HEMISPHERX BIOPHARMA INC
Form 10-Q/A
July 31, 2006

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q/A

Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarterly Period Ended September 30, 2005

Commission File Number: 0-27072

HEMISPHERx BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103
(Address of principal executive offices) (Zip Code)

(215) 988-0080
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and larger accelerated filer in Rule 12b-2 of the Exchange Act.(Check one): |_| Large accelerated filer |X| Accelerated filer
|_| Non-Accelerated filer

62,299,252 shares of common stock were issued and outstanding as of July 12, 2006.

FORM 10-Q/A
EXPLANATORY NOTE

This amendment on Form 10-Q/A amends our Quarterly Report for the third quarter of 2005 initially filed with the Securities and Exchange Commission ("SEC") on November 9, 2005 (the "original Form 10-Q"). It is being filed to reflect the restatement (the "Restatements") of our consolidated balance sheets and related

consolidated statements of operations, cash flows and stockholders' equity and comprehensive loss as of and for the three and nine months ended September 30, 2005 and 2004, as discussed in Note 2 to the consolidated financial statements.

No attempt has been made in this Form 10-Q/A to modify or update disclosures in original Form 10-Q except as required to address the Restatements. Except as described below, this Form 10-Q/A does not reflect events occurring after the filing of the original Form 10-Q or modify or update any related disclosures. Information not affected by the amendment is unchanged and reflects the disclosure made at the time of the filing of the original Form 10-Q with the SEC. Accordingly, this Form 10-Q/A should be read in conjunction with the original Form 10-Q and our filings made with the SEC subsequent to the filing of the original Form 10-Q, including any amendments to those filings.

In accordance with Rule 12b-15 promulgated under the Securities and Exchange Act of 1934, as amended, the complete texts of Part I, Items 1, 2 and 4 are set forth herein, including those portions of the text that have not been amended from that set forth in the original Form 10-Q. The only changes to the text in Part I, Items 1, 2 and 4 of the original Form 10-Q are as follows:

Part I

Item 1.

- The financial statements, including the footnotes, have been revised to reflect the changes required by the Restatements.
- A new footnote (Note 2) has been added to describe the Restatements and the other footnotes have been revised to conform with the footnote presentation and disclosure in our Form 10-Q for the quarter ended March 31, 2006 (which was filed with the SEC on June 30, 2006).
- Note 3: Stock based compensation was revised to include the pro forma effect on the Company's net loss and loss per share had compensation cost for the Company's option plans been determined for the three months ended June 30, 2004 and 2005.
- Note 6: Revenue and Licensing Fee Income was changed to reflect the restatement due to the Company incorrectly recording $241,000 in other income related to the termination of the Memorandum of Understanding notice received by Astellas.
- The paragraph concerning the closing of the August 2004 Private Placement and its triggering of anti-dilution provisions within Note 9: Equity Financing was removed to reflect the changes required by the restatements.

Item 2.

- An additional critical accounting policy titled "Convertible Debentures" has been added.
- The following subsections in both "Three months ended September 30, 2005 versus Three months ended September 30, 2004" and "Nine months ended September 30, 2005 versus Nine months ended September 30, 2004" have been revised as a result of the Restatements: "Net Loss" (which is now "Net Loss Applicable to Common Stockholders"), "General and Administrative Expenses" and "Interest Expense and Financing Costs." In addition, a subsection titled "Deemed Dividend" has been added in the three and nine month comparisons.

- An additional risk factor titled "We reported material weaknesses in our internal control over financial reporting that, if not remedied, could adversely affect our internal controls" has been added.
- The risk factor "We may continue to incur substantial losses and our future profitability is uncertain" has been revised to correct the accumulated deficit as a result of the Restatements.
- The table within "Liquidity and Capital Resources" disclosing information concerning debenture installment payments and conversions to common Shares was changed to conform to Note 8 within the financial statements.

Item 4.

- This Item has been revised in its entirety due to the Restatements.

Summary of Restatements

In 2003 and 2004, we entered into convertible debenture arrangements which are inherently complicated, which have been and continue to be the subject of numerous intricate accounting pronouncements and interpretations and which are not classified as normal recurring transactions. Our convertible debenture transactions were reported within our previously filed financial statements for the years ended December 31, 2003 and 2004. After an extensive review and consultation with the our independent registered public accountants and our audit committee, we determined that we must restate our historical financial statements for the years ended December 31, 2003 and 2004 as well as the interim financial statements for 2003, 2004, and 2005. We determined that, with respect to the accounting for the convertible debentures, the interpretation and application of EITF No. 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" was not correct at the time the convertible debentures were initially recorded and upon conversion price resets related to the convertible debentures. As a result of this determination, we restated our annual financial statements and quarterly results of operations (unaudited) included in our annual report on Form 10-K/A for the period ending December 31, 2005, which was filed on June 5, 2006 and further amended Footnote 19, Quarterly Results of Operations (unaudited), to those financials in our Annual Report on Form 10-K/A-2 for the fiscal year ended December 31, 2005, which was filed on July 31, 2006.

In addition, we restated: (i) our condensed consolidated unaudited interim financial statements for the quarter ended March 31, 2005 included in our quarterly report on Form 10-Q for the quarter ended March 31, 2006, which was filed on June 30, 2006; (ii) our condensed consolidated unaudited interim financial statements for the quarter and six months ended June 30, 2005 and 2004, included in our June 30, 2005 quarterly report on Form 10-Q/A filed on July 31, 2006, and (iii) the condensed consolidated unaudited interim financial statements for quarter and nine months ended September 30, 2005 and 2004 included in this quarterly report on Form 10-Q/A. The modifications in the restated financial statements relate to non-cash charges that do not affect our revenues, cash flows from operations or liquidity.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except share data)

		(
		De
		-
ASSETS		
Current assets:		
Cash and cash equivalents		$
Short term investments		
Inventory, net (Note 5)		
Accounts and other receivables		
Prepaid expenses and other current assets		
Total current assets		-
		-
Property and equipment, net		
Patent and trademark rights, net		
Investment (Note 4)		
Construction in Progress		
Deferred financing costs		
Advance receivable (Note 8)		
Other assets		
Total assets		-
		$
		=
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable		$
Accrued expenses		
Current portion of long-term debt, net		
Total current liabilities		-
		-
Long-Term Debt-net of current portion (Note 8)		
Commitments and contingencies (Note 12)		
Stockholders' equity : Preferred stock par value $0.01 per share Authorized 5,000,000; issued and outstanding; None		
Common stock, par value $0.01 per share, authorized 100,000,000 shares; issued and outstanding_49,631,766 and 52,124,396, respectively		
Additional paid-in capital		
Accumulated other comprehensive income		
Accumulated deficit		
Total stockholders' equity		-
		-

Total liabilities and stockholders' equity	$

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	Three months ended September 30,	
	2004	2005
	(Restated)	(Restated)
Revenues:		
Sales of product net	$ 222	$ 216
Clinical treatment programs	36	55
Total Revenues:	258	271
Costs and expenses:		
Production/cost of goods sold	699	93
Research and development	974	987
General and administrative	1,299	1,384
Total costs and expenses	2,972	2,464
Impairment Loss	(373)	--
Interest and other income	32	250
Interest expense	(66)	(84)
Financing costs (Note 8)	(1,031)	(616)
Net loss	$ (4,152)	$ (2,643)
Deemed Dividend	(1,676)	--
Net loss applicable to common shareholder	$ (5,828)	$ (2,643)
Basic and diluted loss per share	$ (.12)	$ (.05)
Weighted average shares outstanding	47,062,018	51,301,946

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations (Unaudited)
(in thousands, except share and per share data)

	Nine months ended September 30,	
	2004	2005
	(Restated)	(Restated)
Revenues:		
Sales of product net	$ 779	$ 685
Clinical treatment programs	128	144
Total Revenues:	907	829
Costs and expenses:		
Production/cost of goods sold	1,991	294
Research and development	2,696	3,413
General and administrative	5,229	3,933
Total costs and expenses	9,916	7,640
Impairment loss	(373)	--
Interest and other income	56	543
Interest expense	(272)	(297)
Financing costs (Note 8)	(4,402)	(2,403)
Net loss	$ (14,000)	$ (8,968)
Deemed Dividend	(4,031)	--
Net loss applicable to common stockholders	$ (18,031)	$ (8,968)
Basic and diluted loss per share	$ (.41)	$ (.18)
Weighted average shares outstanding	43,725,586	50,461,043

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders'
Equity and Comprehensive Loss
For the Nine Months Ended September 30, 2005 (Unaudited)
(in thousands, except share data)

	Common stock		Additional paid-in	Accumulated o Comprehensive
	Shares	Amount	capital	Income (Loss)
Balance as of December 31, 2004, Restated	49,631,766	$ 50	$ 154,609	$ (10)
Shares issued for:				
Payment of accounts payable	277,230		314	
Conversion of debt	1,066,887	1	1,610	
Warrants converted	5,000		9	
Interest on convertible debt	192,008		317	
Private placement, net of issuance costs	951,505	1	789	--
Options and warrants issued for services			289	
Conversion price adjustment			133	
Net comprehensive loss				(224)
Balance as of September 30, 2005, Restated	52,124,396	$52	$ 158,070,	$ (234)

See accompanying notes to financial statements

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Nine Months Ended September 30, 2004 and 2005 (Unaudited)
(in thousands)

	2004	200
	(Restated)	(Rest
Cash flows from operating activities:		
Net loss	$(14,000)	$ (8,
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	83	
Amortization of patent and trademark rights	276	
Amortization of deferred financing costs	3,872	2,
Financing cost related to redemption obligation	530	
Stock warrant compensation expense	2,000	
Impairment loss	373	
Interest expense	272	
Changes in assets and liabilities:		
Inventory	613	
Accounts and other receivables	185	
Deferred revenue	497	
Prepaid expenses and other		

current assets	103	
Accounts payable	522	
Accrued expenses	(538)	(
Other Assets	(6)	
Net cash used in operating activities	(5,218)	(5,
Cash flows from investing activities:		
Purchase of land and building	(1,689)	
Purchase of property, plant and equipment	--	(
Additions to patent and trademark rights	(168)	(
Maturity of short term investments	1,496	7,
Purchase of short term investments	(6,009)	(6,
Deferred acquisition costs	1,546	
Net cash (used) provided by investing activities	$ (4,824)	$

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the NineMonths Ended September 30, 2004 and 2005(Unaudited)
(in thousands)

	2004	200
	(Restated)	(Resta
Cash flows from financing activities:		
Proceeds from long-term borrowing	7,550	
Advance receivable	(550)	
Proceeds from exercise of stock Warrants	5,100	
Proceeds from sale of stock	6,983	
Net cash provided by financing activities	19,083	
Net increase (decrease) in cash and cash equivalents	9,041	(3,
Cash and cash equivalents at beginning of period	3,764	8,

Cash and cash equivalents at end of period	$ 12,805	$ 4,
Supplemental disclosures of cash flow information:		
Issuance of common stock for accounts payable and accrued expenses	$ 311	$
Issuance of Common Stock for Purchase of building deferred acquisition costs	$ 1,626	$
Issuance of Common Stock for Debt Conversion and Interest Payments on Convertible Debt	$ 7,216	$ 1,

See accompanying notes to consolidated financial statements.

HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1: BASIS OF PRESENTATION

The accompanying consolidated financial statements include the accounts of Hemispherx BioPharma, Inc., a Delaware corporation and its subsidiaries. All significant intercompany accounts and transactions have been eliminated.

In the opinion of management, all adjustments necessary for a fair presentation of such consolidated financial statements have been included. Such adjustments consist of normal recurring items. Interim results are not necessarily indicative of results for a full year.

The interim consolidated financial statements and notes thereto are presented as permitted by the Securities and Exchange Commission (SEC), and do not contain certain information which will be included in our annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with our consolidated financial statements included in our annual report on Form 10-K/A-2 for the year ended December 31, 2005, as filed with the SEC on July 31, 2006.

Note 2: Restatements

In 2003 and 2004, the Company entered into convertible debenture arrangements which are inherently complicated, which have been and continue to be the subject of numerous intricate accounting pronouncements and interpretations and which are not classified as normal recurring transactions. The Company's convertible debenture transactions were reported within the Company's previously filed financial statements for the years ended December 31, 2003 and 2004. After an extensive review and consultation with the the Company's independent registered public accountants and the Company's audit committee, it was determined that the Company must restate its historical financial statements for the years ended December 31, 2003 and 2004 as well as the interim financial statements for 2003, 2004, and 2005. The Company determined that, with respect to the accounting for

the convertible debentures, the interpretation and application of EITF No. 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" was not correct at the time the convertible debentures were initially recorded and upon conversion price resets related to the convertible debentures. As a result of this determination, the Company restated its annual financial statements and quarterly results of operations (unaudited) included in its annual report on Form 10-K/A for the period ending December 31, 2005, which was filed on June 5, 2006 and further amended Footnote 19, Quarterly Results of Operations (unaudited), to those financials in its Annual Report on Form 10-K/A-2 for the fiscal year ended December 31, 2005, which was filed on July 31, 2006.

In addition, the Company restated: (i) its condensed consolidated unaudited interim financial statements for the quarter ended March 31, 2005 included in its quarterly report on Form 10-Q for the quarter ended March 31, 2006, which was filed on June 30, 2006; (ii) its condensed consolidated unaudited interim financial statements for the quarter and six months ended June 30, 2005 and 2004, contained in our June 30, 2005 quarterly report on Form 10-Q/A filed on July 31, 2006, and (iii) the condensed consolidated unaudited interim financial statements for quarter and nine months ended September 30, 2005 and 2004 included in this quarterly report on Form 10-Q/A. The modifications in the restated financial statements relate to non-cash charges that do not affect its revenues, cash flows from operations or liquidity.

(a) Based on SEC guidance presented at the 2005 annual AICPA National Conference on current SEC and PCAOB developments, the Company re-evaluated its accounting for its March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting

for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock". The Company concluded that bifurcation was not required and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") should have been applied. The Company did initially apply EITF 00-27, however as part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment for the Debentures and conversion price resets that was originally applied and reflected in the financial statements included in the Company's Annual Reports on Form 10-K for the years ended December 31, 2004 and 2003, and in the Company's Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 were not correctly applied and that, therefore, a restatement of the Company's financial statements for the periods referenced above was required. To properly account for the initial calculation of the discount and the conversion price resets triggered upon the issuance of the October 2003 Debenture and the August 2004 Private Placement (See Notes 8 & 9 below for more details on these resets), it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures. The total impact of this restatement on the Company's statement of operations was to decrease the net loss applicable to common stockholders for the three months ended September 30, 2004 and 2005 by approximately $2,903,000 and $611,000 or $0.06 and $0.01 per share, respectively, and decrease the net loss applicable to common stockholders for the nine months ended September 30, 2004 and 2005 by approximately $7,237,000 and $1,402,000, or $0.17 and $0.03 per share, respectively.

(b) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in the Company's Annual Report on Form 10-K for the years ended December 31, 2004 and 2003, and the Company's Quarterly reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 and as a result a restatement of the Company's financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to the Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as part of the Debenture issuances was determined to be computed incorrectly at the time of issuance. The total impact of this restatement on the Company's statement of operations was to increase the net loss applicable to common stockholders for the three months ended September 30, 2004 and 2005 by approximately $48,000 and $48,000 or $0.00 and $0.00 per share respectively, and increase the net loss applicable to common stockholders for the nine months ended September 30, 2004 and 2005 by approximately $233,000 and $135,000 or $0.00 and $0.00 per share, respectively.

(c) The accounting treatment for certain warrants and options issued to non-employees and our interpretation and application of FASB No. 123 was not correct in 2005. The total impact of this restatement on the Company's settlement of operations was to increase the net loss for the three months ended September 30, 2005, by approximately $78,000 or $0.00 per share and an increase in the net loss applicable to common stockholders for the nine months ended September 30, 2005 by approximately $236,000 or $0.00 per share.

(d) The accounting treatment set forth in FASB Statement No. 123, "Accounting for Stock-Based Compensation", for the issuance of the May 2009 Warrants that was originally interpreted and reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2003 and 2004, and in the Company's Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 was not correctly applied and as a result a restatement of our financial statements for the periods referenced above was required. The Warrants issued as incentive to exercise prior warrant issuances should be reflected as a deemed dividend at the date of issuance where previously these warrants were either recorded as additional debt discount or as a financing charge at date of issuance. The total impact of this restatement on our statement of operations was to decrease the net loss applicable to common stock holders for the three and nine months ended September 30, 2004 by $1,676,000 and $4,031,000 or $0.04 and $0.09 per share, respectively.

(e) The Company incorrectly recorded $241,000 in other income Memorandum of Understanding ("MOU") in the third quarter 2005 related to the termination of the MOU notice received by Astellas. This amount was subsequently adjusted back to an accrued liability as of September 30, 2005, as the agreement had not yet been formally terminated. The total impact of this restatement on our statement of operations was to increase the net loss for the three and nine months ended September 30, 2005, by approximately

$241,000 or $0.00 and $0.00 per share, respectively.

As a result of the corrections of the errors described above, the Company has restated its financial statements for this Quarterly Report on Form 10-Q/A as follows:

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Three Months Ended September 30, 2005

	September 30, 2005 As previously Reported	Adjustments		Se R
Revenues:				
Sales of product net	$ 216			
Clinical treatment programs	55			
Total Revenues:	271			
Costs and expenses:				
Production/cost of goods sold	93			
Research and development	913	$ (74)	(c)	
General and administrative	1,380	(4)	(c)	
Total costs and expenses	2,386	(78)		
Interest and other income	491	(241)	(e)	
Interest expense	(84)			
Financing costs	(1,179)	563	(a)(b)	
Net loss	$ (2,887)	$ 244		$
Basic and diluted loss per share	$ (.06)	$ 0.01		$
Weighted average shares outstanding	51,301,946			51,

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(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for certain warrants and options issued to non-employees and the Company's interpretation and application of FASB No. 123 was not correct in 2005, as described above.

(e) Includes restatement adjustment for termination of the MOU notice received by Astellas, as described above.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Three Months Ended September 30, 2004

	September 30, 2004 As previously Reported	Adjustments	Se R
Revenues:			
Sales of product net	$ 222		$
Clinical treatment programs	36		
Total Revenues:	258		
Costs and expenses:			
Production/cost of goods sold	699		
Research and development	974		
General and administrative	1,299		
Total costs and expenses	2,972		
Impairment loss	(373)		
Interest and other income	32		
Interest expense	(66)		
Financing costs	(3,886)	$ 2,855 (a)(b)	
Net loss	$ (7,007)	2,855 (a)(b)	$
Deemed Dividend	--	(1,676)(d)	
Net loss applicable to common stockholders	$ (7,007)	$ 1,179	$
Basic and diluted loss per share	$ (.15)	$ 0.03	
Weighted average shares outstanding	47,062,018		47,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustments for investment banking fees related to Cardinal, as described above.

(d) Includes restatement adjustment for the issuance of the June 2009 warrants

as incentive to exercise prior warrant issuances, as described above.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Nine Months Ended September 30, 2005

	September 30, 2005 As previously Reported	Adjustments	Se R
Revenues:			
Sales of product net	$ 685		
Clinical treatment programs	144		
Total Revenues:	829		
Costs and expenses:			
Production/cost of goods sold	294		
Research and development	3,339	$ (74)(c)	
General and administrative	3,771	(162)(c)	
Total costs and expenses	7,404	(236)	
Interest and other income	784	(241)(e)	
Interest expense	(297)		
Financing costs	(3,670)	1,267 (a)(b)	
Net loss	$ (9,758)	$ 790	$
Basic and diluted loss per share	$ (.19)	$ 0.01	
Weighted average shares outstanding	50,461,043		50,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustments for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for certain warrants and options issued to non-employees and the Company's interpretation and application of FASB No. 123 was not correct in 2005, as described above.

(e) Includes restatement adjustment for termination of the MOU notice received by Astellas, as described avove.

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HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Nine Months Ended September 30, 2004

	September 30, 2004 As previously Reported	Adjustments		Se R
Revenues:				
Sales of product net	$ 779			
Clinical treatment programs	128			
Total Revenues:	907			
Costs and expenses:				
Production/cost of goods sold	1,991			
Research and development	2,696			
General and administrative	5,229			
Total costs and expenses	9,916			
Impairment loss	(373)			
Interest and other income	56			
Interest expense	(272)			
Financing costs	(11,406)	$ 7,004	(a)(b)	
Net loss	$ (21,004)	7,004	(a)(b)	$
Deemed Dividend	--	(4,031)	(d)	--
Net loss applicable to common stockholders	$ (21,004)	$ 2,973		$
Basic and diluted loss per share	$ (.48)	$ 0.07		$
Weighted average shares outstanding	43,725,586			43,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on

the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(d) Includes restatement adjustment for the issuance of the May and June 2009 warrants as incentive to exercise prior warrant issuances, as described above.

