.

3.3.4.1 Contract Analytical Lab, Method Transfer, Short Term Stability of Drug Product at Dilutions for Clinical Study: Identify infusion sets, short term stability for at least [+].

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Report on short term stability of drug product under conditions of clinical study.

3.3.4.2 Contract and Initiate [+]: These studies will confirm the stability of the regular [+]. These studies are expected to confirm result from previous stability studies.

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Ongoing stability studies of [+].

3.3.4.3 Refine Stability Indicating Analytical Methods for Drug Substance and Drug Product: Forced degradation studies will identify degradants using HPLC/mass spectrometry. Once peak retention times are matched to degradant/impurity ID, stability program will utilize validated HPLC methods.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Completion of analytical method development for Drug Substance and Drug Product.

3.3.4.4 24 Months Stability Studies Drug Product: Drug substance and the resultant drug product will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. This is applicable to cGMP materials made at both the [+] scales. A final stability report will be written by the Contract organization that performs the stability studies.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Ongoing [+] study with drug product prepared for [+] clinical study in CLIN0001.

3.3.4.5 Ongoing Quality Audits and Review including [+] Stability Programs: Drug substance and the resultant drug product will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. This is applicable to cGMP materials made at both the [+] scales. A final stability report will be written by the Contract organization that performs the stability studies See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits and section 3.2.4.1.4 for a description of cGMP audits. cGMP audits occur, reports are completed and satisfactory responses to audit findings are received from subcontract laboratories conducting stability studies. Analytical testing occurs using QA-approved validated analytical methods and stability specifications compliant with compendia and other regulatory requirements.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Audit report completed and satisfactory responses to audit findings received. Stability data are reported at regular intervals and reviewed by AVI.

3.3.4.6 Ongoing Program Management, Operations and Oversight including [+] Stability Programs: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a [+] basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

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3.3.5 End of [+] FDA Meeting: AVI will request an End of [+] Meeting to discuss the future development plan including design of the [+] and the application of the [+] as soon as the data from the first clinical study is available, and appropriate questions of the agency can be formulated to enable the further clinical development. Agreement will be sought on fixed dose combination drug products, toxicology, toxicokinetics, clinical and pharmaceutical development of the drug substance and drug product, [+] development and review, with advanced notification of USG Program Office. The scheduling will depend on FDA, but the meeting should occur within 75 days of the formal request, and the briefing book will be sent to the FDA, at least 4 weeks ahead of the meeting. FDA feedback will be incorporated into the subsequent development plans. AVI's regulatory affairs staff will plan, prepare and compile the submission documents using electronic templates and e-publishing techniques; documents will be managed and stored electronically using the EDMS.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI submits an End of [+] Meeting Request Letter and Briefing Document to the FDA, participates in the meeting with FDA and prepares meeting notes. AVI reviews the FDA's official Meeting Minutes to assure that key elements of the discussions and agreements reached are documented. The FDA's requirements and expectations for the appropriate regulatory procedural enhancements leading to a potential [+] are clear.

3.3.5.1 [+] FDA Meeting Request [+], Preparation of Briefing Documents: Just before the completion of [+], AVI's regulatory affairs staff will manage, prepare and compile the [+] Meeting Request Letter and Briefing Document, with key components being provided by the research and development staff and subcontractors. The submission will be prepared using electronic templates, published using e-publishing techniques and all documents will be managed and controlled in the EDMS. The [+] Meeting will be planned and held, then AVI will prepare Meeting Notes that will be submitted to the FDA. The FDA's official Meeting Minutes will be reviewed for clarity and agreement with AVI's understanding of the outcomes. As necessary, AVI will continue proactive dialogue with the FDA by mutually convenient means.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: [+] Meeting Request Letter and Briefing Document submitted to the FDA. A meeting date is agreed and the meeting (with participation of appropriate USG representatives) is planned.

3.3.5.2 FDA Meeting, Minutes, Follow up: AVI and USG representatives will attend the End of [+] Meeting. Agreement will be sought on a variety of development and regulatory procedural topics including for example applicability of fixed dose combination drug product requirements, toxicology, toxicokinetics, clinical and pharmaceutical development of the drug substance and drug product, [+] development and review FDA feedback will be incorporated into the subsequent development plans.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: The [+] Meeting with the FDA occurs. AVI's Meeting Notes and the FDA's Meeting Minutes are prepared and reflect mutual agreements and understandings of the requirements for further development and the applicable regulatory procedures.

3.3.6 Complete [+] Clinical Trial and [+]: AVI will complete a [+] study to assess safety, tolerability and pharmacokinetics in [+] (RFP 3.3.2). The results from this first clinical study will be submitted to

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FDA as a supplement to the IND as soon as the data is available and the appropriate study reports are prepared.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct and complete [+] clinical trial Submission of an [+] containing the Final Study Report of the [+] Clinical Trial and other [+] as needed to support continuing nonclinical, pharmaceutical and clinical research and development.

3.3.6.1 Prepare for and Meet with FDA to Discuss [+]: Due to the complexity and uncertainty about the FDA's expectations and requirements for [+] approval using the [+], AVI's regulatory affairs group will plan, request and manage a specific, [+] Meeting with the FDA and other interested USG agencies to discuss the application of the [+]. A Meeting Request Letter and Briefing Document will be prepared and submitted at least 4 weeks ahead of the meeting. AVI will prepare Meeting Notes and will review the FDA's official Meeting Minutes to assure agreement on the issues discussed. If necessary, further clarifications may be requested in writing. AVI will continue an open dialogue with the FDA and USG agencies involved and document those discussions.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Meeting Request and Briefing Document, attendance at the [+] Meeting, AVI's Meeting Notes and FDA's official Meeting Minutes. Agreement with the FDA and USG agencies regarding the applicability and requirements for developing oligomeric drug products under the [+], and for [+] approval.

3.3.6.2 Prepare and Submit [+] and [+]: AVI will submit [+] containing appropriate research and development data to the FDA and provide notifications to USG Program Office The agreement of the FDA will be sought to submit the protocols for the [+] studies as well as the [+] safety study for [+] and the relevant protocols will be submitted. AVI's regulatory affairs staff will plan, prepare and manage all submissions as electronic documents using electronic templates, e-publishing techniques and the EDMS.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] will be submitted as [+] and the FDA's review comments will be incorporated before finalizing study protocols. [+] will be submitted as research and development data reports are available in order to keep the IND as current as possible. Copies of major submissions and correspondence will be forwarded to USG, as required.

3.3.6.3 Project Management, Operations and Oversight:

Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress as part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

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3.3.7 Deliver [+] of Clinical Material to US Government: A sample of the drug product used in the [+] clinical study will be provided to the USG.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample drug product used in [+] clinical safety study to USG.

3.3.7.1 Ship [+] to US Government: At the end of CLIN0001 at least [+] of the drug product(s) will be delivered to the recipient specified by the USG.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG.

3.3.7.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4 CLIN0002: AVI will deliver the developmental therapeutic end item that has achieved [+] clinical trials, based upon CLIN0001, additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for our candidate product to complete the USG Statement of Objectives in CLIN0002.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product on which [+] clinical trials have been completed.

3.4.1 Refine [+]: The critical goal of these studies is to obtain concurrence with FDA on the [+] study to be conducted under the [+]. Critical viral parameters will be addressed in PK/PD studies of [+], and in monitoring [+], both conducted at USAMRIID. The correlation of the [+] from natural infections, will guide the format and goals of the [+] study. The [+] study will be discussed and refined with the FDA. AVI will submit the protocols for the [+] prior to subcontracting the studies to USAMRIID (the proposed vendor to be pre-qualified as acceptable for GLP-compliant studies). The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Establish model for [+] Studies with FDA.

3.4.1.1 Delayed Time to Treatment in [+]: Critical efficacy parameters will be addressed in a study with various preplanned delays between exposure of [+] and initiation of treatment. The work will be conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete Delayed Time to Treatment Efficacy Study.

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3.4.1.2 [+]: Critical viral parameters will be addressed in [+], conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+].

3.4.1.3 Viral Time Course in [+]: Critical viral parameters will be addressed in this study conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete viral timecourse study in [+].

3.4.1.4 [+]: Critical viral parameters will be addressed in [+], conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+].

3.4.1.5 Quality Audits: See section 3.2.3.1.3 for a general description of Quality Audits. Audits of [+] facilities, [+] laboratories, and related study data will be conducted by experienced auditors from the Quality Unit. Audits employ a checklist approach, based on regulatory requirements (21 CFR Part 58 for GLP compliance) and ICH guidelines; the checklists are customized to address the quality and regulatory requirements for each subcontractor facility and type of testing. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of GLP subcontractors is also evaluated.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audit and audit reports are completed and satisfactory responses to audit findings are received from subcontract [+] laboratories testing drug product for nonclinical studies. GLP studies will occur using QA-approved protocols that meet regulatory and IUCAC and USG requirements and validated [+] methods are used for analysis of test articles.

3.4.1.6 Project Management, Operations and Oversight:

Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress as part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.2 Develop and Validate Analytical Assays for Drug Product: AVI will complete analytical

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methods development and validation for drug product and finalization of specifications for lot release of drug product. The development and validation of formulated product analytical test methods utilize the analytical test methods developed and validated for therapeutic drug substance, where applicable. The addition of compendial tests and limits for sterility,, to those for appearance, identification, assay and impurities will meet the regulatory requirements for lot release and for the product lots in ICHcompliant stability testing programs. The Director of QA will participate in the review and approval of analytical test methods, analytical validation protocols and reports, and drug product specifications that comply with compendia and other regulatory requirements.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Complete development of analytical methods, validation and specifications for drug product.

3.4.2.1 Drug Product Analytical Method Development and Validation: Drug product analytical development will exploit similarities between the drug substance and the drug product to accelerate development and minimize validation time. As with drug substance, multiple HPLC methods are required for purity identification. Includes vendor qualification, facilities and API process audits of batch records by AVI QA Unit. AVI will complete analytical methods development and validation for drug product and finalization of specifications for lot release of drug product. The addition of methods for sterility, to those for appearance, identification, assay and impurities will meet the regulatory scrutiny required for cGMP release and ICH stability.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete development of analytical methods for drug product, and audited validation report.

3.4.2.2 Refine Drug Product Lot Release Specification: Based upon the results from the CLIN0001 manufacturing experience product specifications for each of the drug substances and the drug product will be developed. For the individual drug substances these will be similar to those developed in CLIN0001 since [+] studies will have been based upon these specifications that were used in the IND. Refinement of the specifications will be made based upon new assay development and analysis of lots used in the [+] studies and clinical trials.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Develop specifications for each drug substance and drug product.

3.4.2.3 Quality Audits: Documentation for analytical assay method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from subcontract analytical testing laboratories developing and validating analytical methods for drug product for subsequent clinical use. The Director of QA participates in the review and approval of validation protocols and validation reports.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits occur, audit reports are completed and satisfactory responses to audit findings are

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received from the test facilities. Validated analytical methods are developed and approved.

3.4.2.4 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress as part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.3 Scale-up Manufacturing, Qualification and Validation of cGMP Manufacturing Process: Manufacturing goals will include scale-up of the raw material supply [+], as well as that of drug substance. Further suppliers will be qualified. AVI will manufacture the drug substance and drug product supply at [+] batch scale for the [+] clinical studies (. AVI will also initiate the development of the full manufacturing scale of [+] manufacturing, and initiate validation of [+], including for stability at this full [+] scale. The manufacturing facilities will be audited for compliance with cGMP and other quality and regulatory requirements by experienced auditors. The Director of QA will participate in the review and approval of process validation protocols and reports.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product for [+] clinical trials and validated drug substance for [+] clinical trials will be prepared. Release drug product lots for [+] clinical trials manufactured using a validated process at a cGMP-compliant facility. Lots meet the AVI-approved drug product specification and have been tested using validated analytical methods.

3.4.3.1 [+] Manufacturing Scale-Up: As part of the scale up process the [+] manufacturing supply chain needs to be established to produce [+] on the scale required to support the intended manufacturing scale-up. The current production capacity [+] multiple manufacturers will be utilized. However, even this effort will require expansion of [+] facilities for [+] of the activated [+]. [+] are needed to be made at the [+] to support scale up activities.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Assured supply for [+] and other raw materials.

3.4.3.1.1 Contract Additional [+] Manufacturing and [+] Sites: Negotiate and sign contracts with the additional [+] manufacturing and [+] CMOs.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Selection and contract finalization of additional [+] CMOs.

3.4.3.1.2 Manufacture of [+]: Complete tech transfer with all new CMOs. Scale-up the [+] production process and manufacture the required [+] to support the drug substance manufacture.

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Timely supply of [+] to support drug substance manufacture.

3.4.3.1.3 [+] Development and Validation: Evaluate the feasibility of [+] recovery. The Director of QA participates in the review and approval of process protocols and reports.

Period of Work: Approximately [+] months (e.g. [+].

Deliverable: Report on feasibility and impact on cost of [+].

3.4.3.1.4 Quality Audits and Review: See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed audit reports. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO. Approved master batch records are developed for manufacturing [+] at the approved scale.

3.4.3.1.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project plan compliance, report progress. Progress and any issues will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.3.2 Manufacturing Scale-Up, Large Scale Manufacturing and Validation: GMP drug product for [+] clinical trial will be manufactured from cGMP drug substance prepared at [+] scale previously demonstrated in CLIN0001. The process will be scaled from the [+]. The drug substance process will undergo process validation in which [+] lots of drug substance are made at the [+] commercial scale and placed on stability. Material from the first validation lot will be used to manufacture drug product for [+] clinical trial. Quality Audits conducted in this arena are Direct Impact audits of our Contract Manufacturing Organization (CMOs) first cGMP run. It will include observation of the manufacturing process per cGMP/Q7 guidelines and will be documented with a report that will be added to the initial CMO audit and filed within EDMS. The Director of QA participates in the review and approval of process validation protocols and reports.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited validation report for large scale manufacturing at a suitably qualified CMO.

3.4.3.2.1 Manufacture and release cGMP drug substance and drug product Based on experience from CLIN0001, the APIs will be produced under cGMP conditions at the [+] scale at this stage and drug product will be manufactured for [+] clinical trial. Production and QA oversight will be given and data generated carefully reviewed. The Director of QA participates in the review and approval of batch records and in the review of analytical testing of drug substance prior to approving lot

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release

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product for [+] clinical trial.

3.4.3.2.2 Drug Substance Manufacturing Scale Up to [+]: From the [+] scale, the process will be increased to a [+]. The purpose of using a smaller reaction size in a larger capacity reactor is to control costs during clinical development, but enable future scale increases in already qualified equipment. This allows minimization of costs during the program and later enables production of RFP threshold quantities for commercial production.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Demonstration of [+] scale manufacturing process by successful completion of RtP run(s).

3.4.3.2.3 Validation of cGMP Drug Substance Manufacturing Process: Once the [+] scale is established, a process validation protocol will be written and executed under the guidance of the CMO with direct input from AVI. Results of this validation will be reviewed and, if acceptable, approved. The protocol will contain acceptance criteria in order to evaluate the success. The Director of QA participates in the review and approval of validation protocols, validation reports, and master batch records,

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited validation report for drug substance manufacturing process at [+] scale.

3.4.4 Refine and Select Drug Product Formulation: AVI will work with a formulation contract CRO, and a drug product CMO to formulate a [+] drug product that will show enhanced stability without cold storage conditions.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Decision on final formulation for drug product formulation.

3.4.4.1 [+] Product Screening Studies: Determine important physicochemical parameters leading to design of solution [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final lyophilized formulation.

3.4.4.2 Accelerated Stability Studies Leading to Selection of Lyophilized Drug Product Formulation: [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final [+] formulation.

3.4.4.3 Determine Extractables and Leachables: Determine if any chemical components are extracted

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or leached from containers, closures, or materials used in administration of the drug.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final [+] formulation.

3.4.4.4 Quality Audits: Perform audit/review of all documentation See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. The CMO developing the drug product formulation is audited to qualify the contractor as acceptable. An audit report is completed and satisfactory responses to audit findings are received. The formulation study protocols, draft batch records and data obtained during manufacture of the new formulation, and the results of analytical testing are reviewed by the Director of QA. The Director of QA participates in the review and approval of a master batch record, analytical test methods and their validation and proposed specifications derived from the development of a new formulation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed Audit reports. Master batch record, analytical test methods and their validation protocols and reports and revised specifications for the new formulation reviewed and approved by the Director of QA.

3.4.4.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.5 Manufacture cGMP Material at Scale for Nonclinical and Clinical Studies and Consistency Lots: AVI will prepare cGMP drug product for the [+] clinical safety studies from the first validation batch of [+] scale drug substance. Three drug product batches will be validated, and all will provide material for stability studies.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] scale cGMP drug product manufactured for [+].

3.4.5.1 Drug Product Engineering Runs: Drug product configuration and process will be transferred to CMO; engineering runs will be performed to confirm successful transfer.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Process suitable for GMP drug manufacture.

3.4.5.1.1 Drug Product Engineering Run 1 An engineering run is planned with the first drug substance of the combination product manufactured in CLIN0002 for the purposes of testing all fill finish capabilities including [+], formulation testing, and product testing for adherence to product specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Successful tech transfer and final process suitable for GMP drug manufacture.

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3.4.5.1.2 Drug Product Engineering Run 2 An engineering run is planned with the first drug substance of the combination product manufactured in CLIN0002 for the purposes of testing all fill finish capabilities including [+], formulation testing, and product testing for adherence to product specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Successful tech transfer and final process suitable for GMP drug manufacture.

3.4.5.2 Manufacture, Release, Label 3 Consistency Lots of Drug Product: Material produced at scale will be filled for the clinical lots and for the consistency lots at a size commensurate with the production scale of the contract manufacturing organization.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Released, labeled drug product for clinical trials.

3.4.5.3 cGMP Audits: All manufacturing sites for which a scale up is required has been previously audited and approved by QA. The actual scale up of drug product manufacturing includes a review of all relevant documentation for any pertinent quality issues, content uniformity, completion and an onsite QA "for cause" visit if required. See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO. Batch records and analytical test data for lot release are reviewed by the Director of QA. Release and shipping procedures for clinical supplies to clinical facilities are reviewed.

The Director of QA reviews and approves batch records, batch production data and results of analytical testing for lot release.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed audit reports. Audits occur, audit reports completed, satisfactory responses are received for any audit findings, master batch records and other documents are reviewed and approved for manufacturing and release of drug product.

3.4.5.4 Project Management, Operations and Oversight: The program will be managed by AVI personnel and consist of initial technology transfer and reduction to practice lots prior to cGMP production. Hands on training may be provided initially but after establishment of the process and successful manufacturing the program will be managed through conference calls, sites visits, audits, data and document review including specifications and comparison of release data with those specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.6 Stability Studies: Drug product will be evaluated according to ICH stability requirements. The duration of the stability program is [+], and it will exceed the minimum requirement in the statement of objectives and Target Product Profile (TPP) threshold. The stability program includes full term aging studies at [+] will not be performed on the drug substance, but will be performed on the lyophilized drug product.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Stability studies of [+] and validated drug substance have been initiated. Stability studies set up for [+] scale cGMP drug product material manufactured for [+] safety studies.

3.4.6.1 Stability on [+] and Drug Substance ([+] Stability Program Starts): Follow ICH guideline Q1A to acquire data to justify retest date at defined storage condition.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Completion of stability studies from CLIN0001 and initiation of studies on [+] and validated drug substance.

3.4.6.1.1 Ongoing Stability on [+]: This is the completion of the [+] stability program started in CLIN0001.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of stability studies of [+].

3.4.6.1.2 Stability Studies Drug Substance ([+] Stability Program Starts): Each drug substance manufactured will be placed on a [+] stability program in order to demonstrate the long term product characteristics of the material. Since these drug substances are at a new scale of production stability needs to be performed until a suitable quantity of lots have been made to demonstrate shelf life. All lots made in CLIN0002 will be placed on stability.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Initiation of stability program for drug substance.

3.4.6.2 Stability on Drug Product ([+] Stability Program Starts): Follow ICH guideline Q1A to acquire data to justify expiration date at defined storage condition.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Initiation of stability program for drug product.

3.4.6.2.1 Ongoing Drug Product Stability Studies: Continue ICH guideline Q1A to acquire data to justify expiration date at defined storage conditions. Drug product manufactured prior to the start of CLIN0002 will continue on stability and final reports will be issued at the end of the study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Ongoing stability data for drug product.

3.4.6.2.2 Stability Studies Drug Product ([+] Stability Program): New drug product stability studies will be set up for [+]. Multiple temperature storage conditions will be examined to provide the storage conditions for optimal use.

Period of Work: Approximately [+] week (e.g. [+]).

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Deliverable: Initiation of stability program for drug product.

3.4.6.3 cGMP Audit: Stability Study Audits are Direct Impact audits. Audits include a list of questions directly suited to the supplier and a cGMP, GLP (Analytical) checklist (again dependent on supplier). All suppliers (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO conducting stability studies for AVI. The Director of QA reviews and approves stability study protocols as well as reports on stability data.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited final report on stability and shelf life of drug product. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received in order to qualify the CMO. Stability study protocols are reviewed and approved.

3.4.6.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.7 Stability Testing to Define Operational Storage (Time Temperature Indicator): Each drug product is [+], which makes room temperature storage feasible and reduces cold chain requirements, exceeding minimum requirement in the statement of objectives and TPP threshold. The scope of the stability studies will establish the Time Temperature Indicator (TTI), since it includes full term accelerated conditions. Based upon the results, a TTI can be established to support the product shipments. As part of the operational storage and distribution criteria, product shipments will be monitored for excursions during shipment using temperature monitoring devices.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Stability studies set up for [+] scale cGMP product material to establish TTI.

3.4.7.1 Conduct Stability Studies under [+]: These studies will be conducted at [+] temperature than the recommended storage condition to determine additional time that the material may exposed to harsher conditions without risk.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Stability studies completed to establish TTI.

3.4.7.2 Conduct Shipping and Transport Stability Studies: These studies will show that the drug product is stable under the actual conditions of shipping.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Stability studies completed to establish TTI.

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3.4.7.3 Quality Audits: Stability Study Audits are Direct Impact audits. Audits include a list of questions directly suited to the supplier and a cGMP, GLP (Analytical) checklist (again dependent on supplier). All suppliers (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. The Director of QA reviews and approves stability study protocols as well as reports on stability data.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Documented audit findings Approved stability study protocol and approved study data and reports.

3.4.7.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.8 Conduct Nonclinical Studies: In addition to the multiple studies completed to date and forming the basis for the open IND, the studies since then and prior to this award that will supplement that IND, AVI will also complete further [+] studies, for example [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct [+] scale cGMP product material.

3.4.8.1 [+]: [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final Report on [+].

3.4.8.2 [+]: [+] to provide data necessary for registration.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Sufficient [+].

3.4.8.3 [+] Mass Balance: Mass balance study required to show fate of drug in [+]; required data for registration.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final report from CRO on mass balance in the [+].

3.4.8.4 [+] in vivo Metabolism: Provide data on metabolism of drug in [+] model. Required for registration and determination if any metabolites are present that need to be monitored in preclinical and clinical trials.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final report from CRO on in vivo metabolism in the [+].

3.4.8.5 [+]: [+].

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final report from CRO on protein binding.

3.4.8.6 [+] Dose Range Finding Study: To determine the effect of treatment on the [+] development, with determination of appropriate dose levels for the definitive [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited final report on [+] study.

3.4.8.7 [+] Study: The definitive study to determine the effect of treatment on the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report on [+] study.

3.4.8.8 Quality Audits: All preclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLPs and protocol; monitoring will also be done by CRO QA unit. Study reports reviewed by CRO QA unit and by AVI to assure accuracy See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. GLP audits occur, reports are completed and satisfactory responses to audit findings are required from CROs conducting AVI-6002 nonclinical studies and [+] testing facilities. Analytical testing occurs using AVI's QA-approved validated analytical methods. The Director of QA participates in the review and approval of [+] method validation protocols and validation reports. All nonclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLP requirements. Study monitoring will also be done by the CRO's QA unit. Study reports and data listings will be reviewed by the CRO's QA unit and by AVI's monitor and QA Unit to assure accuracy.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from nonclinical CROs and [+] testing facilities. Study reports and data listings will be reviewed and approved by the CRO's QA unit and by AVI's monitor and QA Unit.

3.4.8.9 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.9 [+] Efficacy Studies in [+]: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+]. Using the currently filed IND, clinical safety and any animal data obtained during CLIN0001, any additional preclinical data, and based on the protocol developed with FDA as to the studies necessary under the [+], AVI will conduct the [+] studies, necessary to show protection against an [+] challenge by injection.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale cGMP product material.

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3.4.9.1 [+] Efficacy Studies in [+] #1: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale AVI-6002 cGMP product material

3.4.9.1.1 [+] Acquisition and Acclimation: Prior to [+] protocols are reviewed by [+]. Once protocols are approved, [+]. [+] are held in quarantine to ensure acclimation to the laboratory setting and receive a final health evaluation. Finally, randomization and cage arrangements are finalized.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Sufficient [+] acclimated and released for first pivotal study to begin.

3.4.9.1.2 Conduct Study, Laboratory Analyses, Viral Sequencing: This is the "in-life" phase of the study involving [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of the [+] portion of the first [+] study.

3.4.9.1.3 Data Analyses, Final Study Report: Compile observations and unblind data. Statistical analysis and preparation of a final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Presentation of final study report.

3.4.9.2 [+] Studies in [+]: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale AVI-6002 cGMP product material

3.4.9.2.1 [+] Acquisition and Acclimation: Prior to [+] protocols are reviewed by [+]. Once protocols are approved, [+] acquisition can take place. [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Sufficient [+] acclimated and released for second pivotal study to begin.

3.4.9.2.2 Conduct Study, Laboratory Analyses, [+]: This is the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of the [+] portion of the [+] study.

3.4.9.2.3 Data Analyses, Final Study Report: Compile observations and unblind data. Statistical analysis and preparation of a final study report.

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: Presentation of final study report.

3.4.9.3 Data Management: Full data management and statistical analysis plans will be developed by a qualified Contract Research Organization, and shared with the FDA (and USG) before studies completed. The CRO will monitor source documents (to the extent possible in a BSL4 environment), collect data, ensure all data queries are clarified, lock database, analyze and then reveal treatment allocation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Conduct analyses of pivotal efficacy studies for study reports.

3.4.9.4 GLP Audits: See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. GLP audits occur, reports are completed and satisfactory responses to audit findings are required from CROs conducting nonclinical studies and [+] testing facilities. Analytical testing occurs using AVI's QA-approved validated analytical methods. The Director of QA participates in the review and approval of [+] method validation protocols and validation reports. All nonclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLP requirements. Study monitoring will also be done by the CRO's QA unit. Study reports and data listings will be reviewed by the CRO's QA unit and by AVI's monitor and QA Unit to assure accuracy

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from nonclinical CROs and [+] testing facilities. Study reports and data listings will be reviewed and approved by the CRO's QA unit and by AVI's monitor and QA Unit.

3.4.9.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project plan compliance, report progress. Progress and any issues will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.10 Activities to Achieve Pivotal Efficacy Studies: AVI will prepare and submit [+]. The Final Protocols for the [+] studies will also be submitted after the FDA responses are received from the [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] submitted to the FDA.

3.4.10.1 [+] (Clinical, Nonclinical): [+] will be submitted as soon as study reports are available to keep the [+]. The Final Protocols for the [+] studies will also be submitted as [+] after the FDA responses are received from the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] submitted to the FDA.

3.4.10.2 [+] (Drug Substance, Drug Product): [+] will be submitted as soon as data are available on the lots of drug substance and drug product that will be used in the [+] Studies are available.

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Additional [+] will be submitted as reports and data are available to keep the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Prepare and submit [+].

3.4.10.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.11 Request and Conduct [+] Meeting with the FDA: AVI will request an [+] to provide a summary of results of the [+] clinical studies and to discuss the [+] clinical development plan. The topic of designation as a [+]. A Meeting Request Letter and Briefing Document will be submitted to the FDA. Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG Program Office in a timely manner. After the meeting AVI's regulatory affairs staff will prepare and submit notes of the meeting as an [+]. The FDA's official Meeting Minutes will be reviewed to ensure that they reflect the same meeting outcomes and agreements as those documented by AVI.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] Request and Briefing Document submitted to the FDA. Participate in [+] meeting with FDA. Prepare notes of the meeting and review the FDA's official Meeting Minutes to assure that both the FDA and AVI agree on the outcomes of the discussion and agreements.

3.4.11.1 Prepare Meeting Request and Briefing Document: The Meeting Request Letter and Briefing Document will be prepared as soon as is feasible and submitted to the FDA at least one month in advance of the requested meeting date. . Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG Program Office in a timely manner.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: [+] Meeting Request Letter and Briefing Document submitted to the FDA.

3.4.11.2 [+]: [+].

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Submit request for [+] to the FDA.

3.4.11.3 FDA Meeting, Minutes and Follow Up: AVI will attend the [+] with the FDA. AVI will submit notes of the meeting to the FDA and ensure that the company is in agreement with the outcomes and agreements recorded in the FDA's official Meeting Minutes. Clarifications will be

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requested, as necessary. AVI will continue an open dialogue with the FDA as development continues.

Period of Work: Approximately [+] week (e.g. [+]).

Deliverable: AVI will provide copies of the company's notes and the FDA's official Meeting Minutes to the USG Program office.

3.4.11.4 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track compliance, report progress. Project progress and any issues relative to the development plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+])

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.12 [+]: [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG

3.4.12.1 Ship [+] to US Government: At the end of CLIN0002 at least [+] of the drug product(s) will be delivered to the recipient specified by the US Government.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG

3.4.12.2 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.13 Phase 2 Multidose Dose Escalation Clinical Study: A [+] Volunteers. A goal for this study is to establish a [+], the intended therapeutic schedule. [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Complete [+] clinical study and issue final clinical study report.

3.4.13.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from selected, fully [+] accredited laboratory. Site and laboratory will have had satisfactory GCP/GLP audits and then site will be initiated, monitored through to study completion and close out.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

3.4.13.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study.

3.4.13.1.2 Protocol [+] Approval: Full [+] in parallel; AVI will answer any questions and amend protocol if necessary. The Amended protocol will be submitted to the [+] for approval prior to and notification of site(s) start study. All required information about the investigator, site, testing laboratories and CRO responsibilities will be submitted to the FDA prior to study start at any site.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: FDA, Ethics Committee and [+] approvals received before study start.

3.4.13.1.3 Site Activities First Patient First Visit to Last Patient Last Visit: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the site will be documented. Regular site monitoring will be planned and documented to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+] study and complete electronic case report forms on schedule and within budget.

3.4.13.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.4.13.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

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3.4.13.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team, along with AVI personnel, is responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.4.13.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

3.4.13.2.3 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then [+] meetings with open and closed session. Members of the [+] will be available to [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decisions to [+] as documented in meeting minutes.

3.4.13.2.4 Provide Electronic Data Management with Access to US Government: Enable Medidata web portal with secure access to assigned study, company, vendor, and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure EDC portal access.

3.4.13.2.5 Drug Warehousing and Distribution: Store clinical trial material at [+] in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.4.13.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Shipping receipts showing what was sent to whom and when.

3.4.13.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable:. All study related documents including but not limited to: study plan and timeline, [+] completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.4.13.3.2 Final Study Reports: Prepare submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit compliant and complete [+] will be submitted to the FDA as an [+].

3.4.13.4 GCP Audits: Audits will be performed of Clinical Study Sites.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the CRO's QA unit and by AVI's monitor and QA Unit.

3.4.13.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.14 [+] Clinical Study: AVI will conduct a [+]. A specialized [+], is expected to support efficient enrollment and evaluation. Subject accrual and treatment is scheduled for less than [+] months. The results will be available for the planning of the expanded [+] trial.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct [+] clinical study using [+] scale cGMP drug product material and issue final clinical study report.

3.4.14.1 Clinical Site and Local Laboratory Activities: Clinical sites and laboratories will be audited for compliance with GCP, selected and then initiated, monitored through to study completion and close out. The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from a fully [+] accredited laboratory. From initiation forward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

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3.4.14.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study.

3.4.14.1.2 [+] Approval: Full protocol will be submitted to [+] in parallel; AVI with CRO will answer any questions and amend protocol if necessary to ensure final ethics approval, and notification of site(s) prior to study start.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All approvals received before initiation of clinical study.

3.4.14.1.3 Site Activities First Patient in to Last Patient Out: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the site will be documented. Regular site monitoring will be planned and documented to AVI (or Contract Research Organization staff) will monitor conduct of the [+] study to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete in life portion of [+] study and complete electronic case report forms on schedule and within budget.

3.4.14.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.4.14.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

3.4.14.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team, along with AVI personnel, is responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This

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group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.4.14.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab run at one facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

3.4.14.2.3 [+]: An independent **[+]** will be appointed to oversee and confirm dose escalation decisions. A **[+]** charter will be prepared and agreed with **[+]** members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed session. Members of the **[+]** will be available to review safety data and confirm or reject escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decisions to dose escalate, continue or stop study as documented in meeting minutes.

3.4.14.2.4 Provide Electronic Data Management with Access to US Government: Enable [+] with secure access to assigned study, company, vendor and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure [+] access.