The Company and the Company's audit committee have discussed the above errors and adjustments with the Company's current independent registered public accounting firm and have determined that a restatement was necessary for the period described above.

NOTE 3: STOCK BASED COMPENSATION

The Company follows Statement of Financial Accounting Standards(SFAS) No. 123, "Accounting for Stock-Based Compensation." We chose to apply Accounting Principal Board Opinion 25 and related interpretations in accounting for stock options granted to our employees.

The Company provides pro forma disclosures of compensation expense under the fair value method of SFAS No. 123, "Accounting for Stock-Based Compensation," and SFAS No. 148, "Accounting for Stock-Based Compensation- Transition and Disclosure."

The weighted average assumptions used for the period presented are as follows:

	September 30,	
	2004	2005
Risk-free interest rate	2.25%	4.81%
Expected lives	5 Years-	5 years
Expected volatility	68.92% - 69.68%	58.78% - 60.67%

Had compensation cost for the Company's option plans been determined, using the fair value method at the grant dates, the effect on the Company's net loss and loss per share for the three and nine months ended September 30, 2004 and 2005 would have been as follows:

	(In Thousands) Three Months Ended September 30,		(In Tho Nine Mont Septemb
	2004	2005	2004
Net loss applicable to common stockholders, as restated	$ (5,828)	$ (2,643)	$(18,031)
Add: Stock based employee compensation expenses; included in reported net loss	231	177	2,000
Deduct: Total stock based employee compensation determined under fair value method for all awards	(813)	(291)	(813)

Pro forma net loss	$ (6,410)	$ (2,757)	$(16,844)
Basic and diluted loss per share			
As restated	$ (.12)	$ (.05)	$ (.41)
Pro forma	$ (.14)	$ (.05)	$ (.39)

Note 4: INVESTMENT IN UNCONSOLIDATED AFFILIATES

Investments include an equity investment of $35,000 in Chronix Biomedical ("Chronix"). Chronix focuses upon the development of diagnostics for chronic diseases. This initial investment was made in May 31, 2000 by the issuance of 50,000 shares of the Company's common stock from the treasury. On October 12, 2000, the Company issued an additional 50,000 shares of its common stock and on March 7, 2001 the Company issued 12,000 more shares of its common stock from the treasury to Chronix for an aggregate equity investment of $700,000. The percentage ownership in Chronix is approximately 5.4% and is accounted for under the cost method of accounting. During the quarter ended December 31, 2002, the Company recorded a non-cash charge of $292,000 with respect to the investment in Chronix. The Company recorded an additional non-cash charge of $373,000 during the quarter ended September 30, 2004, due to evidence of a further decline in Chronix's market value. This impairment reduces the carrying value to reflect a permanent decline in Chronix's market value based on its then proposed investment offerings.

Note 5: INVENTORIES

The Company uses the lower of first-in, first-out ("FIFO") cost or market method of accounting for inventory.

Inventories consist of the following:

	(In Thousands)	
	December 31, 2004	September 30, 2005
Raw materials-work in progress	$1,711	$1,711
Finished goods, net of $100,000 reserve	437	123
	$2,148	$1,834

The Company's reserve for R&D utilization as of September 30, 2005, totaled $100,000 for Alferon N Injections(R) finished goods. The FDA recently extended the shelf-life of Alferon N Injection(R) to 24 months. The reserve represents product that may not be sold prior to expiration of its shelf-life.

NOTE 6: REVENUE AND LICENSING FEE INCOME

The Company executed a Memorandum of Understanding (MOU) in January 2004 with Astellas Pharma ("Astellas"), formally Fujisawa Deutschland GmbH, ("Fuji") a major pharmaceutical corporation, granting them an exclusive option for a limited number of months to enter a Sales and Distribution Agreement with

exclusive rights to market Ampligen(R) for ME/CFS in Germany, Austria and Switzerland. The Company received an initial fee of 400,000 Euros (approximately $497,000 US) in 2004. On November 9, 2004, Astellas exercised their right to terminate the MOU. The Company did not agree on the process to be utilized in certain European Territories for obtaining commercial approval for the sale of Ampligen(R) in the treatment of patients suffering from Chronic Fatigue Syndrome (CFS). Instead of a centralized procedure, and in order to obtain an earlier commercial approval of Ampligen(R) in Europe, the Company has determined to follow a decentralized filing procedure which was not anticipated in the MOU. The Company believes that it now is in the best interest of the Company's stockholders to potentially accelerate entry into selected European markets whereas the original MOU specified a centralized registration procedure. Pursuant to the agreement of the parties the Company refunded 200,000 Euros. The company has recorded the remaining 200,000 Euros as an accrued liability as of September 30, 2005. Fuji and Yamanouchi Pharmaceutical Co., Ltd. ("Yamanouchi") have reached a definitive agreement upon the terms of their merger, which took effect on April 1, 2005. Yamanouchi will be the surviving company and Fuji will be dissolved. The combinded company name will be Astellas Pharma, Inc.

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b)non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash received to date.

During the period ended September 30, 2005, the Company did not receive any grant monies from local, state and or Federal Agencies.

Revenue from the sale of Ampligen(R) under cost recovery clinical treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

Revenue from the sale of product are recognized when the product is shipped, as title is transferred to the customer. The Company has no other obligation associated with its products once shipment has occurred.

Note 7: ACQUISITION OF ASSETS OF INTERFERON SCIENCES, INC. ("ISI")

On March 11, 2003, the Company acquired from ISI, ISI's inventory of ALFERON N Injection(R) and a limited license for the production, manufacture, use, marketing and sale of this product. As partial consideration, the Company issued 487,028 shares of its common stock to ISI Pursuant to their agreements with ISI, the Company registered these shares for public sale and ISI reported that it sold all of these shares. The Company also agreed to pay ISI 6% of the net sales of ALFERON N Injection(R).

On March 11, 2003, the Company also entered into an agreement to purchase from ISI all of its rights to the product and other assets related to the product including, but not limited to, real estate and machinery. For these assets, the Company issued to ISI an additional 487,028 shares and issued 314,465 shares and 267,296 shares, respectively to the American National Red Cross and GP Strategies Corporation, two creditors of ISI. The Company guaranteed the market value of all but 62,500 of these shares to be $1.59 per share on the termination date. ISI, GP Strategies and the American National Red Cross have reported that they sold all of their shares.

Pursuant to the Acquisition Agreement the Company satisfied other liabilities of ISI which were past due and secured by a lien on ISI's real estate and pays ISI a 6% royalty on the net sales of products containing natural alpha interferon.

On May 30, 2003, the Company issued the shares to GP Strategies and the American National Red Cross. Pursuant to the Company's agreements with ISI and these two creditors, the Company registered the foregoing shares for public sale. As a result at December 31, 2003 the guaranteed value of these shares ($491,000), which had not been sold by these two creditors, were reclassified to redeemable common stock. At December 31, 2004, all shares had been sold by these two creditors and the redeemable common stock was reclassified to equity.

On November 6, 2003, the Company acquired and subsequently paid, the outstanding ISI property tax lien certificates in the aggregate amount of $457,000 from certain investors. These tax liens were issued for property taxes and utilities due for 2000, 2001 and 2002.

In March 2004, the Company issued 487,028 shares to ISI to complete the acquisition of the balance of ISI's rights to market its product as well as its production facility in New Brunswick, New Jersey. ISI has sold all of its shares. The aggregated cost of the land and buildings was approximately $3,316,000. The cost of the land and buildings was allocated as follows:

Land	$ 423,000
Buildings	2,893,000
Total cost	$ 3,316,000

The Company accounted for these transactions as a Business Combination under SFAS No. 141 Accounting for Business Combinations.

Note 8: DEBENTURE FINANCING

Long term debt consists of the following:

	(in thousands) December 31, 2004	September 30, 2005
	(As Restated)	(As Restated)
October 2003 Debenture	$ 2,071	$ 2,071
January 2004 Debenture	3,083	1,972
July 2004 Debenture	2,000	1,500
Total	7,154	5,543
Less Discounts	(2,842)	(870)
Balance (As Restated)	4,312	4,673

Less Current Portion of long-term debt		
	(3,818)	(4,673)
Total long-term debt (As Restated)	$ 494	$ --

As of September 30, 2005, the Company made aggregate installment payments of $2,389,000 and the investors converted an aggregate $2,210,000 principal amount of debt from the debentures as noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Sha issued f Conversi
October 2003	$ 4,142	$ 2,071	$ --	$ 2,071	1,025
January 2004	4,000	139	1,889	1,972	55
July 2004	2,000	--	500	1,500	--
Totals	$10,142	$ 2,210	$ 2,389	$ 5,543	1,080

As of December 31, 2004, the Company made installment payments of $778,000 and investors converted an aggregate $2,210,000 principal amount of debt from the debentures as noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Sha issued f Conversi
October 2003	$ 4,142	$ 2,071	$ --	$ 2,071	1,025
January 2004	4,000	139	778	3,083	55
July 2004	2,000	--	--	2,000	--
Totals	$10,142	$ 2,210	$ 778	$ 7,154	1,080

July 2003 Debentures

On July 10, 2003, the Company issued an aggregate of $5,426,000 in principal amount of 6% Senior Convertible Debentures due July 31, 2005 (the "July 2003 Debentures") and an aggregate of 507,102 Warrants (the "July 2008 Warrants") in a private placement for aggregate proceeds of $4,650,000. At this time, the $1,550,000 of proceeds from the March 2003 Debentures previously held back from the Company was released to the Company. However, pursuant to the terms of the July 2003 Debentures, $1,550,000 of the proceeds from the sale of the July 2003 Debentures was held back and to be released to the Company if, and only if, the Company acquired ISI's facility with in a set timeframe. These funds were released to the Company in October 2003 although the Company had not acquired

ISI's facility at that time. The Company recorded an additional debt discount of $259,000 upon receiving the held back proceeds of $1,550,000 in October 2003. The July 2003 Debentures were to mature on July 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest were valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the July 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The July 2003 Debentures were convertible at the option of the investors at any time through July 31, 2005 into shares of the Company's common stock. The conversion price under the July 2003 Debentures was fixed at $2.14 per share; however, as part of the subsequent debenture placement closed on October 29, 2003 (see below), the conversion price under the July 2003 Debentures was lowered to $1.89 per share. The conversion price was subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that the Company did pay the redemption price at maturity, the Debenture holders, at their option, could have converted the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date. In 2003, the Company recorded a debt discount of approximately $741,000 upon the conversion price reset to $1.89 per share. The additional debt discount is amortized over the remaining life of these Debenture or, in the event of a conversion, written off to financing costs on a pro-rata basis.

The July 2008 Warrants received by the investors, as amended, were exercisable for an aggregate of 507,102 shares of common stock at a price of $2.46 per share. These Warrants, as amended, did not result in any additional debt. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of $1,247,000.

Pursuant to the Company's agreement with the holders, as discussed below in "Registration Rights Agreements", the Company registered the shares issuable upon conversion of the July 2003 Debentures and upon exercise of the July 2008 Warrants for public sale.

The July 2003 Debentures were recorded at a discount on issuance and with an original issue discount of approximately $2,280,000 and $517,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the July 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the July 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging

Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

During 2003, the investors had converted approximately $1,169,000 principal of the July 2003 Debentures into 618,478 shares of the Company's Common Stock.

During 2004, the investors had converted $4,257,071 principal of the July 2003 Debentures into 2,252,417 shares of the Company's Common Stock. As of December 31, 2004, the investors had converted the total $5,426,000 principal of the July 2003 Debentures into 2,870,900 shares of common stock.

The Company recorded financing costs for the three months ended September 30, 2004 and 2005, with regard to the July 2003 Debentures of approximately $130,000 and $0, respectively.

The Company recorded financing costs for the nine months ended September 30, 2004 and 2005, with regard to the July 2003 Debentures of approximately $1,496,000 and $0, respectively.

October 2003 Debentures

On October 29, 2003, the Company issued an aggregate of $4,142,357 in principal amount of 6% Senior Convertible Debentures due October 31, 2005 (the "October 2003 Debentures") and an aggregate of 410,134 Warrants (the "October 2008 Warrants") in a private placement for aggregate gross proceeds of $3,550,000. Pursuant to the terms of the October 2003 Debentures, $1,550,000 of the proceeds from the sale of the October 2003 Debentures were held back and were to be released to the Company if, and only if, the Company acquired ISI's facility within 90 days of January 26, 2004 and provided a mortgage on the facility as further security for the October 2003 Debentures. In April 2004, the Company acquired the facility and the Company subsequently provided the mortgage of the facility to the Debenture holders and the above funds were released. The Company recorded an additional debt discount of $259,000 upon receiving these held back proceeds. The October 2003 Debentures were to mature on October 31, 2005 and bore interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. Any shares of common stock issued to the investors as payment of interest are to be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms and conditions of the October 2003 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The October 2003 Debentures are convertible at the option of the investors at any time through October 31, 2005 into shares of the Company's common stock. The conversion price under the October 2003 Debentures is fixed at $2.02 per share, subject to adjustment for anti-dilution protection for issuance of common stock

or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that the Company does not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date.

The October 2008 Warrants, as amended, received by the investors were to acquire an aggregate of 410,134 shares of common stock at a price of $2.32 per share. These Warrants were exercised in July 2004 which produced gross proceeds in the amount of approximately $952,000.

Pursuant to the Company's agreement with the holders, the Company registered the shares issuable upon conversion of the October 2003 Debentures and upon exercise of the October 2008 Warrants for public sale.

The October 2003 Debentures were recorded at a discount on issuance and with an original issue discount of $2,000,000 and $333,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the October 2003 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the October 2003 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" ("EITF 00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

In October 2005, the Company entered into an amendment agreement with the October 2003 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see Note 13).

On July 13, 2004, in consideration for the Debenture holders' exercise of all of the July 2003 ("July 2008 Warrants") and October 2003("October 2008 Warrants") Warrants amounting to approximately $2,199,000 in gross proceeds, the Company issued to these holders warrants (the "June 2009 Warrants") to purchase an aggregate of 1,300,000 shares of common stock. The Company recorded charges associated with the issuance of these warrants, as restated, fair valued using the Black-Scholes Method, at $1,676,000, which has been reflected as a deemed dividend.

Pursuant to the Company's agreement with the holders, the Company registered the shares issuable upon exercise of these Warrants for public sale.

The June 2009 Warrants are to acquire at any time commencing on January 13, 2005 through June 30, 2009 an aggregate of 1,300,000 shares of common stock at a price of $3.75 per share. On July 13, 2005, the exercise price of these June 2009 Warrants was reset to $3.33, the lesser of the exercise price then in effect or a price equal to the average of the daily price of the common stock between July 14, 2004 and July 12, 2005. The exercise price (and the reset price) under the June 2009 Warrants also is subject to adjustments for anti-dilution protection similar to those in the other Warrants. Notwithstanding the foregoing, the exercise price as reset or adjusted for anti-dilution, will in no event be less than $3.33 per share. Upon completion of the August 2004 Private Placement (see below), the exercise price was lowered to $3.33 per share. The Company agreed to register the shares issuable upon exercise of the June 2009 Warrants pursuant to substantially the same terms as the registration rights agreements between the Company and the holders. Pursuant to this obligation, the Company has registered the shares.

The Company has paid $1,300,000 into the debenture cash collateral account as required by the terms of the October 2003 Debentures. The amounts paid through March 31, 2005 have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of March 31, 2005. The cash collateral account provides partial security for repayment of the outstanding principal and accrued interest on the Debentures in the event of default.

As of September 30, 2005, the investors had converted $2,071,179 principal amount of the October 2003 Debenture into 1,025,336 shares of Common Stock. The remaining balance of $2,071,178 is convertible into 1,025,336 shares of common stock.

The Company recorded financing costs for the three months ended September 30, 2004 and 2005, with regard to the October 2003 Debentures of $371,000 and $124,000, respectively. Interest expense for the three months ended September 30, 2004 and 2005, with regard to the October 2003 Debentures was approximately $45,000 and $31,000, respectively.

The Company recorded financing costs for the nine months ended September 30, 2004 and 2005, with regard to the October 2003 Debentures of $996,000 and $865,000, respectively. Interest expense for the nine months ended September 30, 2004 and 2005, with regard to the October 2003 Debentures was approximately $84,000 and $93,000, respectively.

January 2004 Debentures

On January 26, 2004, the Company issued an aggregate of $4,000,000 in principal amount of 6% Senior Convertible Debentures due January 31, 2006 (the "January 2004 Debentures"), an aggregate of 790,514 warrants (the "July 2009 Warrants") and 158,104 shares of common stock, and Additional Investment Rights (to purchase up to an additional $2,000,000 principal amount of January 2004 Debentures commencing in six months) in a private placement for aggregate net proceeds of $3,695,000. The January 2004 Debentures were to mature on January 31, 2006 and bear interest at 6% per annum, payable quarterly in cash or, subject to satisfaction of certain conditions, common stock. As discussed below, the maturity date and interest rate were amended. Any shares of common stock issued to the investors as payment of interest shall be valued at 95% of the average closing price of the common stock during the five consecutive business days ending on the third business day immediately preceding the applicable interest payment date. Pursuant to the terms of the January 2004 Debentures, commencing July 26, 2004, the Company began to repay the then outstanding principal amount under the Debentures in monthly installments amortized over 18

months in cash or, at the Company's option, in shares of common stock. Any shares of common stock issued to the investors as installment payments shall be valued at 95% of the average closing price of the common stock during the 10-day trading period commencing on and including the eleventh trading day immediately preceding the date that the installment is due. Pursuant to the terms and conditions of the January 2004 Debentures, the Company pledged all of the Company's assets, other than the Company's intellectual property, as collateral and was subject to comply with certain financial and negative covenants, which included but were not limited to the repayment of principal balances upon achieving certain revenue milestones (see "Collateral and Financial Covenants" below).

The January 2004 Debentures are convertible at the option of the investors at any time through January 31, 2006 into shares of the Company's common stock. The conversion price under the January 2004 Debentures was fixed at $2.53 per share, subject to adjustment for anti-dilution protection for issuance of common stock or securities convertible or exchangeable into common stock at a price less than the conversion price then in effect. In addition, in the event that the Company does not pay the redemption price at maturity, the Debenture holders, at their option, may convert the balance due at the lower of (a) the conversion price then in effect and (b) 95% of the lowest closing sale price of the Company's common stock during the three trading days ending on and including the conversion date. Upon completion of the August 2004 Private Placement (see Note 9), the conversion price was lowered to $2.08 per share. The Company recorded an additional debt discount as restated (see Note 2), of approximately $915,000 due to this conversion price reset.

In October 2005, the Company entered into an amendment agreement with the January 2004 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see Note 13).

There are two classes of July 2009 Warrants received by the Investors: Class A and Class B. The Class A warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of $3.29 per share. The Class B warrants are to acquire any time from July 26, 2004 through July 26, 2009 an aggregate of up to 395,257 shares of common stock at a price of $5.06 per share. On January 27, 2005, the exercise price of these July 2009 Class A and Class B Warrants were reset to the lesser of their respective exercise price then in effect or a price equal to the average of the daily price of the common stock between January 27, 2004 and January 26, 2005. The exercise price (and the reset price) under the July 2009 Warrants also is subject to similar adjustments for anti-dilution protection. Notwithstanding the foregoing, the exercise prices as reset or adjusted for anti-dilution, will in no event be less than $2.58 per share. Upon completion of the August 2004 Private Placement (see Note 9), the exercise price was lowered to $2.58 per share.

Pursuant to the Company's agreement with these investors, the Company registered the shares issuable upon conversion of the January 2004 Debentures and upon exercise of the July 2009 Warrants for public sale.

The January 2004 Debentures were recorded at a discount on issuance and with an original issue discount of $306,000 and $465,000, respectively, due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company,

could require partial settlement of the conversion options to be in cash. In addition, the January 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the January 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF "00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

Section 713 of the American Stock Exchange Company Guide

Section 713 of the American Stock Exchange ("AMEX") Company Guide provides that the Company must obtain stockholder approval before issuance, at a price per share below market value, of common stock, or securities convertible into common stock, equal to 20% or more of the Company's outstanding common stock (the "Exchange Cap"). The Debentures and Warrants have provisions that require the Company to pay cash in lieu of issuing shares upon conversion of the Debentures or exercise of the Warrants if the Company is prevented from issuing such shares because of the Exchange Cap. In May 2004, the Debenture holders agreed to amend the provisions of these Debentures and Warrants to limit the maximum amount of funds that the holders could receive in lieu of shares upon conversion of the Debentures and/or exercise of the Warrants in the event that the Exchange Cap was reached to 119.9% of the conversion price of the relevant Debentures and 19.9% of the relevant Warrant exercise price. See below for the accounting effect on this matter.