3.4.14.2.5 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.4.14.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.4.14.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide

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complete set of documents and forms to effectively and efficiently conduct study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, [+] guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.4.14.3.2 Final Study Report: Prepare Submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: The Final Study Report will be submitted to the FDA as an [+]. Submit compliant and complete final clinical study report.

3.4.14.4 GCP Audits: Audits will be performed of Clinical Study Sites.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the CRO's QA unit and by AVI's monitor and QA Unit.

3.4.14.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.15 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall program are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable. In addition AVI will continue to implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21 CFR Part 11 compliant EDMS and preparation for electronic submission of documents to the FDA. The EDMS will be utilized for document management and control, including collaborative authoring of study reports and eCTD text for the [+], revision and versioning control with metadata for audit trails, and secure document repository. The EDMS will provide authorized representatives of USG electronic access to program status information. The use of eCTD compliant document templates and completed reports for electronic submissions to the FDA will be managed, controlled, archived and regulated under the Quality System in the EDMS.

Period of Work: Concurrent with all CLIN0002 activities. Approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.4.15.1 Program Management: Track progress and manage issues as they arise.

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Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.4.15.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.4.15.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.4.15.4 EDMS and QA: AVI will continue to store all documents on the validated EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.5 CLIN0003: AVI will deliver the developmental therapeutic end item that has achieved [+] Clinical Study, based upon CLIN0001 and CLIN0002 (recognizing that some activities will be concurrent), additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for our candidate drug product to complete the USG Statement of Objectives in CLIN0003.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product on which [+] Clinical Study has been completed.

3.5.1 Complete Pivotal Efficacy Studies: This has been moved to CLIN0002 3.4.9.1 and 3.4.9.2.

3.5.2 [+]: Continue to implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21CFR Part 11 compliant EDMS and preparation for electronic submission of documents to the FDA.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Submit the quality amendment to FDA as a supplement to the AVI-6002 [+].

3.5.2.1 Write and Submit [+]: Update information stored on EDMS and preparation for electronic submission of documents to the FDA.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit the quality amendment to FDA as an [+].

3.5.2.2 Respond to FDA Questions: Develop and provide response to any questions or

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recommendations from FDA following filing of [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit to FDA as an [+].

3.5.2.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report project progress. As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.3 [+] Study: Using the currently filed AVI-6002 [+], clinical safety and any [+] data obtained during CLIN0001 and CLIN0002, AVI will initiate the [+] Study in [+] using the protocols agreed with FDA, while ensuring all necessary [+] study requirements such as [+] review and approval. AVI will conduct this [+]. FDA concurrence that this will be sufficient for the safety database to [+] will be sought.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct and audit [+] study and issue final study report.

3.5.3.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from a fully [+] accredited laboratory. From initiation forward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

3.5.3.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study

3.5.3.1.2 [+] Approval: Full protocol will be submitted to [+] in parallel; AVI with the CRO will answer any questions and amend protocol if necessary to ensure final ethics approval and notification of site(s) prior to study start.

Period of Work: Approximately [+] months (e.g. [+])

Deliverable: FDA, Ethics Committee and [+] approvals received before initiation of the [+] safety study.

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3.5.3.1.3 Site Activities First Patient in to Last Patient Out: The study will be planned and executed at an audited, selected clinical sites. Sites will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the sites will be documented. Regular site monitoring will be planned and documented to AVI (or Contract Research Organization staff) will monitor conduct of the [+] study to ensure data have been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete in life portion of pivotal safety study and complete electronic case report forms on schedule and within budget.

3.5.3.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.5.3.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

3.5.3.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team, along with AVI personnel, is responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.5.3.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

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3.5.3.2.3 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed session. Members of the [+] will be available to review safety data and confirm or reject escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide safety oversight for pivotal safety study. Decisions to dose escalate, continue or stop study as documented in meeting minutes.

3.5.3.2.4 Provide Electronic Data Management with Access to US Government: Enable [+] with secure access to assigned study, company, vendor and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional, secure [+] access.

3.5.3.2.5 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.5.3.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.5.3.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, eCRF completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.5.3.3.2 Final Study Report: Prepare submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit compliant and complete final clinical study report.

3.5.3.4 GCP Audits: Audits will be performed of Clinical Study Sites.

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the CRO's QA unit and by AVI 's monitor and QA Unit.

3.5.3.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.4 Refine and Select Formulation and Delivery System: AVI will continue the assessment of stability for the validation lots prepared in CLIN0002. The drug kit per treatment will comprise [+]. The storage of the kit will be [at room temperature (15°C to 30°C)]. This drug product kit meets the [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Finalize the drug kit components for drug product.

3.5.4.1 Determine Configuration for Market: All details of the commercial formulation are finalized ([+]).

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Finalize the drug kit components for AVI-6002 product.

3.5.4.2 Identify Manufacturer for Packaging Final Product: Establish contract for assembling final marketing packages.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Finalize the vendor for manufacture, labeling and packaging of AVI-6002 product.

3.5.4.3 Continue Drug Substance and Drug Product Stability Studies: Continue drug substance and drug product stability studies.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Continue stability for drug substance and drug product.

3.5.4.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.5 Deliver [+] to US Government: Deliver at least [+] of product, from the lot used for the [+] study.

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Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] study to USG.

3.5.5.1 Deliver [+] to US Government: At the end of CLIN0003 at least [+] of the drug product(s) will be delivered to the recipient specified by the USG.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] study to USG

3.5.5.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.6 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall program are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.5.6.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0003 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3. 5.6.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.5.6.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0003 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.5.6.4 EDMS and QA: AVI will continue to store all documents on the validated EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and

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any follow up action items identified and tracked.

3.6 CLIN0004:AVI will deliver the FDA approved therapeutic end item including all New Drug Application and Approval activities resulting in the delivery of at least [+], based upon CLIN0001, CLIN0002 and CLIN0003 (recognizing that some activities will be concurrent), additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for [+] drug product to complete the USG Statement of Objectives in CLIN0004.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product approved by FDA.

3.6.1 [+] Meeting with the FDA: A [+] Meeting with the FDA will be requested and a Briefing Document submitted approximately one month in advance of the meeting. The FDA will schedule the meeting within 60 days of the request. The purpose of the [+] Meeting is to reach agreement on the electronic format and content of the [+]. The [+] will also be discussed at this meeting. AVI will prepare notes of the meeting that will document the discussion and agreements with the FDA; the notes will be submitted to the FDA. The FDA will issue official Meeting Minutes. AVI will follow up to request clarifications, as needed.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI prepares and submits Request Letter and Briefing Document, participates in the [+] meeting with the FDA, prepares notes of the meeting that are submitted to the FDA.

3.6.1.1 Prepare Meeting Request and Briefing Documents: The [+] Meeting Request Letter and Briefing document will be prepared and submitted as soon as is feasible after the completion of dosing in the clinical trials approximately [+] ahead of the meeting. Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG in a timely manner.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: AVI [+] Meeting Request Letter and Briefing Document are submitted to the FDA.

3.6.1.2 [+] Meeting, Minutes and Follow Up: AVI will participate in the [+] with FDA, take notes and obtain official minutes, following up on any action items due. AVI will provide copies of the FDA's Meeting Minutes to USG.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: AVI's [+] Meeting notes and the FDA's official Meeting Minutes.

3.6.1.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.2 Prepare, Submit and FDA Review of [+]: AVI will electronically submit an [+] that meets the USG's Target Product Profile. By using eligibility as a small business enterprise, and employing regulatory procedural relief benefits due [+], AVI is planning for the [+] to be prior to the completion of the contractual period proposed. During the FDA's review, AVI will remain ready to respond promptly to any questions that arise by using secure email correspondence. The USG will be kept fully informed of progress.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI prepares and electronically submits an [+] that meets the FDA's requirements for review and validation.

3.6.2.1 Complete and Submit [+] and Respond to FDA Review Comments: AVI will complete and submit an [+] to the FDA; and respond in a timely fashion to Information Requests and other comments from the FDA reviewers.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: An [+] that has been submitted electronically to the FDA and accepted for filing as an appropriately structured electronic submission. Responses to Requests for Information and the [+] from the FDA will be answered promptly.

3.6.2.2 Project Management and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.3 [+] and Response to FDA [+]: Given the issues faced by the FDA [+], it is likely that the FDA [+]. AVI will attend and participate in an ACM, and respond promptly to any questions in the [+] approval occurs.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Responses to Requests for Information from the FDA will be submitted promptly. AVI will prepare a Briefing Document and presentation materials for an [+]. Draft notes of the [+] will be prepared.

3.6.3.1 [+]: AVI will plan and prepare and, once confirmed, attend and participate at [+].

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: AVI will prepare a presentation and Briefing Document in advance of the ACM.

3.6.3.2 Prepare and Submit Complete Response to [+]: At the conclusion of their review, the FDA will issue a [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete Response will be made to any questions asked by the FDA.

3.6.3.3 Project Management and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.3.4 [+]: AVI will receive formal confirmation [+]. AVI will submit [+] and participate in the final negotiations of the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Receipt of the [+]. A copy will be sent to the USG Program office.

3.6.4 [+] in Compliance with FDA Requirements: The [+]. The [+], or in the electronic format required by the FDA at that time. The [+] will have been submitted to the FDA in the [+] at that time.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Prepare [+].

3.6.4.1 Structured [+] Review and Responses: Preparation of the draft [+] (i.e. the physician's information and patient information leaflet) will be started before [+] to facilitate discussion with the FDA and information will continue to be added up [+]. Two versions are required to be submitted in the [+], one of which is annotated with the source data for each statement. Both versions are submitted electronically in the required XML format. During review by the FDA Division and by [+], AVI will respond to comments promptly. At the conclusion of the FDA review, AVI will resubmit [the final version of the agreed labeling as an SPL (XML) format]. [+] will be sent to the USG Program Office at time of submission [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Prepare draft labeling in [+] and discussion with the FDA.

3.6.4.2 [+]: During the review of the [+] by the FDA Division and by [+], AVI will respond promptly

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to comments. Recommendations of the FDA will be discussed and incorporated and the finalized files will be resubmitted immediately prior to [+].

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: Final approved [+] to the FDA immediately prior to [+]. Copy of the draft [+] is sent to USG Program Office.

3.6.5 [+] by the FDA to US Government: Deliver [+] by the FDA, to the USG office immediately after the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: [+] configuration approved by the FDA will be delivered to the USG Program Office.

3.6.5.1 [+] to US Government: At the end of CLIN0004 [+] by the FDA will be shipped to the USG Program Office.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: [+] configuration approved by the FDA will be shipped to the USG Program Office.

3.6.5.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.6 Prepare and Deliver [+] to US Government: AVI proposed to subcontract all manufacturing and testing of the drug substance and drug product. The company will submit full details of manufacturing packaging and testing of the drug substance and drug product without divesting intellectual property rights, and it will not be necessary to submit a [+] to FDA. The US GOVERNMENT will have the right of access to the full documentation for the [+] as agreed in the contract.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: AVI will send an electronic and a paper copy of the approved [+] to the USG Program Office.

3.6.6.1 Ensure completion of [+] at CMO: The CMOs and manufacturers of some of the components of the final drug product configuration [+]. A copy of the CMO's Letter of Authorization permitting the FDA to access their confidential information in connection with the [+] will have been submitted in the [+]. AVI will endeavor to ensure that the CMO updates and maintains the conditions of the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: A copy of the Letter of Authorization for FDA to [access the DMF information] in connection with the review of the [+].

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3.6.6.2 Submit Letter of Authorization for FDA review of [+] to US Government: The CMOs and manufacturers of some of the components of the final drug product configuration [+] will [+] that will be referenced by the name and address of the supplier and reference number in the [+]. A copy of the CMO's Letter of Authorization permitting the FDA to access their confidential information in connection with the [+] will have been submitted in the [+]. AVI will endeavor to ensure that the CMO updates and maintains the conditions of the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver a copy of Letter of Authorization (to FDA) to USG.

3.6.6.3 Program management, operations and oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.7 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall study are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.6.7.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.6.7.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.6.7.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

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3.6.7.4 EDMS and QA: The EDMS will have been fully implemented and routinely used to prepare, review and store documents for the [+], and regulatory and quality compliance documents. AVI will continue to store all documents in the validated EDMS and will make electronic document submissions to the FDA, as needed. AVI will train all pertinent staff on the EDMS, including Quality Assurance staff.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.6.8 Drug Substance and Drug Product Ongoing Stability Studies: Continue manufacturing assessment of stability [+] prepared in CLIN0002.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Continue assessment of stability study data (to include both drug substance and drug product).

3.6.8.1 Continue Drug Substance Stability Studies: Continue stability study.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Continue assessment of drug substance stability data.

3.6.8.2 Continue Drug Product Stability Studies: Continue stability study.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Continue assessment of drug product stability data.

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Appendix B: Revised Statement of Work

3.0 CONTRACT

AVI BioPharma (AVI) Statement of Work for AVI-6003 as an effective therapeutic for Marburgvirus:

3.2 CLIN0001 Technology Development (Part 1): AVI will deliver the developmental therapeutic end item that has completed [+] clinical trials, with all the associated preclinical and regulatory requirements sufficient and in place to support its delivery. This will comprise all those activities necessary for our candidate drug product to complete the US GOVERNMENT (USG) Statement of Objectives for CLIN0001. We will complete the planning (including assessment and mitigation of risks) for manufacturing the drug supply, and execute process development to enable scale up from the current [+] batch GLP material, through a [+] batch cGMP engineering development scale, in anticipation of an ultimate [+] modular manufacturing scale; includes analytical methods development and validation ([+], drug substance) and method qualification (drug product), and development of specifications for lot release.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Drug product with which [+] clinical trials have been completed.

3.2.2 [+] Process Development and Qualification: AVI will prepare drug substance for use in subsequent [+] studies (includes the use of previously manufactured components outside this RFP to prepare drug substance). The [+] development program will improve process reproducibility and prepare for manufacturing at larger scales. AVI will investigate several steps that have shown variability [+], and examine steps that have challenges in scale-up [+]. The overall goal of drug substance development is to design a [+] process that is highly reproducible and that can be demonstrated at [+] scale, and usable in the final manufacturing [+] scale. [+]. A stable, [+] form of the drug substance will be produced.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Design scalable processes for [+] and drug substance.

3.2.2.1 [+] Process Development and Qualification: The [+] development program is aimed at improving reproducibility and scalability and ensuring the quality of the product. The overall goal is to design [+] process that is highly reproducible and easily scalable.

Period of Work: Approximately [+] day from time of award (e.g. [+]).

Deliverable: Finalization of a highly reproducible and easily scalable [+] process in preparation for manufacturing at larger scales.

3.2.2.1.1 Synthesis and Characterization of Authentics: This project will help ensure a consistent quality of product. [+]. These authentics will be used as markers in the analytical method validation to check the resolution of the methods.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Preparation of authentic impurity markers

3.2.2.1.2 [+] Process Development: The [+] development program is aimed at improving reproducibility and scalability. It will investigate several steps that have shown [+]. The overall goal is to design a [+] process that is highly reproducible and easily scalable.

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Period of Work: Approximately [+] months from time of award (e.g.[+]).

Deliverable: Improvement of specific steps and finalization of a highly reproducible and easily scalable [+] process.

3.2.2.1.3 Project Management, Operations and Oversight: Project management will oversee the CROs that are working [+] process development and will also manage the in-house development effort.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.2.2 Drug Substance [+] Process Development: The drug substance [+] process development program will involve optimization of the [+] components of the manufacturing process. The overall goal is to design a highly reproducible and scalable [+] drug substance manufacturing process that can be demonstrated at an [+] and is usable at the final manufacturing [+] scale.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Demonstration of a reproducible and scalable manufacturing process for drug substance.

3.2.2.2.1 Drug Substance [+] Process Development: Development activities are to include optimization of [+] to produce a scalable synthesis process as well as optimization of current [+] process to increase efficiency of [+]. Investigation of alternative [+] methods [+] will also be conducted.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Optimization of the synthesis and [+] components of the manufacturing process.

3.2.2.2.2 Project Management, Operations and Oversight: This element entails oversight and guidance of the development activities, as well as management of technical personnel.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.3 Manufacturing for Nonclinical Studies: [+]** production will occur at [+], and they will supply all the [+] needed for CLIN0001 drug substance manufacture, plus a contingency plan for any drug substance batch needing to be repeated (this is essential to ensure concordance with the timeline). Any excess [+] will be used during the scale up in CLIN0002. The current [+] drug substance process will be transferred to a contract manufacturing organization (CMO) accomplished in the [+] manufacture of oligomeric therapeutic drugs. The CMO will perform scaling of process to [+], plus process development and Reduction to Practice (RtP) run(s). Material for toxicology studies will be made.