Taken separately, the March, July, October and January 2004 debenture transactions do not trigger Section 713. However, the AMEX took the position that these transactions should be aggregated and, as such, stockholder approval was required for the issuance of common stock for a portion of the potential exercise of the warrants and conversion of the Debentures in connection with the January 2004 Debentures. The amount of potential shares that the Company could exceed the Exchange Cap amounted to approximately 1,299,000. In accordance with EITF 00-19, Accounting For Derivative Financial Instruments Indexed to and Potentially Settled in a Company's Own Stock, the Company recorded on January 26, 2004, a redemption obligation of approximately $2,160,000, as restated, with a corresponding increase to debt discount to be amortized over the life of the debt or until the Company obtains shareholder approval. Any remaining discount would be reclassed to additional paid in capital.

In addition, in accordance with EITF 00-19, the Company revalued this redemption obligation as of March 31, 2004. The Company increased the redemption obligation and recorded additional finance charge of $1,024,000 as a result of this revaluation. The Company also incurred $104,000 in financing charges related to the amortization of the related discount during the first quarter of 2004.

Stockholder approval was obtained at the Company's Annual Meeting of Stockholders on June 23, 2004. In accordance with EITF 00-19, the Company revalued this redemption obligation associated with the 1,299,000 shares as of

June 23, 2004 (date of shareholder approval). The Company recorded a reduction in the value of the redemption obligation and financing charge of $839,000 as a result of this revaluation and additional financing charge of $242,000 related to the amortization of the debt discount in the second quarter 2004. In addition, upon receiving the requisite stockholder approval on June 23, 2004, the redemption obligation of $2,345,000 and the remaining unamortized debt discount of $1,815,000 were reclassified as additional paid in capital.

As of September 30, 2005, the Company has made aggregate installment payments of $1,888,888 and the investors have converted an aggregate of $139,150 of principal amount of the January 2004 Debentures into 1,094,149 and 55,000 shares of common stock, respectively. During the nine months ended September 30, 2005, the investors converted approximately $1,111,111_of principal amount of the January 2004 Debentures into 735,217 shares of common stock. The remaining principal on these Debentures was $1,972,000 as of September 30, 2005.

The Company recorded financing costs for the three months ended September 30, 2004 and 2005 with regard to the January 2004 Debentures of $216,000 and $236,000, respectively. Interest expense for the three months ended September 30, 2004 and 2005, with regard to the January 2004 Debentures was approximately $54,000 and $25,000, respectively.

The Company recorded financing costs for the nine months ended September 30, 2004 and 2005 with regard to the January 2004 Debentures of $483,000 and $746,000, respectively. Interest expense for the nine months ended September 30, 2004 and 2005, with regard to the January 2004 Debentures was approximately $157,000 and $117,000, respectively.

July 2004 Debentures

Pursuant to the Additional Investment Rights issued in connection with the January 2004 Debentures, the Company issued to the investors an additional $2,000,000 principal amount of January 2004 Debentures (the "July 2004 Debentures"). The July 2004 Debentures are identical to the January 2004 Debentures except that the conversion price is $2.58. The investors exercised the Additional Investment Rights on July 13, 2004 and the Company received net proceeds of $1,860,000. Upon completion of the August 2004 Private Placement (see Note 9), the conversion price of the July 2004 Debentures was lowered to $2.08 per share. The Company recorded an additional debt discount of approximately $632,000 upon the conversion price reset to $2.08 per share, which is being amortized over the remaining life of the debenture in accordance with the effective interest method of accounting.

The July 2004 Debentures were recorded at a discount on issuance of $628,000 due to ascribing value to the beneficial conversion feature and fair value of warrants based on the relative fair value of the proceeds.

The conversion option and detachable warrant carry registration rights and a feature that in certain circumstances, deemed in the control of the Company, could require partial settlement of the conversion options to be in cash. In addition, the July 2004 Debentures include other features including mandatory conversion option and optional redemption rights if contingent transactions occur. To determine whether the July 2004 Debentures had embedded derivatives, including the conversion option, that required bifurcation and fair value accounting, the Company analyzed the terms of the debentures in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("FAS 133"), and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock" (EITF

00-19"). The Company concluded that bifurcation was not required for the conversion option and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") was the appropriate accounting to be applied. The warrants were deemed to be permanent equity. The mandatory conversion option and optional redemption rights were deemed to be derivatives requiring bifurcation and thus the Company obtained a third party valuation for the aggregate fair value of these derivatives that showed the fair value to be immaterial at inception and for each subsequent reporting period.

In October 2005, the Company entered into an amendment agreement with the July 2004 Debenture holders to amend the maturity date from October 31, 2005 to June 30, 2007, and increase the interest rate from 6% to 7% (see Note 13).

The remaining principal amount on these debentures was $1,500,000 as of September 30, 2005.

The Company recorded financing costs for the three months ended September 30, 2004 and 2005 with regard to the July 2004 Debentures of $124,000_and $113,000, respectively. Interest expense for the three months ended September 30, 2004 and 2005, with regard to the January 2004 Debentures was approximately $31,000_ and $27,000, respectively

The Company recorded financing costs for the nine months ended September 30, 2004 and 2005 with regard to the July 2004 Debentures of $124,000_and $361,000, respectively. Interest expense for the nine months ended September 30, 2004 and 2005, with regard to the January 2004 Debentures was approximately $31,000_ and $87,000, respectively.

Conversion of Convertible Debt

The maximum number of shares issuable upon debt conversion, including interest as well as 135% of the shares issuable upon conversion and interest payments were 5,011,525 and 3,759,094 shares at December 31, 2004 and September 30, 2005, respectively.

Collateral and Financial Covenants

The Company paid $1,300,000 in 2003 into the debenture cash collateral account held by the debenture holders as required by the terms of the October 2003 Debentures. The amounts paid have been accounted for as advances receivable and are reflected as such on the accompanying balance sheet as of September 30, 2005. The cash collateral account provides partial security for repayment of the outstanding Debentures in the event of default.

Pursuant to the terms and conditions of all of the outstanding Debentures, the Company has pledged all of the Company's assets, other than the Company's intellectual property, as collateral, and the Company is subject to comply with certain financial covenants.

Note 9: EQUITY FINANCING

On August 5, 2004, the Company closed a private placement with select institutional investors ("August 2004 Private Placement") for approximately 3,617,300 shares of its Common Stock and warrants to purchase an aggregate of up to approximately 1,085,200 shares of its Common Stock. Jefferies & Company, Inc. acted as Placement Agent for which it received a fee and warrants to purchase Common Stock. The Company raised approximately $6,984,000 net proceeds from this private offering.

The Warrant issued to each purchaser is exercisable for up to 30% of the number of shares of Common Stock purchased by such Purchaser, at an exercise price equal to $2.86 per share. Each Warrant has a term of five years and is fully exercisable from the date of issuance. Pursuant to the Registration Rights Agreement, made and entered into as of August 5, 2004 (the "Rights Agreement"), the Company registered the resales of the shares issued to the Purchasers and shares issuable upon the exercise of the Warrants.

By agreement with Cardinal Securities, LLC, for general financial advisory services and in conjunction with the August 2004 Private Placement with select institutional investors, the Company paid Cardinal Securities, LLC an investment banking fee of $140,000. The Company paid Cardinal one-half of the fee in cash with the remainder being paid with the issuance of 50,000 warrants to purchase common stock exercisable at $2.50 per share expiring on March 31, 2010 and 46,667 shares of common stock. By agreement with Cardinal Securities, LLC, the Company has agreed to register all of the foregoing shares and shares issuable upon exercise of the above mentioned warrants for public resale.

On July 8, 2005, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC, pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day $40,000 of the Company's common stock up to an aggregate of $20.0 million over approximately a 25 month period, subject to earlier termination at the Company's discretion. In the Company's discretion, the Company may elect to sell less of the Company's common stock to Fusion Capital than the daily amount and the Company may increase the daily amount as the market price of the Company's stock increases. The purchase price of the shares of common stock will be equal to a price based upon the future market price of the common stock without any fixed discount to the market price. Fusion Capital does not have the right or the obligation to purchase shares of the Company's common stock in the event that the price of the Company's common stock is less than $1.00.

Pursuant to the agreement with Fusion Capital, the Company has registered for public sale by Fusion Capital up to 10,795,597 shares of the Company's common stock. However, in the event that the Company decides to issue more than 10,113,278, i.e. greater than 19.99% of the outstanding shares of common stock as of the date of the agreement, the Company would first seek stockholder approval in order to be in compliance with American Stock Exchange rules. As of September 30, 2005 Fusion Capital has purchased 548,707 shares amounting to $789,994 in gross proceeds to the Company.

In connection with entering into the above agreement with Fusion Capital, the Company, in July 2005, issued to Fusion Capital 402,798 shares of its common stock. 392,798 of these shares represented 50% of the commitment fee due Fusion Capital with the remaining 10,000 shares issued as reimbursement for expenses. An additional 392,799 shares, representing the remaining balance of the commitment, are issuable in conjuction with daily purchases of common stock by Fusion Capital. These additional commitment shares will be issued in an amount equal to the product of (x) 392,799 and (y) the Purchase Amount Fraction. The purchase price at which the shares are being purchased by Fusion Capital and the denominator of which is $20,000,000. As of September 30, 2005, Fusion Capital was issued 16,301 shares towards this commitment fee.

Note 10: EXECUTIVE COMPENSATION

In order to facilitate the Company's need to obtain financing and prior to our stockholders approving an amendment to our corporate charter to increase the

number of authorized shares, Dr. Carter agreed to waive his right to exercise certain warrants and options unless and until our stockholders approved an increase in our authorized shares of Common Stock.

In October 2003, in recognition of this action as well as Dr. Carter's prior and on-going efforts relating to product development securing critically needed financing and the acquisition of a new product line, the Compensation Committee determined that Dr. Carter be awarded bonus compensation in 2003 consisting of $196,636 and a grant of 1,450,000 stock warrants with an exercise price of $2.20 per share. This additional compensation was reviewed by an independent valuation firm and found to be fair and reasonable within the context of total compensation paid to chief executive officers of comparable biotechnology companies.

In the quarter ended March 31, 2004, Dr. Carter was awarded an additional bonus of $99,481 by the Compensation Committee. In addition, The Company recorded a non-cash stock compensation charge of $1,769,000 during the first quarter 2004 resulting from warrants issued to Dr. Carter in 2003 that vested upon the execution of the second ISI asset closing on March 17, 2004. This was determined by subtracting the exercise price from the stock closing price on March 17, 2004 and multiplying the result by the number of warrants.