**Drug Product for the [+] clinical trial has already been manufactured and is currently stored awaiting final preparations for the start of the study.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Produce drug substance for [+] studies using [+] scale drug substance process.

3.2.3.1 Manufacturing [+]: This production is planned to occur at [+]. It will produce all the [+] needed for CLIN0001 drug substance manufacture plus a contingency if a drug substance batch needs to be repeated.

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Any excess [+] will be used during the scale up in CLIN0002.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Timely supply of [+] to support CLIN0001 drug substance development and manufacture.

3.2.3.1.1 Contract Negotiation, Material Acquisition: Finalize and sign contracts for production. Order long lead time and custom reagents to support upcoming campaign.

Period of Work: Approximately [+] month from time of award (e.g. [+]).

Deliverable: Contract and materials in place for [+] manufacture.

3.2.3.1.2 Manufacture [+]: Produce all the [+] needed for CLIN0001 drug substance development and manufacture.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Timely supply of [+] to support CLIN0001 drug substance development and manufacture.

3.2.3.1.3 Quality Audits and Review: Quality audits are managed by the Director of QA and scheduled in accordance with the Audit Master Schedule. Automatic audit reminders are issued by the EDMS. Auditors schedule travel to and from audits, write audit reports and provide lists of findings and make recommendations. The Director of QA oversees all operational aspects of audits and procedures connected with audits and audit reports. Audit findings, recommendations and responses are reviewed by the Director of QA, the VP of Regulatory Affairs and QA and non-compliance issues are brought to the attention of the Chief Executive Officer (CEO), personally, by the Director of QA on a biweekly basis. In addition, a QA Unit and Compliance Report is written monthly by the Director of QA and presented to the CEO in a 1:1 meeting. Functional management and staffing of the QA Unit is the responsibility of and managed by the VP of Regulatory Affairs and QA.

Quality Audits, depending on the process step may include audits of non-regulated facilities (non-cGMP and non-GLP facilities) or audits of facilities that are required to comply with cGMP or GLP. These are Direct Impact audits of Contract Manufacturing Organizations (CMOs), quality control testing, storage and distribution facilities connected with the manufacture of [+] and activated tails. Audit documentation includes a list of questions directly suited to the service provided by the CMO and an ICH Q7-compliant audit checklist. All CMOs must be audited and approved by QA and, when applicable, readiness for Pre-Approval Inspection (PAI) by the FDA or other regulatory agency is evaluated during an audit. Audit records have limited, controlled review access for authorized departmental and senior management staff and are reviewed through and archived using the EDMS.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: QA approved CMO (vendor) and release of manufactured [+] for AVI-6003 program. Audit report completed and satisfactory resolution of responses to findings for CMO providing [+]. Lot release of [+] for drug substance manufacturing program in accordance with QA-approved specifications using analytical methods.

3.2.3.1.4 Project Management, Operations and Oversight: Project management will oversee the CMO that is doing the CLIN001 production.

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Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.3.2 Manufacture Drug Substance: Select CMO experienced in [+] synthesis of [+] drugs. Tech transfer of [+] scale process for drug substance; scale-up of process to [+], process development and RtP run(s); determine stable [+] form for drug substance.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Achieve [+] scale drug substance process and produce material for [+] studies.

3.2.3.2.1 Select and Contract CMO: CMOs capable of performing [+] synthesis have been reviewed for suitability for the API manufacture, [+], and isolation. Site visits will be performed, followed by quality audits, contract negotiations, technical transfer, and Quality agreement execution.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Selection and completion of contracts with a suitable CMO for API manufacture.

3.2.3.2.2 Manufacturing Tech Transfer at 8L: Production will be introduced at the current [+] scale to allow comparability of previous lots and to transfer knowledge to the new CMO. Each API will be made and purified at this scale with the objective being to produce material suitable for toxicological studies.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Demonstration of successful tech transfer of current [+] sale and production of material suitable for [+] studies.

3.2.3.2.3 Process Development, Reduction to Practice at [+]: After the [+] tech transfer campaigns, the process size will be adapted to a [+] size as part of normal development in order to produce more material suitable for [+] studies. At this point process changes may be introduced to make the process more efficient as long as the impurity profiles remain unchanged.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Demonstration of scalability of manufacturing process to [+] scale by successful completion of RtP run(s).

3.2.3.2.4 Project Management, Operations and Oversight: As part of the normal course of outsourcing production, regular team meetings will be held and updates provided. Production oversight from site visits and data review will be shared and discussed. Regular conference calls with the CMO will be established to review progress and results.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.4 Develop and Validate Analytical Assays and Lot Release Specifications: Existing analytical methods will be refined and validated for each [+]. Methods for drug substance will be developed and validated to meet characterization criteria set with the FDA for release. For the drug product assays, development will utilize synergies with drug substance methods to reduce time and cost of method qualification. For both drug substance and drug product, AVI will qualify vendors, facilities and conduct

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audits.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Validated assays for [+] and drug substance, qualification of the drug product assays, and development of lot release specifications for [+], drug substance and drug product.

3.2.4.1 [+] Analytical Method Development and Validation: Existing analytical methods will be refined and validated for each [+].

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Audited report for validated analytical methods for each [+].

3.2.4.1.1 Method Development and Validation: Methods confirming process consistency will be developed by a qualified subcontractor. Methods for assay and impurity profile will be validated to established criteria for cGMP starting materials.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audited report for validated analytical methods for each [+].

3.2.4.1.2 Identify Impurities above ID Threshold: Process-critical impurities will be synthesized and included in the validation process. Markers for known impurities will be synthesized as part of the impurity profile. Chromatograms of historic lots will be generated using the refined analytical methods. A team of chemists will work on identifying and synthesizing all impurities that occur [+]

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Identification and preparation of markers for all impurities that occur above the [+].

3.2.4.1.3 Develop (Assess and Refine) Lot Release Specifications: To ensure consistent quality, a team will assess and refine all the [+] lot release specifications.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Preparation of a lot release specification for each [+].

3.2.4.1.4 cGMP Audits: See section 3.2.3.1.3 Quality Audits and Review for general description of Quality Audits. cGMP audits are performed by experienced auditors for the Contract Manufacturing Organizations (CMOs), quality control testing and storage and distribution facilities. Audits employ a checklist approach, based on regulatory requirements and ICH Q7 guidelines, which are customized to comply with requirements for each subcontractor site and circumstance. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of cGMP and GLP subcontractors is also evaluated. Under the Quality System, batch release specifications, test methods and quality control test results, protocols for stability studies and analytical methods and study reports or data are reviewed for compliance with regulations and guidelines and approved by the Director of QA.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audit report completed and satisfactory resolution of responses to findings by subcontract laboratories testing [+] for drug substance for subsequent clinical use.

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3.2.4.1.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.4.2 Drug Substance (DS) Analytical Method Development and Validation: Drug substance analytical methods will be developed and validated to meet characterization criteria set forth by regulatory agency for release. Impurities will be isolated and identified. Subcontractors will be qualified, and audits performed, by AVI QA Unit.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Audited report for validated analytical methods for drug substance release.

3.2.4.2.1 Method Development and Validation: Methods, compliant with regulatory expectations, will be developed for impurity profile, assay, identity and description. Method validation will be performed by qualified vendor.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Methods for impurity profile, assay, identity and description, validated and audited report as appropriate.

3.2.4.2.2 Identify Impurities above [+]: Impurities will be identified and the identity verified by synthesis of authentic compounds. Detection level of impurities will be established.

Period of Work: Approximately [+] months from analytical method development and validation (e.g. [+]).

Deliverable: Establish identity and detection levels of impurities.

3.2.4.2.3 Develop (Assess and Refine) Lot Release Specifications: Release specifications will be established that ensure consistency between production lots. RTP batches will be used to refine release specifications and assess the analytical method capability to meet the specification threshold according to ICH Q6A recommendations. Director of QA participates in review and approval of specifications that are compliant with cGMP and compendial requirements.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: cGMP-compliant lot release specifications are approved for drug substance for subsequent clinical use.

3.2.4.2.4 Quality Audits and review: Documentation for drug substance (DS) analytical method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, reports are completed and satisfactory responses are received to audit findings. Director of QA reviews and approves validation protocols and validation reports for the analytical methods.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audits occur, audit reports are completed audit findings are resolved and validated analytical tests and methods are approved for drug substance.

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3.2.4.2.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.4.3 Drug Product (DP) Analytical Method Development and Qualification: Drug product analytical method development and qualification will characterize phosphate buffered saline filled drug product. Method development will utilize synergies with drug substance methods to reduce time and cost of method qualification. Includes subcontractor qualification and audits by AVI QA Unit.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Qualified analytical test methods (validated assay method) that comply with the FDA's quality and regulatory requirements for release of drug product.

3.2.4.3.1 Method Development and Qualification: Methods, compliant with regulatory expectations, will be developed for impurity profile, assay, identity, and description. Method qualification will be performed by qualified vendor. A contract analytical development laboratory will be chosen and methods for drug product analysis and release will be developed that comply with the FDA's quality and regulatory requirements.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audited reports for qualified methods for impurity profile, identity, and description and validated method for assay.

3.2.4.3.2 Identify Impurities above ID Threshold: Impurities will be identified and the identity verified by synthesis of authentic compounds. Detection level of impurities will be established.

Period of Work: Approximately [+] months from analytical method development and validation (e.g. [+]).

Deliverable: Establish identity and detection levels of impurities.

3.2.4.3.3 Develop (Assess and Refine) Lot Release Specifications: Release specifications will be established that ensure consistency between production lots. RTP batches will be used to refine release specifications and assess the analytical method capability to meet the specification threshold according to ICH Q6A recommendations.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Lot release specification in compliance with the FDA's quality and regulatory requirements for drug product for subsequent clinical use.

3.2.4.3.4 cGMP Audits: Documentation for drug product (DP) analytical method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.4.1.4 above. Audit occurs, report completed and satisfactory resolution of responses to findings by subcontract testing laboratories developing analytical methods and testing drug product for subsequent clinical use. Lot release of will occur using QA-approved validated analytical methods and specifications compliant with compendia and other regulatory requirement.

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Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Completed and QA reviewed validation reports. Audit report completed and satisfactory resolution of responses to findings by subcontract testing laboratories. Lot release tests and specifications that comply with the FDA's quality and regulatory requirements are approved by the Director of QA.

3.2.4.3.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.5 Nonclinical Toxicology: AVI will conduct [+] studies [+]. A new assay will be used for the determination of drug levels in biological matrices, and each component of the study drug will be assayed independently. The method will be validated (GLP) in plasma as is required for study protocols for pharmacokinetic analysis. An existing [+] will be transferred and validated (GLP) for the analysis of dosing solutions, over a [+]. The single dose [+] will evaluate the effect of a single dose on target organs observed. Quality Audits will be conducted on the contract research organization (CRO) and the audit records maintained by the AVI EDMS.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Completed GLP-compliant non-clinical toxicology study reports for studies in [+], including [+] reports.

3.2.5.1 [+] Method Validation: Feasibility studies have proven a [+] method acceptable for the determination of drug levels in biological matrices. Each component of the study drug is assayed independently. The method will be validated (GLP) in matrices corresponding to samples specified by study protocols for pharmacokinetic analysis [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report on validated [+] method for detection of drug levels in biological matrices.

3.2.5.2 Analytical Method Validation for Determination of Dose Solution Concentration: An existing [+] method will be transferred and validated (GLP) for the analysis of dosing solutions. The method will be validated over a concentration range suitable for determination of concentration, homogeneity, and stability of the dose formulations for the non-clinical toxicology studies.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Audited final report on validated method for concentration of drug levels.

3.2.5.3 [+]: The single dose [+] study will evaluate the effect of a [+]. The results will have an impact on the dosages and escalation in the [+] trial. This study requires validation of the analytical method.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

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3.2.5.4 [+]: This study provides supportive data for the repeat dose study [+] that has been completed. Allow correlation of observed effects with exposure.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.5 [+]: In vitro study to assess the effects of the test article on [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.6 [+]: To investigate the actions of the test article/vehicle on action potential [+] methods. This study will identify potential risk of [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] study.

3.2.5.7 [+] with Long Recovery: [+] - this study will determine [+] in multidose clinical trial.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report for [+] Study with Long Recovery.

3.2.5.8 cGLP Audits: Quality Audits conducted in this arena are Direct Impact audits of our Contract Research Organizations (CRO). Audits include a list of questions directly suited to the CRO and a GLP/cGMP [+] checklist. All CROs (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. See section 3.2.3.1.3 for general description of Quality Audits. Audits of [+] facilities, [+] laboratories, and related study data will be conducted by experienced auditors from the Quality Unit. Audits employ a checklist approach, based on regulatory requirements (21 CFR Part 58 for GLP compliance) and ICH guidelines; the checklists are customized to comply with requirements applicable for each subcontractor facility and type of testing. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of GLP subcontractors is also evaluated.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Audit and audit report completed and acceptable responses to findings are received from subcontract [+] facilities and [+] laboratories testing AVI-6003 for [+]. GLP studies will occur using QA-approved protocols that meet regulatory and IUCAC and USG requirements and validated [+] methods are used.

3.2.5.9 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.2.6 Pilot [+] Studies (Complete).

3.2.7 Contract Program Management:** AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government

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regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall study are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

**Work will continue during period [+] on this program — namely [+] and regulatory to prepare for [+] clinical study. Program management will be required to oversee those tasks.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.2.7.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.2.7.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.2.7.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0001 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance**.**

3.2.7.4 EDMS Installation, Validation, Implementation, Training and QA: AVI will implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21CFR Part 11 compliant EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system will have been selected, installed and fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.3 CLIN0001 Technology Development — [+] Clinical Study (Part 2): Using the currently filed IND, and [+] data obtained subsequently, AVI will establish agreement with the FDA for the acceptable protocol** [+], such as [+] review and approval. AVI will conduct and report the [+] clinical study in healthy [+].

**Discussions with the FDA are planned for [+] which will cover the [+] and additional input to the proposed [+] study may be requested.

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Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Final study report for [+] clinical study agreed upon by the government.

3.3.1 Support [+] Submission: An [+] cannot be granted until the appropriate legislative order has been given by Congress, however, AVI will submit a Request for Consideration for an [+] and briefing document (per Section 564(c) of the FD&C Act), amendments under Project Bioshield Act of 2004, and draft FDA Guideline of June 2005. The Request for Consideration will contain data from all available research and nonclinical studies together with draft protocol synopses for the [+] studies and the first clinical study. The FDA will be asked to provide advice on the additional requirements to achieve an [+].

As requested by the FDA in the meeting, AVI will continue to submit additional scientific, [+] and [+] study data in final study reports as [+] when the final reports are available with the intention of fulfilling all requirements for an [+] before such use is required.

Period of Work: Approximately [+] days from start of preparation of the Request for Consideration and Briefing Document to final receipt of FDA"s Minutes of the Meeting (e.g. [+]).

Deliverable: Letter to the FDA requesting a meeting to discuss the Request for Consideration as an [+] and Briefing Document submitted as an [+]. In addition, after the meeting with the FDA the company's notes of the meeting with the FDA will be submitted as an [+].

3.3.1.1 Support [+] Submission, Meeting with FDA and USG: AVI's regulatory affairs, staff will prepare the Meeting Request Letter and Briefing Document for the Request for Consideration as an [+] Meeting with the FDA and submit them as [+]. After the Meeting with the FDA, AVI's regulatory affairs staff will prepare notes of the meeting and submit them as an [+]. The Request for Consideration as an [+] submissions will be planned, prepared and managed by AVI's regulatory affairs staff, using FDA compliant electronic templates, e-publishing techniques and the EDMS. Meeting arrangements and follow-up Meeting Minutes will also be prepared and managed by RA. Oversight will be provided by AVI's senior management.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Letter to the FDA requesting a meeting to discuss a Request for Consideration as an [+] and Briefing Document submitted as an [+]. After the meeting with the FDA the Company's notes of the [+] with the FDA will be submitted as an [+].

3.3.1.2 Project Management, Operations and Oversight: Consideration as an [+] request managed by AVI regulatory affairs, using FDA compliant electronic templates, electronic document management and e-submission. Meeting arrangements and follow-up meeting minutes also managed by RA. Oversight is provided by AVI's senior management.

Period of Work: Approximately [+] month from meeting date being offered with FDA (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones to timeline and budget.

3.3.2 [+] Clinical Study: The [+] will be conducted with [+] to this award. The timeline will not allow AVI to wait for full manufacturing scale [+] cGMP drug product material, however the drug product used will be comparable and the assay method validated. The study and discussions with the FDA will be based on the IND already opened for drug product. Dosing will start at the [+]. Based on the pharmacokinetics, safety and general tolerability, [+].

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] clinical study report; study conducted with research scale cGMP drug product.