Note 11: EQUITY INCENTIVE PLAN

The Equity Incentive Plan authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. The Equity Incentive Plan provides for awards to be made to such officers, other key employees, non-employee directors, consultants and advisors of the Company and its subsidiaries as the board of directors may select. A maximum of 8,000,000 shares of common stock is reserved for potential issuance. Unless sooner terminated, the Equity Incentive Plan will continue in effect for a period of 10 years from its effective date. As of September 30, 2005, the Company has granted 221,895 options to directors, officers and employees pursuant to the terms of this plan.

Note 12: COMMITMENTS

In May 2005, the Company committed to purchase lab equipment related to the manufacture of Ampligen(R) raw material in the amount of approximately $628,000. The Company paid the initial deposit of approximately $31,400 in May 2005.

On September 9, 2005, the Company signed a Letter of Intent ("LOI") with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R). In November 2005, the Company paid $100,000 upon executing the LOI in order to initiate the manufacturing project. The LOI shall remain in full force and effect for 90 calendar days or until a definitive agreement is reached. Based on the LOI, Hollister-Stier has agreed to formulate and bottle Ampligen(R) using raw materials received from the Company. The Company has an executed confidentiality agreement in place and; therefore, has commenced the preliminary transfer of the manufacturing technology to Hollister-Stier. The Company's decision to transfer relevant manufacturing technology absent of an executed agreement, was done in part to expedite the eventual manufacture of Ampligen(R) by Hollister-Stier. If the Company is unable to negotiate and finalize an agreement with Hollister-Stier, in a timely manner its plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

Note 13: SUBSEQUENT EVENTS

On October 6, 2005, the Company entered into a material definitive agreement with the October 2003, January 2004 and July 2004 debenture holders to 1) amend the remaining outstanding Debentures that were to mature on October 31, 2005 (as amended, the "October 2003 Debenture") and the two traunches of outstanding debentures due to mature on January 31, 2006 (as amended, respectively, the "January 2004 and July 2004 Debentures"), to a maturity date of June 30, 2007, 2) to increase the interest rate from 6% per annum to 7% per annum. In consideration for extending the maturity date of the outstanding debentures, the Company issued an aggregate of 225,000 Warrants (the "October 2009 Warrants") to the debenture holders to acquire common stock at a price of $2.50 per share at any time from October 31, 2005 through October 31, 2009. The October 2009 Warrants contain provisions for adjustment of the exercise price in the event of certain anti-dilution events. The Company agreed to register 135% of the shares issuable as interest shares that might result due to the amendments to the Debentures and issuable upon exercise of the October 2009 Warrants.

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

Special Note Regarding Forward-Looking Statements

Certain statements in this document constitute "forwarding-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1995 (collectively, the "Reform Act"). Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward- looking terminology such as "believes," "expects," "may," "will," "should," or "anticipates" or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. All statements other than statements of historical fact, included in this report regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements. Without limiting the broader description of forward-looking statements above, we specifically note that statements regarding potential drugs, their potential therapeutic effect, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, market acceptance or our ability to earn a profit from sales or licenses of any drugs or our ability to discover new drugs in the future are all forward-looking in nature.

Such forward-looking statements involve known and unknown risks, uncertainties and other factors, including but not limited to, the risk factors discussed below, which may cause the actual results, performance or achievements of Hemispherx and its subsidiaries to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements and other factors referenced in this report. We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

Overview

We are a biopharmaceutical company engaged in the clinical development, manufacture, marketing and distribution of new drug entities based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s, as a contract researcher for the National Institutes of Health. After almost 30 years, we have established a strong foundation of laboratory, pre-clinical, and clinical data with respect to the development of nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of chronic diseases. We own a U.S. Food

and Drug Administration ("FDA") approved GMP (good manufacturing practice) manufacturing facility in New Jersey, and our corporate offices are in Philadelphia, PA.

Our flagship products include Ampligen(R) and Alferon N Injection(R). Ampligen(R) is an experimental drug undergoing clinical development for the treatment of: Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS" or "CFS"), and HIV. In August 2004, we completed a Phase III clinical trial ("AMP 516") treating over 230 ME/CFS patients with Ampligen(R) and are in the process of preparing a new drug application ("NDA") to be filed with the FDA. Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities (or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards. In addition, Ampligen(R) is undergoing pre-clinical testing for possible treatment of avian influenza ("bird flu"). Alferon N Injection(R) is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of genital warts. Alferon N Injection(R) is also in clinical development for treating Multiple Sclerosis and West Nile Virus ("WNV").

With the threat of an avian influenza pandemic rising and health officials warning that the virus could develop resistance to current flu treatments, the pursuit of a cost-effective and complementary treatment to existing antivirals and vaccines has become critical. This combination may permit the use of lower dosages and fewer injections of the antivirals and vaccines used to combat avian flu, thereby decreasing the cost of both immunization programs and treatment

programs for the full-blown disease.

In antimicrobial (antibacterial) therapy, which is the best-studied clinical model, synergistic drug combinations may result in curative conditions/outcomes, often not observed when the single drugs are given alone. In the case of avian influenza where global drug supplies are presumptively in very limited supply relative to potential needs, therapeutic synergistic combinations could not only affect the disease outcome, but also the number of individuals able to access therapies.

We recently announced that true therapeutic synergy had been observed in the interaction between Ampligen(R) and Tamiflu in the inhibition of the Avian influenza virus. Cell destruction was measured in vitro using different drug combinations. True therapeutic synergy is defined by mathematical equations which indicate that the therapeutic effect observed is in fact greater than the expected arithmetic sum of the two drugs working independently, and is referred to by pharmacologists as the "Chou/Talalay" equations developed at Johns Hopkins University.

In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen is a dsRNA which currently is undergoing testing in this animal model.

For more detailed information concerning our Research and Development activities, please refer to Item 2. "Management's Discussion and Analysis on Results of Operations - Research and Development Costs."

We have over 100 patents worldwide with 9 additional patents pending comprising our intellectual property. We continually review our patents rights to determine whether they have continuing value. Such review includes an analysis of the patent's ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans. We have a fully commercialized product (Alferon N Injection(R)), and a GMP certified manufacturing facility.

In March 2004, we completed the step-by-step acquisition from Interferon Sciences, Inc. ("ISI") of ISI's commercial assets, Alferon N Injection(R) inventory, a worldwide license for the production, manufacture, use, marketing and sale of Alferon N Injection(R). As well as, a 43,000 square foot manufacturing facility in New Jersey and the acquisition of all intellectual property related to Alferon Injection(R). Alferon N Injection(R) is a natural alpha interferon that has been approved by the FDA for commercial sale for the intra-lesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. The acquisition was completed in Spring 2004 with the acquisition of all world wide commercial rights.

We outsource certain components of our research and development, manufacturing, marketing and distribution while maintaining control over the entire process through our quality assurance group and our clinical monitoring group.

Since the completion of our AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS we have received inquiries from and, under confidentiality agreements, are having dialogue with other companies regarding marketing opportunities. No proposals or agreements have resulted from the dialogue, nor can we be assured that any proposals or agreements will result

from these inquiries.

Restatements

In 2003 and 2004, we entered into convertible debenture arrangements which are inherently complicated, which have been and continue to be the subject of numerous intricate accounting pronouncements and interpretations and which are not classified as normal recurring transactions. Our convertible debenture transactions were reported within our previously filed financial statements for the years ended December 31, 2003 and 2004. After an extensive review and consultation with the our independent registered public accountants and our

audit committee, we determined that we must restate our historical financial statements for the years ended December 31, 2003 and 2004 as well as the interim financial statements for 2003, 2004, and 2005. We determined that, with respect to the accounting for the convertible debentures, the interpretation and application of EITF No. 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" was not correct at the time the convertible debentures were initially recorded and upon conversion price resets related to the convertible debentures. As a result of this determination, we restated our annual financial statements and quarterly results of operations (unaudited) included in our annual report on Form 10-K/A for the period ending December 31, 2005, which was filed on June 5, 2006 and further amended Footnote 19, Quarterly Results of Operations (unaudited), to those financials in our Annual Report on Form 10-K/A-2 for the fiscal year ended December 31, 2005, which was filed on July 31, 2006.

In addition, we restated: (i) our condensed consolidated unaudited interim financial statements for the quarter ended March 31, 2005 included in our quarterly report on Form 10-Q for the quarter ended March 31, 2006, which was filed on June 30, 2006; (ii) our condensed consolidated unaudited interim financial statements for the quarter and six months ended June 30, 2005 and 2004, contained in our June 30, 2005 quarterly report on Form 10-Q/A filed on July 31, 2006, and (iii) the condensed consolidated unaudited interim financial statements for quarter and nine months ended September 30, 2005 and 2004 included in this quarterly report on Form 10-Q/A. The modifications in the restated financial statements relate to non-cash charges that do not affect our revenues, cash flows from operations or liquidity.

(a) Based on SEC guidance presented at the 2005 annual AICPA National Conference on current SEC and PCAOB developments, we re-evaluated our accounting for our March 2003, July 2003, October 2003, January 2004 and July 2004 Debentures (collectively, "the Debentures") to determine whether the embedded conversion options required bifurcation and fair value accounting in accordance with FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities", and EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in a Company's Own Stock". We concluded that bifurcation was not required and that EITF 00-27: "Application of Issue No. 98-5 to Certain Convertible Instruments" ("EITF 00-27") should have been applied. We did initially apply EITF 00-27, however as part of performing an analysis on the guidelines set forth in EITF 00-27 it was determined that the initial accounting treatment for the Debentures and conversion price resets that was originally applied and reflected in the financial statements included in our Annual Reports on Form 10-K for the years ended December 31, 2004 and 2003, and in our Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 were not correctly applied and that, therefore, a restatement of our financial

statements for the periods referenced above was required. To properly account for the initial calculation of the discount and the conversion price resets triggered upon the issuance of the October 2003 Debenture and the August 2004 Private Placement, it was determined, under guidance from EITF 00-27 that the debt discount should be restated for the Debentures. The total impact of this restatement on our statement of operations was to decrease the net loss applicable to common stockholders for the three months ended September 30, 2004 and 2005 by approximately $2,903,000 and $611,000, or $0.06 and $0.01 per share, respectively and decrease the net loss applicable to common stockholders for the nine months ended September 30, 2004 and 2005 by approximately $7,237,000 and $1,402,000, or $0.17 and $0.03 per share, respectively.

(b) The estimation of fair value ascribed to and the accounting treatment of the investment banking fees paid to Cardinal Capital, LLC ("Cardinal") in connection with the Debenture issuances, at inception, was inaccurately reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2004 and 2003, and our Quarterly reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 and as a result a restatement of our financial statements for the periods referenced above was required. In connection with the initial recording of the Debentures mentioned above, it was determined that the fair value of the warrants issued as investment banking fees paid to Cardinal, be accounted for as a discount to the Debentures. These investment banking fees should have been capitalized as deferred financing costs and amortized over the life of the Debentures or charged to earnings on the earlier conversion thereof. In addition, the initial calculation of the fair value of the warrants issued to Cardinal as part of the Debenture issuances was determined to be computed incorrectly at the time of issuance. The total impact of this restatement on our statement of operations was to increase the net loss applicable to common stockholders for the three months ended September 30, 2004 and 2005, by approximately $48,000 and $48,000 or $0.00 and $0.00 per share respectively, and increase in the net loss applicable to common stockholders for the nine months ended September 30, 2004 and 2005 by approximately $233,000 and $135,000 or $0.00 and $0.00 per share, respectively.

(c) The accounting treatment for certain warrants and options issued to non-employees and our interpretationand application of FASB No. 123 was not correct in 2005. The total impact of this restatement on our settlement of operations was to increase the net loss for the three months ended September 30, 2005, by approximately $78,000 or $0.00 per share and an increase in the net loss applicable to common stockholders for the nine months ended September 30, 2005 by approximately $236,000 or $0.00 per share.

(d) The accounting treatment set forth in FASB Statement No. 123, "Accounting for Stock-Based Compensation", for the issuance of the May 2009 Warrants that was originally interpreted and reflected in the financial statements included in our Annual Report on Form 10-K for the years ended December 31, 2003 and 2004, and in our Quarterly Reports on Form 10-Q during the quarterly periods in fiscal 2003, 2004 and 2005 was not correctly applied and as a result a restatement of our financial statements for the periods referenced above was required. The Warrants issued as incentive to exercise prior warrant issuances should be reflected as a deemed dividend at the date of issuance where previously these warrants were either recorded as additional debt discount or as a financing charge at date of

issuance. The total impact of this restatement on our statement of operations was to decrease the net loss applicable to common stockholders for the three and nine months ended September 30, 2004 by $1,676,000 and $4,031,000, or $0.04 and $0.09 per share, respectively.

(e) The Company incorrectly recorded $241,000 in other income in the third quarter 2005 related to the termination of the Memorandum of Understanding ("MOU") notice received by Astellas. This amount was subsequently adjusted back to an accrued liability as of September 30, 2005, as the agreement has not yet been formally terminated. The total impact of the restatement on our statement of operations was to increase the net loss for the three and nine months ended September 30, 2005, by approximately $241,000 or $0.00 and $0.00 per share, respectively.

As a result of the corrections of the errors described above, we, have restated our financial statements within this Quarterly Report on Form 10-Q/A as follows:

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Three Months Ended September 30, 2005

	September 30, 2005 As previously Reported	Adjustments		Se R
Revenues:				
Sales of product net	$ 216			
Clinical treatment programs	55			
Total Revenues:	271			
Costs and expenses:				
Production/cost of goods sold	93			
Research and development	913	$ (74)	(c)	
General and administrative	1,380	(4)	(c)	
Total costs and expenses	2,386	(78)		
Interest and other income	491	(241)	(e)	
Interest expense	(84)			
Financing costs	(1,179)	563	(a)(b)	
Net loss	$ (2,887)	$ 244		$
Basic and diluted loss per share	$ (.06)	$ 0.01		$
Weighted average shares outstanding	51,301,946			51,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustments for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for certain warrants and options issued to non-employees and the Company's interpretation and application of FASB No. 123 was not correct in 2005, as described above.

(e) Include restatement adjustment for termination of the MOU notice received by Astellas, as described above.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Three Months Ended September 30, 2004

	September 30, 2004 As previously Reported	Adjustments	Se R
Revenues:			
Sales of product net	$ 222		$
Clinical treatment programs	36		
Total Revenues:	258		
Costs and expenses:			
Production/cost of goods sold	699		
Research and development	974		
General and administrative	1,299		
Total costs and expenses	2,972		
Impairment loss	(373)		
Interest and other income	32		
Interest expense	(66)		
Financing costs	(3,886)	$ 2,855 (a)(b)	
Net loss	$ (7,007)	2,855 (a)(b)	$
Deemed Dividend	--	(1,676)(d)	
Net loss applicable to common			

stockholders	$ (7,007)	$ 1,179	$
Basic and diluted loss per share	$ (.15)	$ 0.03	
Weighted average shares outstanding	47,062,018		47,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustment for investment banking fees related to Cardinal, as described above.

(d) Includes restatement adjustment for the issuance of the June 2009 warrants as incentive to exercise prior warrant issuances, as described above.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Nine Months Ended Septmeber 30, 2005

	September 30, 2005 As previously Reported	Adjustments	Se R
Revenues:			
Sales of product net	$ 685		
Clinical treatment programs	144		
Total Revenues:	829		
Costs and expenses:			
Production/cost of goods sold	294		
Research and development	3,339	$ (74)(c)	
General and administrative	3,771	(162)(c)	
Total costs and expenses	7,404	(236)	
Interest and other income	784	(241)(e)	
Interest expense	(297)		
Financing costs	(3,670)	1,267 (a)(b)	
Net loss	$ (9,758)	$ 790	$
Basic and diluted loss per share	$ (.19)	$ 0.01	

Weighted average shares outstanding	50,461,043		50,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustments for investment banking fees related to Cardinal, as described above.

(c) Includes restatement adjustments for certain warrants and options issued to non-employees and the Company's interpretation and application of FASB No. 123 was not correct in 2005, as described above.

(e) Includes restatement adjustment for termination of the MOU notice received by Astellas, as described avove.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Unaudited Consolidated Statements of Operations
(in thousands, except share and per share data)
Nine Months Ended September 30, 2004

	September 30, 2004 As previously Reported	Adjustments		Se R
Revenues:				
Sales of product net	$ 779			
Clinical treatment programs	128			
Total Revenues:	907			
Costs and expenses:				
Production/cost of goods sold	1,991			
Research and development	2,696			
General and administrative	5,229			
Total costs and expenses	9,916			
Impairment loss	(373)			
Interest and other income	56			
Interest expense	(272)			
Financing costs	(11,406)	$ 7,004	(a)(b)	
Net loss	$ (21,004)	7,004	(a)(b)	$
Deemed Dividend	--	(4,031)	(d)	

Net loss applicable to common stockholders	$ (21,004)	$ 2,973	$
Basic and diluted loss per share	$ (.48)	$ 0.07	$
Weighted average shares outstanding	43,725,586		43,

(a) Includes restatement adjustments for the Debentures relating to the initial recording of and the effect of certain Conversion Price Resets on the Debentures, as described above.

(b) Includes restatement adjustments for investment banking fees related to Cardinal, as described above.

(d) Includes restatement adjustment for the issuance of the May and June 2009 warrants as incentive to exercise prior warrant issuances, as described above.

We and our audit committee have discussed the above errors and adjustments with our current independent registered public accounting firm and have determined that a restatement was necessary for the periods described above.

RISK FACTORS

The following cautionary statements identify important factors that could cause our actual result to differ materially from those projected in the forward-looking statements made in this report. Among the key factors that have a direct bearing on our results of operations are:

No assurance of successful product development

Ampligen(R) and related products. The development of Ampligen(R) and our other related products is subject to a number of significant risks. Ampligen(R) may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our products are in various stages of clinical and pre-clinical development and, require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen(R) or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

The clinical development of the experimental therapeutic, Ampligen(R) for CFS was initiated approximately 16 years ago. To date federal health agencies have yet to reach a consensus regarding various aspects of ME/CFS, including parameters of "promising therapies" for ME/CFS and which aspects of ME/CFS are anticipated to be "serious or life-threatening".

Over its developmental history, Ampligen(R) has received various

designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities(or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

ALFERON N Injection(R). Although ALFERON N Injection(R) is approved for marketing in the United States for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older; to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments such as multiple sclerosis and cancer.

Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval, our operations will be significantly affected.

All of our drugs and associated technologies, other than ALFERON N Injection(R), are investigational and must receive prior regulatory approval by appropriate regulatory authorities for general use and are currently legally available only through clinical trials with specified disorders. At present, ALFERON N Injection(R) is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of ALFERON N Injection(R) for other indications will require regulatory approval. In this regard, ISI, the company from which we obtained our rights to ALFERON N Injection(R), conducted clinical trials related to use of ALFERON N Injection(R) for treatment of HIV and Hepatitis C. In both instances, the FDA determined that additional studies were necessary in order to fully evaluate the efficacy of ALFERON N Injection(R) in the treatment of HIV and Hepatitis C diseases. We have no immediate plans to conduct these additional studies at this time.

Our products, including Ampligen(R), are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, and the Agency for the Evaluation of Medicinal Products ("EMEA") in Europe. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen(R) or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen(R) will ultimately be demonstrated to be safe or efficacious. In addition, while Ampligen(R) is authorized for use in clinical trials in the United States, we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. If Ampligen(R) or one of our other products does not receive regulatory approval in the U.S. or elsewhere, our operations most likely will be materially adversely affected.

Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avain influenza, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment.

Ampligen(R) is undergoing pre-clinical testing for possible treatment of avian flu. Although preliminary in vitro testing indicates that Ampligen(R) enhances the effectiveness of different drug combinations on avain flu, preliminary testing in the laboratory is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Ampligen(R) in the treatment of Avian flu requires prior regulatory approval. Only the FDA can determine whether a drug is safe, effective or promising for treating a specific application. As discussed in the prior risk factor, obtaining regulatory approvals is a rigorous and lengthy process.

In addition, Ampligen(R) is being tested on one strain of avian flu. There are a number of strains and strains mutate. No assurance can be given that a Ampligen(R) will be effective on any strains that might infect humans.

We may continue to incur substantial losses and our future profitability is uncertain.

We began operations in 1966 and last reported net profit from 1985 through 1987. Since 1987, we have incurred substantial operating losses, as we pursued our clinical trial effort and expanded our efforts in Europe. As of September 30, 2005 our accumulated deficit, as restated, was approximately $144,174,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

We may require additional financing which may not be available.