3.3.2.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at an audited, selected [+] Clinical Research Facility with support from a fully CLIA accredited laboratory. From initiation onward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

Final report describing [+] clinical study conducted with research scale cGMP drug product manufactured at a cGMP-compliant facility.

3.3.2.1.1 Contracts and Budget: Contract and budget will be negotiated and agreed with the [+] CRO and supporting laboratories.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All contracts (site and laboratories) to permit study to be executed are agreed and signed.

3.3.2.1.2 Final Protocol to FDA; [+] submissions: Final [+] protocol submitted to FDA, [+]; feedback received and incorporated prior to study initiation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All approvals received before initiation of clinical study.

3.3.2.1.3 Site Activities: First Subject In to Last Subject Out: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with site will be documented. Regular site monitoring will be planned and documented to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] clinical study conducted under cGCP and completed on schedule, within budget.

3.3.2.1.4 Site Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.3.2.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study.

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Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirming that subcontractors are trained to the study and ready to perform services.

3.3.2.2.1 [+] Method Validation: Feasibility studies have proven a [+] method acceptable for the determination of drug levels in [+] matrices. Each component of the study drug is assayed independently. The method will be validated (GLP) in matrices corresponding to samples specified by the clinical study protocol for pharmacokinetic analysis [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Validated [+] assay for drug levels in [+] matrices.

3.3.2.2.2 Clinical Research Organization and Data Management: The CRO is key to study success. Their team along with AVI personnel are responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.3.2.2.3 Central Laboratory Services and Data Transfer: Exploratory [+] accessioning and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data report.

3.3.2.2.4 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] charter will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed sessions. Members of the [+] will be available to review safety data and confirm or reject dose escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decision to dose escalate; continue or stop study as documented in meeting minutes.

3.3.2.2.5 Provide Electronic Data Management with Access to US Government: Enable [+] web portal with secure access to assigned study, company, vendor, and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure EDC portal access.

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3.3.2.2.6 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.3.2.3 Study Documents for Clinical Sites and Final Study Report: The Clinical Research Organization (CRO) is responsible for preparing and providing to AVI for review all appropriate study specific documents, except the clinical protocol. Upon AVI authorization the CRO will send these documents to the sites in preparation for study start. Additionally, should any unexpected or serious safety events be reported, the CRO will document, discuss with AVI medical monitor, and complete the appropriate forms. At the study end, the CRO will prepare the tables, listings and figures and draft the final study report which will then be finalized with AVI input.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.3.2.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], safety reporting, and Good Clinical Practice regulations.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, eCRF completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.3.2.3.2 Final Study Report: Prepare compliant and complete final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submission ready final clinical study report.

3.3.2.4 Regulatory Submissions and Templates: The near final draft clinical protocol, FDA Form 1571, FDA Form 3674, FDA Form 1572, information on the investigators (including a copy of the cv of the Principal Investigator), study facility, and [+] will be submitted as an [+] for review by the FDA. An electronic template that is compliant with electronic submission requirements will be used for the protocol. Other "Essential Documents" specified by the ICH guideline on Good Clinical Practice and 21 CFR will be collected and reviewed for compliance. The clinical study will be registered on www.Clinicaltrials.gov or an equivalent public access database.

Period of Work: Approximately [+] months from start of collection of "Essential Documents" to notification from the FDA that it is "Safe to Proceed" (not including [+] reviews and approvals). (e.g. [+]).

Deliverable: FDA Letter confirming that it is "Safe to Proceed" with the clinical study.

3.3.2.5 GCP Audits: Clinical data and document quality checks are carried out by clinical monitors

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during routine monitoring of each clinical study, as required under GCP. See section 3.2.1.3 for general description of quality Audits and Review. Quality Audits performed by experienced auditors from the QA Unit at clinical investigational sites (hospitals, etc.) are Direct Impact audits that will be specifically designed to verify compliance with GCP requirements and local and international regulatory regulations and guidelines. Audits will include, contractor site selection audit, study audits during the study and an end of study audit. Audit documentation will be managed and archived in the EDMS.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audit and audit report are completed and satisfactory responses to audit findings are received from CRO"s clinical facilities and [+] laboratories testing drug product in clinical studies. GCP-compliant clinical studies will occur using QA-approved protocols that meet regulatory and Institutional Review Board, HIPAA and USG requirements. Validated [+] methods are used for testing clinical samples.

3.3.2.6 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.3 Store Drug Product from Clinical Lot for 2 Years Past End of Study: Samples from the drug product batches used in the [+] clinical study will be stored under specified controlled storage conditions for 2 years past the completion of the study.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Store samples of drug product used in [+] clinical study.

3.3.3.1 Initiate Drug Product Storage at Drug Distributor Warehouse: Drug product from the clinical trial will be retained for at least 2 years past the end of the clinical study end. These samples will be held at the recommended storage temperature in a secured refrigerated unit that is calibrated and monitored.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Store samples of drug product used in [+] clinical study.

3.3.3.2 cGMP Audits: See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the subcontract facility storing and distributing AVI-6003 drug product for subsequent clinical use. Release and shipping of clinical supplies to clinical facilities will occur using QA-approved procedures that are compliant with GCP and local and international regulatory requirements.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audit and audit report are completed and satisfactory responses to audit findings are received from the CMO drug product storage facility and conditions are acceptable for drug product lots for subsequent distribution for clinical use.

3.3.3.3 Project Management, Operations and Oversight: Oversight of warehouse storage of drug product will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.4. Stability Studies: Samples from the [+] (drug substance and drug product) and [+] scale (drug substance), will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. A final stability report will be written by the Contract organization that performs the stability studies.

Period of Work: Approximately [+] days from time of award (e.g. [+]).

Deliverable: Samples of drug substance and drug product set up for [+] stability studies.

3.3.4.1 Contract Analytical Lab, Method Transfer, Short Term Stability of Drug Product at Dilutions for Clinical Study: Identify infusion sets, short term stability for at least [+].

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Report on short term stability of drug product under conditions of clinical study.

3.3.4.2 Contract and Initiate [+]: These studies will confirm the stability of the regular [+]. These studies are expected to confirm result from previous stability studies.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Ongoing stability studies of [+].

3.3.4.3 Refine Stability Indicating Analytical Methods for Drug Substance and Drug Product: Forced degradation studies will identify degradants using HPLC/mass spectrometry. Once peak retention times are matched to degradant/impurity ID, stability program will utilize validated HPLC methods.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Completion of analytical method development for Drug Substance and Drug Product.

3.3.4.4 24 Months Stability Studies Drug Product: Drug substance and the resultant drug product will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. This is applicable to cGMP materials made at both the [+] scales. A final stability report will be written by the Contract organization that performs the stability studies.

Period of Work: Approximately [+] months from time of award (e.g. [+]).

Deliverable: Ongoing [+] study with drug product prepared for [+] clinical study in CLIN0001.

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3.3.4.5 Ongoing Quality Audits and Review including [+] Stability Programs: Drug substance and the resultant drug product will be placed on a stability study at recommended storage temperature and an elevated temperature as per ICH guidelines for a minimum of [+] consistent with the RFP. This is applicable to cGMP materials made at both the [+] scales. A final stability report will be written by the Contract organization that performs the stability studies See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits and section 3.2.4.1.4 for a description of cGMP audits. cGMP audits occur, reports are completed and satisfactory responses to audit findings are received from subcontract laboratories conducting stability studies. Analytical testing occurs using QA-approved validated analytical methods and stability specifications compliant with compendia and other regulatory requirements.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Audit report completed and satisfactory responses to audit findings received. Stability data are reported at regular intervals and reviewed by AVI.

3.3.4.6 Ongoing Program Management, Operations and Oversight including [+] Stability Programs: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a [+] basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.5 End of [+] FDA Meeting: AVI will request an End of [+] Meeting to discuss the future development plan including design of the [+] and the application of the [+] as soon as the data from the first clinical study is available, and appropriate questions of the agency can be formulated to enable the further clinical development. Agreement will be sought on fixed dose combination drug products, toxicology, toxicokinetics, clinical and pharmaceutical development of the drug substance and drug product, [+] development and review, with advanced notification of USG Program Office. The scheduling will depend on FDA, but the meeting should occur within 75 days of the formal request, and the briefing book will be sent to the FDA, at least 4 weeks ahead of the meeting. FDA feedback will be incorporated into the subsequent development plans. AVI's regulatory affairs staff will plan, prepare and compile the submission documents using electronic templates and e-publishing techniques; documents will be managed and stored electronically using the EDMS.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI submits an End of [+] Meeting Request Letter and Briefing Document to the FDA, participates in the meeting with FDA and prepares meeting notes. AVI reviews the FDA"s official Meeting Minutes to assure that key elements of the discussions and agreements reached are documented. The FDA"s requirements and expectations for the appropriate regulatory procedural enhancements leading to a potential [+] are clear.

3.3.5.1 [+] FDA Meeting Request [+], Preparation of Briefing Documents: Just before the completion of [+], AVI's regulatory affairs staff will manage, prepare and compile the [+] Meeting Request Letter and Briefing Document, with key components being provided by the research and development staff and

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subcontractors. The submission will be prepared using electronic templates, published using e-publishing techniques and all documents will be managed and controlled in the EDMS. The [+] Meeting will be planned and held, then AVI will prepare Meeting Notes that will be submitted to the FDA. The FDA's official Meeting Minutes will be reviewed for clarity and agreement with AVI's understanding of the outcomes. As necessary, AVI will continue proactive dialogue with the FDA by mutually convenient means.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: [+] Meeting Request Letter and Briefing Document submitted to the FDA. A meeting date is agreed and the meeting (with participation of appropriate USG representatives) is planned.

3.3.5.2 FDA Meeting, Minutes, Follow-up: AVI and USG representatives will attend the End of [+] Meeting. Agreement will be sought on a variety of development and regulatory procedural topics including for example applicability of fixed dose combination drug product requirements, toxicology, toxicokinetics, clinical and pharmaceutical development of the drug substance and drug product, [+] development and review FDA feedback will be incorporated into the subsequent development plans.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: The [+] Meeting with the FDA occurs. AVI"s Meeting Notes and the FDA"s Meeting Minutes are prepared and reflect mutual agreements and understandings of the requirements for further development and the applicable regulatory procedures.

3.3.6 Complete [+] Clinical Trial and [+]: AVI will complete a [+] study to assess safety, tolerability and pharmacokinetics in [+] (RFP 3.3.2). The results from this first clinical study will be submitted to FDA as a supplement to the IND as soon as the data is available and the appropriate study reports are prepared.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct and complete [+] clinical trial Submission of an [+] containing the Final Study Report of the [+] Clinical Trial and other [+] as needed to support continuing nonclinical, pharmaceutical and clinical research and development.

3.3.6.1 Prepare for and Meet with FDA to Discuss [+]: Due to the complexity and uncertainty about the FDA's expectations and requirements for [+] approval using the [+], AVI's regulatory affairs group will plan, request and manage a specific, [+] Meeting with the FDA and other interested USG agencies to discuss the application of the [+]. A Meeting Request Letter and Briefing Document will be prepared and submitted at least 4 weeks ahead of the meeting. AVI will prepare Meeting Notes and will review the FDA's official Meeting Minutes to assure agreement on the issues discussed. If necessary, further clarifications may be requested in writing. AVI will continue an open dialogue with the FDA and USG agencies involved and document those discussions.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Meeting Request and Briefing Document, attendance at the [+] Meeting, AVI's Meeting Notes and FDA's official Meeting Minutes. Agreement with the FDA and USG agencies regarding the applicability and requirements for developing oligomeric drug products under the [+], and for [+] approval.

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3.3.6.2 Prepare and Submit [+] and [+]: AVI will submit [+] containing appropriate research and development data to the FDA and provide notifications to USG Program Office The agreement of the FDA will be sought to submit the protocols for the [+] studies as well as the [+] safety study for [+] and the relevant protocols will be submitted. AVI's regulatory affairs staff will plan, prepare and manage all submissions as electronic documents using electronic templates, e-publishing techniques and the EDMS.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] will be submitted as [+] and the FDA"s review comments will be incorporated before finalizing study protocols. [+] will be submitted as research and development data reports are available in order to keep the IND as current as possible. Copies of major submissions and correspondence will be forwarded to USG, as required.

3.3.6.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress. As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.3.7 Deliver [+] of Clinical Material to US Government: A sample of the drug product used in the [+] clinical study will be provided to the USG.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample drug product used in [+] clinical safety study to USG.

3.3.7.1 Ship [+] to US Government: At the end of CLIN0001 at least [+] of the drug product(s) will be delivered to the recipient specified by the USG.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG.

3.3.7.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4 CLIN0002: AVI will deliver the developmental therapeutic end item that has achieved [+] clinical trials, based upon CLIN0001, additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for our candidate product to complete the USG Statement of Objectives in CLIN0002.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product on which [+] clinical trials have been completed.

3.4.1 Refine [+]: The critical goal of these studies is to obtain concurrence with FDA on the [+] study to be conducted under the [+]. Critical viral parameters will be addressed in PK/PD studies of [+], and in monitoring [+], both conducted at USAMRIID. The correlation of the [+] from natural infections, will guide the format and goals of the [+] study. The [+] study will be discussed and refined with the FDA. AVI will submit the protocols for the [+] prior to subcontracting the studies to USAMRIID (the proposed vendor to be pre-qualified as acceptable for GLP-compliant studies). The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Establish model for [+] Studies with FDA.

3.4.1.1 Delayed Time to Treatment in [+]: Critical efficacy parameters will be addressed in a study with various preplanned delays between exposure of [+] and initiation of treatment. The work will be conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete Delayed Time to Treatment Efficacy Study.

3.4.1.2 [+]: Critical viral parameters will be addressed in [+], conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+].

3.4.1.3 Viral Time Course in [+]: Critical viral parameters will be addressed in this study conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete viral timecourse study in [+].

3.4.1.4 [+]: Critical viral parameters will be addressed in [+], conducted at USAMRIID. The final protocols and final study reports will be submitted to FDA as [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+].

3.4.1.5 Quality Audits: See section 3.2.3.1.3 for a general description of Quality Audits. Audits of [+] facilities, [+] laboratories, and related study data will be conducted by experienced auditors from the Quality Unit. Audits employ a checklist approach, based on regulatory requirements (21 CFR Part 58 for GLP compliance) and ICH guidelines; the checklists are customized to address the quality and regulatory requirements for each subcontractor facility and type of testing. When applicable, the readiness for a Pre-Approval Inspection by the FDA or other regulatory agency (PAI) of GLP subcontractors is also

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evaluated.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audit and audit reports are completed and satisfactory responses to audit findings are received from subcontract [+] laboratories testing drug product for nonclinical studies. GLP studies will occur using QA-approved protocols that meet regulatory and IUCAC and USG requirements and validated [+] methods are used for analysis of test articles.

3.4.1.6 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.2 Develop and Validate Analytical Assays for Drug Product: AVI will complete analytical methods development and validation for drug product and finalization of specifications for lot release of drug product. The development and validation of formulated product analytical test methods utilize the analytical test methods developed and validated for therapeutic drug substance, where applicable. The addition of compendial tests and limits for sterility,, to those for appearance, identification, assay and impurities will meet the regulatory requirements for lot release and for the product lots in ICHcompliant stability testing programs. The Director of QA will participate in the review and approval of analytical test methods, analytical validation protocols and reports, and drug product specifications that comply with compendia and other regulatory requirements.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Complete development of analytical methods, validation and specifications for drug product.

3.4.2.1 Drug Product Analytical Method Development and Validation: Drug product analytical development will exploit similarities between the drug substance and the drug product to accelerate development and minimize validation time. As with drug substance, multiple HPLC methods are required for purity identification. Includes vendor qualification, facilities and API process audits of batch records by AVI QA Unit. AVI will complete analytical methods development and validation for drug product and finalization of specifications for lot release of drug product. The addition of methods for sterility, to those for appearance, identification, assay and impurities will meet the regulatory scrutiny required for cGMP release and ICH stability.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete development of analytical methods for drug product, and audited validation report.

3.4.2.2 Refine Drug Product Lot Release Specification: Based upon the results from the CLIN0001 manufacturing experience product specifications for each of the drug substances and the drug product will be developed. For the individual drug substances these will be similar to those developed in

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CLIN0001 since [+] studies will have been based upon these specifications that were used in the IND. Refinement of the specifications will be made based upon new assay development and analysis of lots used in the [+] studies and clinical trials.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Develop specifications for each drug substance and drug product.

3.4.2.3 Quality Audits: Documentation for analytical assay method development and validation will be reviewed by QA for compliance with regulatory requirements. See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from subcontract analytical testing laboratories developing and validating analytical methods for drug product for subsequent clinical use. The Director of QA participates in the review and approval of validation protocols and validation reports.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the test facilities. Validated analytical methods are developed and approved.

3.4.2.4 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report progress As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the study plan. Study progress and any issues relative to the study plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.3 Scale-up Manufacturing, Qualification and Validation of cGMP Manufacturing Process: Manufacturing goals will include scale-up of the raw material supply [+], as well as that of drug substance. Further suppliers will be qualified. AVI will manufacture the drug substance and drug product supply at [+] batch scale for the [+] clinical studies (. AVI will also initiate the development of the full manufacturing scale of [+] manufacturing, and initiate validation of [+], including for stability at this full [+] scale. The manufacturing facilities will be audited for compliance with cGMP and other quality and regulatory requirements by experienced auditors. The Director of QA will participate in the review and approval of process validation protocols and reports.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product for [+] clinical trials and validated drug substance for [+] clinical trials will be prepared. Release drug product lots for [+] clinical trials manufactured using a validated process at a cGMP-compliant facility. Lots meet the AVI-approved drug product specification and have been tested using validated analytical methods.

3.4.3.1 [+] Manufacturing Scale-Up: As part of the scale up process the [+] manufacturing supply chain needs to be established to produce [+] on the scale required to support the intended manufacturing scale-up. The current production capacity [+] multiple manufacturers will be utilized. However, even this effort will

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require expansion of [+] facilities for [+] of the activated [+]. [+] are needed to be made at the [+] to support scale up activities.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Assured supply for [+] and other raw materials.

3.4.3.1.1 Contract Additional [+] Manufacturing and [+] Sites: Negotiate and sign contracts with the additional [+] manufacturing and [+] CMOs.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Selection and contract finalization of additional [+] CMOs.

3.4.3.1.2 Manufacture of [+]: Complete tech transfer with all new CMOs. Scale-up the [+] production process and manufacture the required [+] to support the drug substance manufacture.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Timely supply of [+] to support drug substance manufacture.

3.4.3.1.3 [+] Development and Validation: Evaluate the feasibility of [+]
recovery. The Director of QA participates in the review and approval of process protocols and reports.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Report on feasibility and impact on cost of [+].

3.4.3.1.4 Quality Audits and Review: See section 3.2.3.1.3 Quality Audits and Review and section 3.2.4.1.4 cGMP Audits. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed audit reports. Audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO. Approved master batch records are developed for manufacturing [+] at the approved scale.

3.4.3.1.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project plan compliance, report progress. Progress and any issues will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.3.2 Manufacturing Scale-Up, Large Scale Manufacturing and Validation: GMP drug product for [+] clinical trial will be manufactured from cGMP drug substance prepared at [+] scale previously demonstrated in CLIN0001. The process will be scaled from the [+]. The drug substance process will undergo process validation in which [+] lots of drug substance are made at the [+] commercial scale

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and placed on stability. Material from the first validation lot will be used to manufacture drug product for [+] clinical trial. Quality Audits conducted in this arena are Direct Impact audits of our Contract Manufacturing Organization (CMOs) first cGMP run. It will include observation of the manufacturing process per cGMP/Q7 guidelines and will be documented with a report that will be added to the initial CMO audit and filed within EDMS. The Director of QA participates in the review and approval of process validation protocols and reports.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited validation report for large scale manufacturing at a suitably qualified CMO.

3.4.3.2.1 Manufacture and release cGMP drug substance and drug product: Based on experience from CLIN001, the APIs will be produced under cGMP conditions at the [+] scale at this stage and drug product will be manufactured for [+] clinical trial. Production and QA oversight will be given and data generated carefully reviewed. The Director of QA participates in the review and approval of batch records and in the review of analytical testing of drug substance prior to approving lot release.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product for [+] clinical trial.

3.4.3.2.2 Drug Substance Manufacturing Scale Up to [+]: From the [+] scale, the process will be increased to a [+]. The purpose of using a smaller reaction size in a larger capacity reactor is to control costs during clinical development, but enable future scale increases in already qualified equipment. This allows minimization of costs during the program and later enables production of RFP threshold quantities for commercial production.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Demonstration of [+] scale manufacturing process by successful completion of RtP run(s).

3.4.3.2.3 Validation of cGMP Drug Substance Manufacturing Process: Once the [+] scale is established, a process validation protocol will be written and executed under the guidance of the CMO with direct input from AVI. Results of this validation will be reviewed and, if acceptable, approved. The protocol will contain acceptance criteria in order to evaluate the success. The Director of QA participates in the review and approval of validation protocols, validation reports, and master batch records.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited validation report for drug substance manufacturing process at [+] scale.

3.4.4 Refine and Select Drug Product Formulation: AVI will work with a formulation contract CRO, and a drug product CMO to formulate a [+] drug product that will show enhanced stability without cold storage conditions.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Decision on final formulation for drug product formulation.

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3.4.4.1 [+] Product Screening Studies: Determine important physicochemical parameters leading to design of solution [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final [+] formulation.

3.4.4.2 Accelerated Stability Studies Leading to Selection of [+] Drug Product Formulation: [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final [+] formulation.

3.4.4.3 Determine Extractables and Leachables: Determine if any chemical components are extracted or leached from containers, closures, or materials used in administration of the drug.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Data to support decision on final [+] formulation.

3.4.4.4 Quality Audits: Perform audit/review of all documentation See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. The CMO developing the drug product formulation is audited to qualify the contractor as acceptable. An audit report is completed and satisfactory responses to audit findings are received. The formulation study protocols, draft batch records and data obtained during manufacture of the new formulation, and the results of analytical testing are reviewed by the Director of QA. The Director of QA participates in the review and approval of a master batch record, analytical test methods and their validation and proposed specifications derived from the development of a new formulation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed Audit reports. Master batch record, analytical test methods and their validation protocols and reports and revised specifications for the new formulation reviewed and approved by the Director of QA.

3.4.4.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.5 Manufacture cGMP Material at Scale for Nonclinical and Clinical Studies and Consistency Lots: AVI will prepare cGMP drug product for the [+] clinical safety studies from the first validation batch of [+] scale drug substance. Three drug product batches will be validated, and all will provide material for stability studies.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] scale cGMP drug product manufactured for [+].

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3.4.5.1 Drug Product Engineering Runs: Drug product configuration and process will be transferred to CMO; engineering runs will be performed to confirm successful transfer.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Process suitable for GMP drug manufacture.

3.4.5.1.1 Drug Product Engineering Run 1: An engineering run is planned with the first drug substance of the combination product manufactured in CLIN0002 for the purposes of testing all fill finish capabilities including [+], formulation testing, and product testing for adherence to product specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Successful tech transfer and final process suitable for GMP drug manufacture.

3.4.5.1.2 Drug Product Engineering Run 2: An engineering run is planned with the first drug substance of the combination product manufactured in CLIN0002 for the purposes of testing all fill finish capabilities including [+], formulation testing, and product testing for adherence to product specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Successful tech transfer and final process suitable for GMP drug manufacture.

3.4.5.2 Manufacture, Release, Label 3 Consistency Lots of Drug Product: Material produced at scale will be filled for the clinical lots and for the consistency lots at a size commensurate with the production scale of the contract manufacturing organization.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Released, labeled drug product for clinical trials.

3.4.5.3 cGMP Audits: All manufacturing sites for which a scale up is required has been previously audited and approved by QA. The actual scale up of drug product manufacturing includes a review of all relevant documentation for any pertinent quality issues, content uniformity, completion and an onsite QA "for cause" visit if required. See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO. Batch records and analytical test data for lot release are reviewed by the Director of QA. Release and shipping procedures for clinical supplies to clinical facilities are reviewed.

The Director of QA reviews and approves batch records, batch production data and results of analytical testing for lot release.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completed audit reports. Audits occur, audit reports completed, satisfactory responses are received for any audit findings, master batch records and other documents are reviewed and approved for manufacturing and release of drug product.

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3.4.5.4 Project Management, Operations and Oversight: The program will be managed by AVI personnel and consist of initial technology transfer and reduction to practice lots prior to cGMP production. Hands on training may be provided initially but after establishment of the process and successful manufacturing the program will be managed through conference calls, sites visits, audits, data and document review including specifications and comparison of release data with those specifications.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.6 Stability Studies: Drug product will be evaluated according to ICH stability requirements. The duration of the stability program is [+], and it will exceed the minimum requirement in the statement of objectives and Target Product Profile (TPP) threshold. The stability program includes full term aging studies at [+] will not be performed on the drug substance, but will be performed on the [+] drug product.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Stability studies of [+] and validated drug substance have been initiated. Stability studies set up for [+] scale cGMP drug product material manufactured for [+] safety studies.

3.4.6.1 Stability on [+] and Drug Substance ([+] Stability Program Starts): Follow ICH guideline Q1A to acquire data to justify retest date at defined storage condition.

Period of Work: Approximately [+] Days (e.g. [+]).

Deliverable: Completion of stability studies from CLIN0001 and initiation of studies on [+] and validated drug substance.

3.4.6.1.1 Ongoing Stability on [+]: This is the completion of the [+] stability program started in CLIN0001.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of stability studies of [+].

3.4.6.1.2 Stability Studies Drug Substance ([+] Stability Program Starts): Each drug substance manufactured will be placed on a [+] stability program in order to demonstrate the long term product characteristics of the material. Since these drug substances are at a new scale of production stability needs to be performed until a suitable quantity of lots have been made to demonstrate shelf life. All lots made in CLIN0002 will be placed on stability.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Initiation of stability program for drug substance.

3.4.6.2 Stability on Drug Product ([+] Stability Program Starts): Follow ICH guideline Q1A to acquire data to justify expiration date at defined storage condition.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Initiation of stability program for drug product.

3.4.6.2.1 Ongoing Drug Product Stability Studies: Continue ICH guideline Q1A to acquire data to justify expiration date at defined storage conditions. Drug product manufactured prior to the start of CLIN0002 will continue on stability and final reports will be issued at the end of the study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Ongoing stability data for drug product.

3.4.6.2.2 Stability Studies Drug Product ([+] Stability Program): New drug product stability studies will be set up for [+]. Multiple temperature storage conditions will be examine to provide the storage conditions for optimal use.

Period of Work: Approximately [+] week (e.g. [+]).

Deliverable: Initiation of stability program for drug product.

3.4.6.3 cGMP Audit: Stability Study Audits are Direct Impact audits. Audits include a list of questions directly suited to the supplier and a cGMP, GLP (Analytical) checklist (again dependent on supplier). All suppliers (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. See section 3.2.3.1.3 Quality Audits and Review for general description of quality audits and section 3.2.4.1.4 for description of cGMP audits. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received from the CMO conducting stability studies for AVI. The Director of QA reviews and approves stability study protocols as well as reports on stability data.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited final report on stability and shelf life of drug product. Full cGMP audits occur, audit reports are completed and satisfactory responses to audit findings are received in order to qualify the CMO. Stability study protocols are reviewed and approved.

3.4.6.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.7 Stability Testing to Define Operational Storage (Time Temperature Indicator): Each drug product is [+], which makes room temperature storage feasible and reduces cold chain requirements, exceeding minimum requirement in the statement of objectives and TPP threshold. The scope of the stability studies will establish the Time Temperature Indicator (TTI), since it includes full term accelerated conditions. Based upon the results, a TTI can be established to support the product shipments. As part of the operational storage and distribution criteria, product shipments will be monitored for excursions during shipment using temperature monitoring devices.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Stability studies set up for [+] scale cGMP product material to establish TTI.

3.4.7.1 Conduct Stability Studies under [+]: These studies will be conducted at [+] temperature than the recommended storage condition to determine additional time that the material may exposed to harsher conditions without risk.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Stability studies completed to establish TTI.

3.4.7.2 Conduct Shipping and Transport Stability Studies: These studies will show that the drug product is stable under the actual conditions of shipping.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Stability studies completed to establish TTI.

3.4.7.3 Quality Audits: Stability Study Audits are Direct Impact audits. Audits include a list of questions directly suited to the supplier and a cGMP, GLP (Analytical) checklist (again dependent on supplier). All suppliers (through audits) are approved (or rejected) by QA and audit records are maintained by the AVI EDMS. The Director of QA reviews and approves stability study protocols as well as reports on stability data.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Documented audit findings Approved stability study protocol and approved study data and reports.

3.4.7.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.8 Conduct Nonclinical Studies: In addition to the multiple studies completed to date and forming the basis for the open IND, the studies since then and prior to this award that will supplement that IND, AVI will also complete further [+] studies, for example [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct [+] scale cGMP product material.

3.4.8.1 [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final Report on [+].

3.4.8.2 [+] to provide data necessary for registration.

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: Sufficient [+].

3.4.8.3 [+] Mass Balance: Mass balance study required to show fate of drug in [+]; required data for registration.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final report from CRO on mass balance in the [+].

3.4.8.4 [+] in vivo Metabolism: Provide data on metabolism of drug in [+] model. Required for registration and determination if any metabolites are present that need to be monitored in preclinical and clinical trials.

Period of Work: Approximately [+] months (e.g. [+]).

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Deliverable: Final report from CRO on in vivo metabolism in the [+].

3.4.8.5 [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Final report from CRO on protein binding.

3.4.8.6 [+] Dose Range Finding Study: To determine the effect of treatment on the [+] development, with determination of appropriate dose levels for the definitive [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Audited final report on [+] study.

3.4.8.7 [+] Study: The definitive study to determine the effect of treatment on the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audited final report on [+] study.

3.4.8.8 Quality Audits: All preclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLPs and protocol; monitoring will also be done by CRO QA unit. Study reports reviewed by CRO QA unit and by AVI to assure accuracy See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. GLP audits occur, reports are completed and satisfactory responses to audit findings are required from CROs conducting AVI-6003 nonclinical studies and [+] testing facilities. Analytical testing occurs using AVI"s QA-approved validated analytical methods. The Director of QA participates in the review and approval of [+] method validation protocols and validation reports. All nonclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLP requirements. Study monitoring will also be done by the CRO"s QA unit. Study reports and data listings will be reviewed by the CRO"s QA unit and by AVI "s monitor and QA Unit to assure accuracy.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from nonclinical CROs and [+] testing facilities. Study reports and data listings will be reviewed and approved by the CRO"s QA unit and by AVI"s monitor and QA Unit.

3.4.8.9 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.9 [+] Efficacy Studies in [+]: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+]. Using the currently filed IND, clinical safety and any [+] obtained during CLIN0001, any additional preclinical data, and based on the protocol developed with FDA as to the studies necessary under the [+], AVI will conduct the [+] studies, necessary to show protection against an [+] challenge by injection.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale cGMP product material.

3.4.9.1 [+] Efficacy Studies in [+] #1: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale AVI-6003 cGMP product material

3.4.9.1.1 [+] Acquisition and Acclimatization: Prior to [+] protocols are reviewed by [+]. Once protocols are approved, [+]. [+] are held in quarantine to ensure acclimation to the laboratory setting and receive a final health evaluation. Finally, randomization and cage arrangements are finalized.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Sufficient [+] acclimated and released for first pivotal study to begin.

3.4.9.1.2 Conduct Study, Laboratory Analyses, Viral Sequencing: This is the [+] of the study involving [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of the [+] portion of the first [+] study.

3.4.9.1.3 Data Analyses, Final Study Report: Compile observations and unblind data. Statistical analysis and preparation of a final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Presentation of final study report.

3.4.9.2 [+] Studies in [+]: The [+] studies will confirm therapeutic efficacy at specific dose levels and expected exposures that will be mimicked in [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct NHP [+] studies using [+] scale AVI-6003 cGMP product material.

3.4.9.2.1 [+] Acquisition and Acclimation: Prior to [+] protocols are reviewed by [+]. Once protocols are approved, [+] acquisition can take place. [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Sufficient [+] acclimated and released for second pivotal study to begin.

3.4.9.2.2 Conduct Study, Laboratory Analyses, [+]: This is the [+], treatment with the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Completion of the [+] portion of the [+] study.

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3.4.9.2.3 Data Analyses, Final Study Report: Compile observations and unblind data. Statistical analysis and preparation of a final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Presentation of final study report.

3.4.9.3 Data Management: Full data management and statistical analysis plans will be developed by a qualified Contract Research Organization, and shared with the FDA (and USG) before studies completed. The CRO will monitor source documents (to the extent possible in [+] environment), collect data, ensure all data queries are clarified, lock database, analyze and then reveal treatment allocation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Conduct analyses of pivotal efficacy studies for study reports.

3.4.9.4 GLP Audits: See section 3.2.3.1.3 Quality Audits and Review for a general description of quality audits. GLP audits occur, reports are completed and satisfactory responses to audit findings are required from CROs conducting nonclinical studies and [+] testing facilities. Analytical testing occurs using AVI"s QA-approved validated analytical methods. The Director of QA participates in the review and approval of [+] method validation protocols and validation reports. All nonclinical studies will be monitored by AVI during critical in-life phases to assure adherence to GLP requirements. Study monitoring will also be done by the CRO"s QA unit. Study reports and data listings will be reviewed by the CRO"s QA unit and by AVI"s monitor and QA Unit to assure accuracy.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from nonclinical CROs and [+] testing facilities. Study reports and data listings will be reviewed and approved by the CRO"s QA unit and by AVI"s monitor and QA Unit.

3.4.9.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project plan compliance, report progress. Progress and any issues will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.10 Activities to Achieve Pivotal Efficacy Studies: AVI will prepare and submit [+]. The Final Protocols for the [+] studies will also be submitted after the FDA responses are received from the [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] submitted to the FDA.

3.4.10.1 [+] (Clinical, Nonclinical): [+] will be submitted as soon as study reports are available to keep the [+]. The Final Protocols for the [+] studies will also be submitted as [+] after the FDA responses are received from the [+].

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: [+] submitted to the FDA.

3.4.10.2 [+] (Drug Substance, Drug Product): [+] will be submitted as soon as data are available on the lots of drug substance and drug product that will be used in the [+] Studies are available. Additional [+] will be submitted as reports and data are available to keep the [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Prepare and submit [+].

3.4.10.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.11 Request and Conduct [+] Meeting with the FDA: AVI will request an [+] to provide a summary of results of the [+] clinical studies and to discuss the [+] clinical development plan. The topic of designation as a [+]. A Meeting Request Letter and Briefing Document will be submitted to the FDA. Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG Program Office in a timely manner. After the meeting AVI"s regulatory affairs staff will prepare and submit notes of the meeting as an [+]. The FDA"s official Meeting Minutes will be reviewed to ensure that they reflect the same meeting outcomes and agreements as those documented by AVI.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: [+] Request and Briefing Document submitted to the FDA. Participate in [+] with FDA. Prepare notes of the meeting and review the FDA"s official Meeting Minutes to assure that both the FDA and AVI agree on the outcomes of the discussion and agreements.

3.4.11.1 Prepare Meeting Request and Briefing Document: The Meeting Request Letter and Briefing Document will be prepared as soon as is feasible and submitted to the FDA at least one month in advance of the requested meeting date. . Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG Program Office in a timely manner.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: [+] Request Letter and Briefing Document submitted to the FDA.

3.4.11.2 [+].

Period of Work: Approximately [+] month (e.g. [+]).

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Deliverable: Submit request for [+] to the FDA.

3.4.11.3 FDA Meeting, Minutes and Follow Up: AVI will attend the [+] with the FDA. AVI will submit notes of the meeting to the FDA and ensure that the company is in agreement with the outcomes and agreements recorded in the FDA"s official Meeting Minutes. Clarifications will be requested, as necessary. AVI will continue an open dialogue with the FDA as development continues.

Period of Work: Approximately [+] week (e.g. [+]).

Deliverable: AVI will provide copies of the company"s notes and the FDA"s official Meeting Minutes to the USG Program office.

3.4.11.4 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track compliance, report progress. Project progress and any issues relative to the development plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.12 [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG.

3.4.12.1 Ship [+] to US Government: At the end of CLIN0002 at least [+] of the drug product(s) will be delivered to the recipient specified by the US Government.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] clinical safety study to USG.

3.4.12.2 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.13 [+] Clinical Study: A [+] Volunteers. A goal for this study is to establish a [+], the intended therapeutic schedule. [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Complete [+] clinical study and issue final clinical study report.

3.4.13.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from selected, fully [+] accredited laboratory. Site and laboratory will have had satisfactory GCP/GLP audits and then site will be initiated,

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monitored through to study completion and close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

3.4.13.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study.

3.4.13.1.2 Protocol [+] Approval: Full [+] in parallel; AVI will answer any questions and amend protocol if necessary. The Amended protocol will be submitted to the [+] for approval prior to and notification of site(s) start study. All required information about the investigator, site, testing laboratories and CRO responsibilities will be submitted to the FDA prior to study start at any site.

Period of Work: Approximately [+] months (e.g [+]).

Deliverable: FDA, Ethics Committee and [+] approvals received before study start.

3.4.13.1.3 Site Activities First Patient First Visit to Last Patient Last Visit: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the site will be documented. Regular site monitoring will be planned and documented to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete [+] study and complete electronic case report forms on schedule and within budget.

3.4.13.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.4.13.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

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Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

3.4.13.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team along with AVI personnel are responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.4.13.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

3.4.13.2.3 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then [+] meetings with open and closed session. Members of the [+] will be available to [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decisions to [+] as documented in meeting minutes.

3.4.13.2.4 Provide Electronic Data Management with Access to US Government: Enable [+] web portal with secure access to assigned study, company, vendor, and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure EDC portal access.

3.4.13.2.5 Drug Warehousing and Distribution: Store clinical trial material at [+] in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.4.13.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.4.13.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, [+] completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.4.13.3.2 Final Study Reports: Prepare submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit compliant and complete [+] will be submitted to the FDA as an [+].

3.4.13.4 GCP Audits: Audits will be performed of Clinical Study Sites.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the CRO"s QA unit and by AVI"s monitor and QA Unit.

3.4.13.5 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.14 [+] Clinical Study: AVI will conduct a [+]. A specialized [+], is expected to support efficient enrollment and evaluation. Subject accrual and treatment is scheduled for less than [+] months. The results will be available for the planning of the expanded [+] trial.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct [+] clinical study using [+] scale cGMP drug product material and issue final clinical study report.

3.4.14.1 Clinical Site and Local Laboratory Activities: Clinical sites and laboratories will be audited for compliance with GCP, selected and then initiated, monitored through to study completion and close out. The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from a fully [+] accredited laboratory. From initiation forward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] Days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

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3.4.14.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study.

3.4.14.1.2 [+] Approval: Full protocol will be submitted to [+] in parallel; AVI with CRO will answer any questions and amend protocol if necessary to ensure final ethics approval, and notification of site(s) prior to study start.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All approvals received before initiation of clinical study.

3.4.14.1.3 Site Activities First Patient in to Last Patient Out: The study will be planned and executed at an audited, selected [+] Clinical Research Facility. Site will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the site will be documented. Regular site monitoring will be planned and documented to AVI (or Contract Research Organization staff) will monitor conduct of the [+] study to ensure data has been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete in life portion of [+] study and complete electronic case report forms on schedule and within budget.

3.4.14.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.4.14.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

3.4.14.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team along with AVI personnel are responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management,

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data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.4.14.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab run at one facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

3.4.14.2.3 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] charter will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed session. Members of the [+] will be available to review safety data and confirm or reject escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Decisions to dose escalate, continue or stop study as documented in meeting minutes.

3.4.14.2.4 Provide Electronic Data Management with Access to US Government: Enable [+] with secure access to assigned study, company, vendor, and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional secure [+] access.

3.4.14.2.5 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.4.14.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.4.14.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study.

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, [+] guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.4.14.3.2 Final Study Report: Prepare Submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: The Final Study Report will be submitted to the FDA as an [+]. Submit compliant and complete final clinical study report.

3.4.14.4 GCP Audits: Audits will be performed of Clinical Study Sites.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the CRO"s QA unit and by AVI"s monitor and QA Unit.

3.4.14.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.4.15 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall program are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable. In addition AVI will continue to implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21 CFR Part 11 compliant EDMS and preparation for electronic submission of documents to the FDA. The EDMS will be utilized for document management and control, including collaborative authoring of study reports and eCTD text for the [+], revision and versioning control with metadata for audit trails, and secure document repository. The EDMS will provide authorized representatives of USG electronic access to program status information. The use of eCTD compliant document templates and completed reports for electronic submissions to the FDA will be managed, controlled, archived and regulated under the Quality System in the EDMS.

Period of Work: Concurrent with all CLIN0002 activities. Approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.4.15.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

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3.4.15.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.4.15.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.4.15.4 EDMS and QA: AVI will continue to store all documents on the validated EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.5 CLIN0003: AVI will deliver the developmental therapeutic end item that has achieved [+] Clinical Study, based upon CLIN0001 and CLIN0002 (recognizing that some activities will be concurrent), additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for our candidate drug product to complete the USG Statement of Objectives in CLIN0003.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product on which [+] Clinical Study has been completed.

3.5.1 Complete Pivotal Efficacy Studies: This has been moved to CLIN0002 3.4.9.1 and 3.4.9.2.

3.5.2 [+]: Continue to implement enhancements to the Quality Systems Approach already in place, including installation of a secure 21CFR Part 11 compliant EDMS and preparation for electronic submission of documents to the FDA.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Submit the quality amendment to FDA as a supplement to the AVI-6003 [+].

3.5.2.1 Write and Submit [+]: Update information stored on EDMS and preparation for electronic submission of documents to the FDA.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit the quality amendment to FDA as an [+].

3.5.2.2 Respond to FDA Questions: Develop and provide response to any questions or recommendations from FDA following filing of [+].

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit to FDA as an [+].

3.5.2.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track protocol compliance, report project progress. As part of the normal course of conducting clinical trials, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget

3.5.3 [+] Study: Using the currently filed AVI-6003 [+], clinical safety and any [+] data obtained during CLIN0001 and CLIN0002, AVI will initiate the [+] Study in [+] using the protocols agreed with FDA, while ensuring all necessary [+] study requirements such as [+] review and approval. AVI will conduct this [+]. FDA concurrence that this will be sufficient for the safety database to [+] will be sought.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Conduct and audit [+] study and issue final study report.

3.5.3.1 Clinical Site and Local Laboratory Activities: The study will be planned and executed at audited, selected [+] Clinical Research site(s) with support from a fully [+] accredited laboratory. From initiation forward the site(s) will be monitored through to study completion and site close out.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Plan, conduct and complete [+] clinical study. Provide all required data to the CRO for final study report.

3.5.3.1.1 Contracts and Budgets: Contracts will be negotiated with vendors for the execution of this study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Signed contracts in place with all vendors before initiation of [+] clinical study.

3.5.3.1.2 [+] Approval: Full protocol will be submitted to [+] in parallel; AVI with the CRO will answer any questions and amend protocol if necessary to ensure final ethics approval and notification of site(s) prior to study start.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: FDA, Ethics Committee and [+] approvals received before initiation of the [+] study.

3.5.3.1.3 Site Activities First Patient in to Last Patient Our: The study will be planned and executed at an audited, selected clinical sites. Sites will be involved with review of study specific documentation and trained prior to first subject first visit. All interactions with the sites will be documented. Regular site

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monitoring will be planned and documented to AVI (or Contract Research Organization staff) will monitor conduct of the [+] study to ensure data have been verified and entered in a timely fashion, while ensuring subject safety. Any compliance issues will be raised to the clinical team for response.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete in life portion of pivotal safety study and complete electronic case report forms on schedule and within budget.

3.5.3.1.4 Site(s) Close Out: After completion of the last subject last visit, all data queries will be completed by the site and/or laboratory, previously validated database locked, analyses run, and draft study report prepared. In parallel formal close out of the clinical site, with disposal of unused drug supplies and completion of all outstanding documentation will occur.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: All open queries and action items associated with clinical study execution are completed and documented in a site close out visit report.

3.5.3.2 Outsource Services: Identify, select and qualify subcontractors needed to execute clinical study. Assigned vendor personnel will participate in a kick off meeting in which study expectations and needs, including timelines, will be discussed. Protocol and procedure training will occur. A communication plan and reports needed will be developed prior to first subject enrolled.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Training records, meeting minutes confirm that subcontractors are trained to the study and ready to perform services.

3.5.3.2.1 Clinical Research Organization and Data Management: The CRO is key to study success. Their team along with AVI personnel are responsible for site start up activities, site training, and study execution, including data collection and management. The statistical support is part of the CRO. This group and Data Management will develop the plans necessary for data collection, query management, data analysis and quality checks. They will prepare reports for the [+] reviews. The final clinical study report will be written by CRO personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Executed contract between AVI and CRO.

3.5.3.2.2 Central Laboratory Services and Data Transfer: [+] and analyses will each be conducted at a central lab facility. Data from each will be sent to data management vendor for inclusion in final study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Laboratory data reports provided to data management vendor.

3.5.3.2.3 [+]: An independent [+] will be appointed to oversee and confirm dose escalation decisions. A [+] will be prepared and agreed with [+] members, a contract developed and a kickoff meeting and then dose escalation meetings with open and closed session. Members of the [+] will be available to review

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safety data and confirm or reject escalation to the next higher dose.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide safety oversight for pivotal safety study. Decisions to dose escalate, continue or stop study as documented in meeting minutes.

3.5.3.2.4 Provide Electronic Data Management with Access to US Government: Enable [+] with secure access to assigned study, company, vendor, and USG personnel.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Functional, secure [+] access.

3.5.3.2.5 Drug Warehousing and Distribution: Store clinical trial material at refrigerated conditions in secure, temperature controlled and monitored unit. Implement traceable distribution system with chain of custody documentation.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Provide clinical trial material on time to site(s) and keep adequate records.

3.5.3.3 Provide Documents to Clinical Sites and Complete Study Reports: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study, including but not limited to: study specific data collection forms (electronic case report forms), the study operations manual, training on the protocol, clinical trial material storage, inventory and administration, use of [+], and Good Clinical Practice regulations.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Shipping receipts showing what was sent to whom and when.

3.5.3.3.1 Prepare and Distribute Study Documents: CRO, lab vendors and drug warehouse provide complete set of documents and forms to effectively and efficiently conduct study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: All study related documents including but not limited to: study plan and timeline, eCRF completion guidelines, monitoring reports, protocol compliance tracking, communication plan, meeting minutes, training materials and logs, drug accountability logs and final study report.

3.5.3.3.2 Final Study Report: Prepare submission ready final clinical study report.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Submit submission and complete final clinical study report.

3.5.3.4 GCP Audits: Audits will be performed of Clinical Study Sites.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Audits will occur, audit reports completed and satisfactory responses to audit findings will be required from clinical sites. Study reports and data listings will be reviewed and approved by the

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CRO"s QA unit and by AVI"s monitor and QA Unit.

3.5.3.5 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.4 Refine and Select Formulation and Delivery System: AVI will continue the assessment of stability for the validation lots prepared in CLIN0002. The drug kit per treatment will comprise [+]. The storage of the kit will be [+]. This drug product kit meets the [+].

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Finalize the drug kit components for drug product.

3.5.4.1 Determine Configuration for Market: All details of the commercial formulation are finalized ([+]).

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Finalize the drug kit components for AVI-6003 product.

3.5.4.2 Identify Manufacturer for Packaging Final Product: Establish contract for assembling final marketing packages.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Finalize the vendor for manufacture, labeling and packaging of AVI-6003 product.

3.5.4.3 Continue Drug Substance and Drug Product Stability Studies: Continue drug substance and drug product stability studies.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Continue stability for drug substance and drug product.

3.5.4.4 Project Management, Operations and Oversight: Track progress and manage issues as they arise.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.5 Deliver [+] to US Government: Deliver at least [+] of product, from the lot used for the [+] study.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver sample of drug product used in [+] study to USG.

3.5.5.1 Deliver [+] to US Government: At the end of CLIN0003 at least [+] of the drug product(s) will be delivered to the recipient specified by the USG.

Period of Work: Approximately [+] day (e.g. [+]).

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Deliverable: Deliver sample of drug product used in [+] study to USG.

3.5.5.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.5.6 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall program are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.5.6.1 Program Management: Track progress and manage issues as they.

Period of Work: Concurrent with all CLIN0003 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.5.6.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0002 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.5.6.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0003 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.5.6.4 EDMS and QA: AVI will continue to store all documents on the validated EDMS and preparation for electronic document submission to the FDA. AVI will train all pertinent staff on EDMS and Quality Assurance.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.6 CLIN0004: AVI will deliver the FDA approved therapeutic end item including all New Drug

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Application and Approval activities resulting in the delivery of at least [+], based upon CLIN0001, CLIN0002 and CLIN0003 (recognizing that some activities will be concurrent), additional prior studies and all the associated regulatory requirements sufficient and in place to support this. This will comprise all those activities necessary for [+] drug product to complete the USG Statement of Objectives in CLIN0004.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Drug product approved by FDA.

3.6.1 [+] Meeting with the FDA: A [+] Meeting with the FDA will be requested and a Briefing Document submitted approximately one month in advance of the meeting. The FDA will schedule the meeting within 60 days of the request. The purpose of the [+] Meeting is to reach agreement on the electronic format and content of the [+]. The [+] will also be discussed at this meeting. AVI will prepare notes of the meeting that will document the discussion and agreements with the FDA; the notes will be submitted to the FDA. The FDA will issue official Meeting Minutes. AVI will follow up to request clarifications, as needed.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI prepares and submits Request Letter and Briefing Document, participates in the [+] meeting with the FDA, prepares notes of the meeting that are submitted to the FDA.

3.6.1.1 Prepare Meeting Request and Briefing Documents: The [+] Meeting Request Letter and Briefing document will be prepared and submitted as soon as is feasible after the completion of dosing in the clinical trials approximately [+] ahead of the meeting. Advanced notification of the meeting, plus copies of all meeting-related documents will be provided to the USG in a timely manner.

Period of Work: Approximately [+] month (e.g. [+]).

Deliverable: AVI [+] Meeting Request Letter and Briefing Document are submitted to the FDA.

3.6.1.2 [+] Meeting, Minutes and Follow Up: AVI will participate in the [+] with FDA, take notes and obtain official minutes, following up on any action items due. AVI will provide copies of the FDA's Meeting Minutes to USG.

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: AVI's [+] Meeting notes and the FDA's official Meeting Minutes.

3.6.1.3 Project Management, Operations and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally.

This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

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3.6.2 Prepare, Submit and FDA Review of [+]: AVI will electronically submit an [+] that meets the "USG"s Target Product Profile. By using eligibility as a small business enterprise, and employing regulatory procedural relief benefits due [+], AVI is planning for the [+] to be prior to the completion of the contractual period proposed. During the FDA"s review, AVI will remain ready to respond promptly to any questions that arise by using secure email correspondence. The USG will be kept fully informed of progress.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: AVI prepares and electronically submits an [+] that meets the FDA's requirements for review and validation.

3.6.2.1 Complete and Submit [+] and Respond to FDA Review Comments: AVI will complete and submit an [+] to the FDA; and respond in a timely fashion to Information Requests and other comments from the FDA reviewers.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: An [+] that has been submitted electronically to the FDA and accepted for filing as an appropriately structured electronic submission. Responses to Requests for Information and the [+] from the FDA will be answered promptly.

3.6.2.2 Project Management and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.3 [+] and Response to FDA [+]: Given the issues faced by the FDA [+], it is likely that the FDA [+]. AVI will attend and participate in an [+], and respond promptly to any questions in the [+] approval occurs.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Responses to Requests for Information from the FDA, will be submitted promptly. AVI will prepare a Briefing Document and presentation materials for an [+]. Draft notes of the [+] will be prepared.

3.6.3.1 [+]: AVI will plan and prepare and, once confirmed, attend and participate at [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: AVI will prepare a presentation and Briefing Document in advance of the [+].

3.6.3.2 Prepare and Submit Complete Response to [+]: At the conclusion of their review the FDA will issue a [+].

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Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Complete Response will be made to any questions asked by the FDA.

3.6.3.3 Project Management and Oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.3.4 [+]: AVI will receive formal confirmation [+]. AVI will submit [+] and participate in the final negotiations of the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Receipt of the [+]. A copy will be sent to the USG Program office.

3.6.4 [+] in Compliance with FDA Requirements: The [+]. The [+], or in the electronic format required by the FDA at that time. The [+] will have been submitted to the FDA in the [+] at that time.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Prepare [+].

3.6.4.1 Structured [+] Review and Responses: Preparation of the draft [+] (i.e. the physician's information and patient information leaflet) will be started before [+] to facilitate discussion with the FDA and information will continue to be added up [+]. Two versions are required to be submitted in the [+], one of which is annotated with the source data for each statement. Both versions are submitted electronically in the required XML format. During review by the FDA Division and by [+], AVI will respond to comments promptly. At the conclusion of the FDA review, AVI will resubmit [+]. [+] will be sent to the USG Program Office at time of submission [+].

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Prepare draft labeling in [+] and discussion with the FDA.

3.6.4.2 [+]: During the review of the [+] by the FDA Division and by [+], AVI will respond promptly to comments. Recommendations of the FDA will be discussed and incorporated and the finalized files will be resubmitted immediately prior to [+].

Period of Work: Approximately [+] weeks (e.g. [+]).

Deliverable: Final approved [+] to the FDA immediately prior to [+]. Copy of the draft [+] is sent to USG Program Office.

3.6.5 [+] by the FDA to US Government: Deliver [+] by the FDA, to the USG office immediately after the [+].

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Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: [+] configuration approved by the FDA will be delivered to the USG Program Office.

3.6.5.1 [+] to US Government: At the end of CLIN0004 [+] approved by the FDA will be shipped to the USG Program Office.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: [+] approved by the FDA will be shipped to the USG Program Office.

3.6.5.2 Project Management, Operations and Oversight: Oversight of inventory and distribution will be managed by AVI personnel through site visits, audits, and records review.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.6 Prepare and Deliver [+] to US Government: AVI proposed to subcontract all manufacturing and testing of the drug substance and drug product. The company will submit full details of manufacturing packaging and testing of the drug substance and drug product without divesting intellectual property rights, and it will not be necessary to submit a [+] to FDA. The US GOVERNMENT will have the right of access to the full documentation for the [+] as agreed in the contract.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: AVI will send an electronic and a paper copy of the approved [+] to the USG Program Office.

3.6.6.1 Ensure completion of [+] at CMO: The CMOs and manufacturers of some of the components of the final drug product configuration [+]. A copy of the CMO's Letter of Authorization permitting the FDA to access their confidential information in connection with the [+] will have been submitted in the [+]. AVI will endeavor to ensure that the CMO updates and maintains the conditions [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: A copy of the Letter of Authorization for FDA to [+] in connection with the review of the [+].

3.6.6.2 Submit Letter of Authorization for FDA review of [+] to US Government: The CMOs and manufacturers of some of the components of the final drug product configuration [+] will [+] that will be referenced by the name and address of the supplier and reference number in the [+]. A copy of the CMO"s Letter of Authorization permitting the FDA to access their confidential information in connection with the [+] will have been submitted in the [+]. AVI will endeavor to ensure that the CMO updates and maintains the conditions of the [+].

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Deliver a copy of Letter of Authorization (to FDA) to USG.

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3.6.6.3 Program management, operations and oversight: Develop timeline, manage vendors, anticipate and resolve problems, track project compliance, report project progress. As part of the normal course of executing project, regular team meetings will be held with each vendor and held internally. This team is responsible for the project plan. Project progress and any issues relative to the project plan will be documented and addressed with the Product Development Team on at least a monthly basis. Regular conference calls with the TMTI will be established to review progress and results.

Period of Work: Approximately [+] day (e.g. [+]).

Deliverable: Plan, monitor, and report overall delivery of milestones and budget.

3.6.7 Contract Program Management: AVI will track progress on each element in the contract, including all financial and reporting requirements; ensure compliance with contract and all government regulations. AVI will manage all subcontracts and ensure that their timelines are met, and the components contributed by each to the overall study are coordinated, on budget, and that they are compliant with all contract and Government regulations that are applicable.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract management and financial oversight ensuring compliance.

3.6.7.1 Program Management: Track progress and manage issues as they arise.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project management ensuring compliance.

3.6.7.2 Finance and [+]: Track financial work process and reporting.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide project financial management ensuring compliance.

3.6.7.3 Contract and Subcontract Management: Manage our compliance with contract and USG regulations; manage subcontractors and relationship with them.

Period of Work: Concurrent with all CLIN0004 activities, a period of approximately [+] days (e.g. [+]).

Deliverable: Provide contract and subcontract management ensuring compliance.

3.6.7.4 EDMS and QA: The EDMS will have been fully implemented and routinely used to prepare, review and store documents for the [+], and regulatory and quality compliance documents. AVI will continue to store all documents in the validated EDMS and will make electronic document submissions to the FDA, as needed. AVI will train all pertinent staff on the EDMS, including Quality Assurance staff.

Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: EDMS system fully operational. QA audits of all vendors will have been performed and any follow up action items identified and tracked.

3.6.8 Drug Substance and Drug Product Ongoing Stability Studies: Continue manufacturing assessment of stability [+] prepared in CLIN0002.

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Period of Work: Approximately [+] days (e.g. [+]).

Deliverable: Continue assessment of stability study data (to include both drug substance and drug product).

3.6.8.1 Continue Drug Substance Stability Studies: Continue stability study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Continue assessment of drug substance stability data.

3.6.8.2 Continue Drug Product Stability Studies: Continue stability study.

Period of Work: Approximately [+] months (e.g. [+]).

Deliverable: Continue assessment of drug product stability data.

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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY		
CLIN 0001	A	TDP	TM	OTHER

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
HFV Develo mental Therapeutic		TBD

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A001	Contract Work Breakdown Structure (CWBS)	

4. AUTHORITY *(Data Acquisition **Document** No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-81334C	NA	DTRAfTMTI

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	*NA*	See BIR 16	See Blk 16

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
A	See Blk 16	See Blk 16

b. COPIES	Draft	Final Reg	Final Repro
DTRA/TMTI		1	0
CBMS/KO		1	
15. TOTAL		2	0

16. REMARKS

The CWBS and CWBS dictionary shall be updated semi-annually. The CWBS shall extend to elements to completely define the entire proposed effort. The CWBS shall be to a depth and breadth necessary to accurately describe the Offerors proposed effort, to a minimum of a one level below the Control Account (Reference EVMS CDRL) level. The initial CWBS shall be submitted in conjunction with the proposal. A revised CWBS based on the awarded scope shall be submitted within 30 days of contract award. Government will review initial and all subsequent CWBS and CWBS dictionary. for organization, level of decomposition, and conformance with the tasks in the statement of work. Contractor has 15 days to respond and resubmit upon receipt of Government final comments.

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A002	Contractor's Progress, Status, & Management (PSM) Report	NA

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-80227	NA	DTRA/TMTI

7. ED 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY •	12, DATE OF FIRST SUBMISSION
LT	NA	Monthly	See Blk 16

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
A	See Blk 16	See Blk 16

b. COPIES	Draft	Final Reg	Final Repro
DTRA/TMTI	0	1	0
CBMS/KO		1	
15. TOTAL A	0	2	0

16. REMARKS

The Contractor's Progress, Status & Management report will indicate the work progress and program status. The report will include performance, schedule (CDRL A004) and cost (CDRL A005) updates. It shall also address information related to risks, risk Mitigation activities, and issues. The report is due the 15th of each month after award until contract conclusion. Government will review submissions for compliance with the Statement of Work and other contract provisions. Provide final document within 10 days after approval of changes is received. Contractor has 10 days to respond and resubmit upon receipt of Government final comments.

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
/s/ Authorized Signatory	*21 Jun 10*	*/s/ Authorized Signatory*	*21 Jun 10*

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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO,	B. EXHIBIT	C. CATEGORY		
CLIN 0001	• A	TDP	TM	OTHER

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
1-lFV Developmental Therapeutic		TBD

1. DATA ITEM NO.	2, TITLE OF DATA ITEM	3. SUBTITLE
A003	Contract Funds Status Report, DD Form 1586	

4, AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-81468	NA	DTRA/TMTI

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	Quarterly	See Blk 16

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION		b. COPIES		
					Final	
A	See Blk 16	See Blk. 16		Draft	Reg	Repro
			DTRA/TMTI		1	0
			CBMS/KO		1	
			15. TOTAL		2	0

16. REMARKS

First report due within 15 days after the end of the Contractor's first Fiscal Quarter (FQ) after award. Subsequent reports due within 15 days of the end of each Contractors FQ. Government will review reports for accuracy, completeness and compliance with contract provisions. Provide final document within 10 days after receipt of Government comments.

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A004	Integrated Master Schedule (IMS)	NA

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-81650	NA	DTRA/TMTI

7. DD 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	See Blk 16	See Blk 16

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION •		b. COPIES		
					Final	
A	See Blk 16	See Blk 16		Draft	Reg	Repro
			DTRA/TMTI		1	0
			CBMS/KO		1	
			15. TOTAL		2	0

16. REMARKS

The IMS shall include activities to completely address the SOW & CWBS (CDRL A001). First report due 15 days prior to Kick-off. • Microsoft Project compatible file required. Subsequent updates due within 15 days of each Government Fiscal Quarter (Quarter (Q) 1 ends 31 Dec, Q2 ends 30 Mar, Q3 ends 30 Jun, Q4 ends 30 Sep). Government will review IMS submissions to determine that it accurately documents the delivery date for each CLIN, critical path, major milestones, tasks/activities, duration, lead/lag/slack time, and schedule relationships, and is directly traceable to the SOW, Project Management Plan and the CWBS. The Government will. evaluate whether the tasks/activities in the IMS show predecessor/successor relationships and are sufficient to account for the entire scope of work. Provide final document within 10 days after receipt of Government comments

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
/s/ Authorized Signatory	*21 Jun 10*	*/s/ Authorized Signatory*	*21 Jun 10*

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CONTRACT DATA REQUIREMENTS LIST
(2 Data Items)

Form Approved
OMB No. 0704-0188

A. CONTRACT LINE ITEM NO.	B. EXHIBIT	C. CATEGORY		
CLIN 0001	A	TDP	TM	OTHER

D. SYSTEM/ITEM	E. CONTRACT/PR NO.	F. CONTRACTOR
HFV Developmental Therapeutic		TBD

1. DATA ITEM NO,	2. TITLE OF DATA ITEM	3. SUBTITLE
A005	Contract Performance Report	

4. AUTHORITY *(Data Acquisition Document No.)*	5. CONTRACT REFERENCE	6. REQUIRING OFFICE
DI-MGMT-81466A	N/A	DTRA/TMTI

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10 FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	monthly	See Blk 16

8. APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
A	See Blk 16	See Blk 16

b. COPIES			
		Final	
	Draft	Reg.	Repro
DTRA/TMTI		1	0
CBMS/KO		1	
15. TOTAL		2	0

16. REMARKS

The CPR shall be submitted monthly. All reports shall be submitted no later than 15 working days following the Contractor's accounting period cutoff date.

DD Forms are available and shall be used to submit required formats as follows:

CPR Format	DD Form Sample Number	Format No.
Work Breakdown Structure	2734/1	1
Organizational Categories	2734/2	2
Baseline	2734/3	3
Staffing	2734/4	4
Explanations and Problem Analyses	2734/5	5

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE
A006	In Process Review	

4. AUTHORITY *(Data Acquisition* Document No.)	5. CONTRACT REFERENCE
DI-MGMT-80227 & DI-MGMT 80555A	NA

7. DO 250 REQ	9. DIST STATEMENT REQUIRED	10. FREQUENCY	12. DATE OF FIRST SUBMISSION
LT	NA	Semi-monthly	See Blk 16

8, APP CODE	11. AS OF DATE	13. DATE OF SUBSEQUENT SUBMISSION
A	See Blk 16	See Blk 16

5• COPIES			
		Final	
	Draft	Reg	Repro
DTRA/TMTI		1	0
CBMS/KO		1	
15. TOTAL		2	0

16. REMARKS

Contractor shall present project status formally to the Government every 6 months in accordance with a Government provided agenda The information contained in the In Process Review (IPR) is similar to that contained in the Contractor PSM Report (CDRL A002). The Contractor shall provide a MS PowerPoint read ahead 48 hours prior to the IPR.

1. DATA ITEM NO.	2. TITLE OF DATA ITEM	3. SUBTITLE

G. PREPARED BY	H. DATE	I. APPROVED BY	J. DATE
/s/ Authorized Signatory	*21 Jun 10*	*/s/ Authorized Signatory*	*21 Jun 10*

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EXHIBIT 31.1

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, J. David Boyle II, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVI BioPharma, Inc. (the "Registrant").

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and I have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared; and

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2010

By: /s/ J. David Boyle II

J. David Boyle II
Interim President and Chief Executive Officer, and Senior Vice President and Chief Financial Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Melinda K. Miles, certify that:

1. I have reviewed this quarterly report on Form 10-Q of AVI BioPharma, Inc. (the "Registrant").

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report.

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report.

4. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and I have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me by others within those entities, particularly during the period in which this report is being prepared; and

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report my conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2010

By: /s/ Melinda K. Miles

Melinda K. Miles
Controller and Chief Accounting Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CEO AND CFO PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of AVI BioPharma, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, J. David Boyle II, as Interim President and Chief Executive Officer and Senior Vice President and Chief Financial Officer of the Company, and I Melinda K. Miles, Controller and Chief Accounting Officer of the Company, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ J. David Boyle II
J. David Boyle II
Interim President and Chief Executive Officer, and Senior Vice President and Chief Financial Officer
AVI BioPharma, Inc.
November 9, 2010

/s/ Melinda K. Miles
Melinda K. Miles
Controller and Chief Accounting Officer
AVI BioPharma, Inc.
November 9, 2010

This certification accompanies the Report pursuant to § 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

See also the certification pursuant to Sec. 302 of the Sarbanes-Oxley Act of 2002, which is also attached to this report.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to AVI BioPharma, Inc. and will be retained by AVI BioPharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.