The development of our products will require the commitment of substantial resources to conduct the time-consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of September 30, 2005, we had approximately $11,632,000 in cash and cash equivalents and short-term investments. These funds should be sufficient to meet our operating cash requirements, including debt service, for the near term. However, we may need to raise additional funds through additional equity or debt financing or from other sources in order to complete the necessary clinical trials and the regulatory approval processes including the commercializing of Ampligen(R) products. There can be no assurances that we will raise adequate funds which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

Under the common stock purchase agreement signed with Fusion Capital on July 8, 2005, we only have the right to receive $40,000 per trading day unless our stock price equals or exceeds $2.00, in which case the daily amount may be increased under certain conditions as the price of our common stock increases (For a more detailed description of the terms of this agreement, see the agreement filed as an exhibit to our Current Report on Form 8-K filed with the SEC on July 11, 2005). Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $1.00. Since we initially registered 10,000,000 shares purchasable by Fusion Capital pursuant to the common stock purchase agreement, the selling price of our common stock to Fusion Capital will have to average at least $2.00 per share for us to receive the maximum proceeds of $20.0 million without registering additional shares of common stock. As of November 1, 2005, we need an average selling price of $2.11 per share for the remainder of the agreement to realize the $20,000,000 in proceeds. The closing price of our stock was $2.84 on November 1, 2005. Subject to approval by our board of directors, we have the right, but not the obligation, to issue more than 10,000,000 shares to Fusion Capital. In the event we elect to issue more than 10,000,000 shares, we will be required to file a new registration statement and have it declared effective by the Securities and Exchange Commission. In the event that we decide to issue more than 10,113,278 (19.99% of our outstanding shares of common stock as of the date of our agreement), we would first be required to seek stockholder approval in order to be in compliance with the American Stock Exchange Market rules.

The extent to which we rely on Fusion Capital as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any trading days that the market price of our common stock is less than $1.00. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to commercialize and sell Ampligen(R) and/or increase sales of ALFERON N Injection(R) or our other products, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we are able to access the full $20.0 million under the common stock purchase agreement with Fusion Capital, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences would materially adversely affect our business, operating results, financial condition and prospects.

We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents.

We need to preserve and acquire enforceable patents covering the use of Ampligen(R) for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen(R) for such disease. We obtained all rights to ALFERON N Injection(R), and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our drug product which are carried out according to standard operating procedure manuals. We have been issued certain patents including those on the use of Ampligen(R) and Ampligen(R) in combination with certain other drugs for the treatment of HIV. We also have been issued patents on the use of Ampligen(R) in combination with certain other drugs for the treatment of chronic Hepatitis B virus, chronic Hepatitis C virus, and a patent which affords protection on the use of Ampligen(R) in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen(R) as a sole treatment for any of the cancers, which we have sought to target. With regard to ALFERON N Injection(R), we have acquired from ISI its patents for natural alpha interferon produced from human peripheral blood leukocytes and its production process. We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing such. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

The patent position of biotechnology and pharmaceutical firms is highly uncertain and involves complex legal and factual questions.

To date, no consistent policy has emerged regarding the breadth of protection afforded by pharmaceutical and biotechnology patents. There can be no assurance that new patent applications relating to our products or technology will result in patents being issued or that, if issued, such patents will afford meaningful protection against competitors with similar technology. It is generally anticipated that there may be significant litigation in the industry regarding patent and intellectual property rights. Such litigation could require substantial resources from us and we may not have the financial resources necessary to enforce the patent rights that we hold. No assurance can be made that our patents will provide competitive advantages for our products or will not be successfully challenged by competitors. No assurance can be given that patents do not exist or could not be filed which would have a materially adverse effect on our ability to develop or market our products or to obtain or maintain any competitive position that we may achieve with respect to our products. Our patents also may not prevent others from developing competitive products using related technology.

There can be no assurance that we will be able to obtain necessary licenses if we cannot enforce patent rights we may hold. In addition, the failure of third parties from whom we currently license certain proprietary information or from whom we may be required to obtain such licenses in the future, to adequately enforce their rights to such proprietary information, could adversely affect the value of such licenses to us.

If we cannot enforce the patent rights we currently hold we may be required to obtain licenses from others to develop, manufacture or market our

products. There can be no assurance that we would be able to obtain any such licenses on commercially reasonable terms, if at all. We currently license certain proprietary information from third parties, some of which may have been developed with government grants under circumstances where the government maintained certain rights with respect to the proprietary information developed. No assurances can be given that such third parties will adequately enforce any rights they may have or that the rights, if any, retained by the government will not adversely affect the value of our license.

There is no guarantee that our trade secrets will not be disclosed or known by our competitors.

To protect our rights, we require certain employees and consultants to enter into confidentiality agreements with us. There can be no assurance that these agreements will not be breached, that we would have adequate and enforceable remedies for any breach, or that any trade secrets of ours will not otherwise become known or be independently developed by competitors.

If our distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent on the efforts of third parties, and there is no assurance that these efforts will be successful. Our agreement with Accredo offers the potential to provide some marketing and distribution capacity in the United States while agreements with Bioclones (Proprietary), Ltd ("Bioclones"), Biovail Corporation and Laboratorios Del Dr. Esteve S.A. may provide a sales force in South America, Africa, United Kingdom, Australia and New Zealand, Canada, Spain and Portugal. On December 27, 2004, we initiated a lawsuit in Federal Court identifying a conspiratorial group seeking to illegally manipulate our stock for purposes of bringing about the hostile takeover of Hemispherx. This conspiratorial group includes Bioclones and the potential legal action may adversely effect our agreement with Bioclones and the potential for marketing and distribution capacity in South America, Africa, United Kingdom, Australia and New Zealand. See Item 1: "Legal Proceedings" in Part II - Other Information below for more information.

We cannot assure that our domestic or foreign marketing partners will be able to successfully distribute our products, or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a materially adverse effect on us.

There are no long-term agreements with suppliers of required materials. If we are unable to obtain the required raw materials, we may be required to scale back our operations or stop manufacturing ALFERON N Injection(R) and/or Ampligen(R).

A number of essential materials are used in the production of ALFERON N Injection(R), including human white blood cells. We do not have long-term agreements for the supply of any of such materials. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

At present, we do not have any agreements with third parties for the supply of any polymers for use in manufacturing Ampligen(R). We are establishing relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen(R) raw materials in order to obtain polymers on a more consistent manufacturing basis. The establishment of an Ampligen(R) raw materials production line within our own facilities, while having obvious advantages with respect to regulatory compliance (other parts of the 43,000 sq. ft. wholly owned facility are already in compliance for Alferon N Injection(R) manufacture), may delay certain steps in the commercialization process, specifically a targeted NDA filing.

If we are unable to obtain or manufacture the required raw materials, we may be required to scale back our operations or stop manufacturing. The costs and availability of products and materials we need for the production of Ampligen(R) and the commercial production of ALFERON N Injection(R) and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all.

There is no assurance that successful manufacture of a drug on a limited scale basis for investigational use will lead to a successful transition to commercial, large-scale production.

Small changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen(R) and other RNA drugs, as well as their safety and efficacy, and can, among other things, require new clinical studies and affect orphan drug status, particularly, market exclusivity rights, if any, under the Orphan Drug Act. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and will require additional management and technical personnel and capital to the extent such manufacturing is not handled by third parties. There can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, capable of being manufactured economically in commercial quantities or successfully marketed.

We have limited manufacturing experience and capacity.

Ampligen(R) has been only produced in limited quantities for use in our clinical trials and we are dependent upon third party suppliers for key components of our products and for substantially all of the production process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse affect on us. Also, to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. To the extent we are involved in the production process, our current facilities are not adequate for the production of our proposed products for large-scale commercialization, and we currently do not have adequate personnel to conduct commercial-scale manufacturing. We intend to utilize third-party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to current Good Manufacturing Practices ("cGMP") regulations. There can be no assurance that such facilities can be used, built, or acquired on

commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for our long-term needs.

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("Schering") entered into a "Consent Decree" with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen(R) (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering has advised us that it would no longer manufacture Ampligen(R) in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities.

On September 9, 2005, we signed a Letter of Intent ("LOI") with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R). In November 2005, we paid $100,000 upon executing the LOI in order to initiate the manufacturing project. The LOI shall remain in full force and effect for 90 calendar days or until a definitive agreement is reached. The achievement of the initial objectives described in the LOI, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for

approximately 10,000 doses of Ampligen(R) per week. Based on the LOI, Hollister-Stier has agreed to formulate and bottle Ampligen(R) using raw materials received from us. We have an executed confidentiality agreement in place and; therefore, have commenced the preliminary transfer of our manufacturing technology to Hollister-Stier. Our decision to transfer relevant manufacturing technology absent of an executed agreement, was done in part to expedite the eventual manufacture of Ampligen(R) by Hollister-Stier. If we are unable to negotiate and finalize an agreement with Hollister-Stier, in a timely manner our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

We have identified two other capable cGMP facilities in the US for the manufacture of Ampligen(R) and obtained proposals from both. If either of these two facilities are acceptable, we would be able to maintain a minimum of two independent production sites. We are in the process of reviewing these other proposals.

The purified drug concentrate utilized in the formulation of ALFERON N Injection(R) is manufactured in our New Brunswick, New Jersey facility and ALFERON N Injection(R) was formulated and packaged at a production facility formerly owned and operated by Abbott Laboratories located in Kansas. Abbott Laboratories has sold the facility to Hospira. We currently have 12,000 vials at Hospira as work-in-progress inventory. We anticipate the conversion of these vials to finished goods will be complete by mid-November 2005. Hospira is ceasing the labeling and packaging of Alferon N Injection(R) as they are seeking larger production runs for cost efficiency puposes. We have identified five new potential contract manufacturers, obtained proposals from all five, and have audited two, concerning the future formulation and packaging of Alferon N Injection(R). If we are unable to secure a new facility within a reasonable period of time to formulate and package ALFERON N Injection(R) at an acceptable cost, our ability to sell ALFERON N Injection(R) and to generate profits therefrom will be adversely affected.

We may not be profitable unless we can produce Ampligen(R) or other products in commercial quantities at costs acceptable to us.

We have never produced Ampligen(R) or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third-party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen(R) or enter into third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. Also, each production lot of Alferon N Injection(R) is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell.

Rapid technological change may render our products obsolete or non-competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase. Most of these entities have significantly greater research and development capabilities than us, as well as substantial marketing, financial and managerial resources, and represent significant competition for us. There can be no assurance that developments by others will not render our products or technologies obsolete or noncompetitive or that we will be able to keep pace with technological developments.

Our products may be subject to substantial competition.

Ampligen(R). Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than us in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating ME/CFS in the United States. The dominant competitors with drugs to treat HIV diseases include Gilead Pharmaceutical, Pfizer, Bristol-Myers, Abbott Labs, Glaxo Smithkline, Merck and Schering-Plough Corp. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen(R) on the immune system, we cannot assure that we will be able to compete.

ALFERON N Injection(R). Many potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. ALFERON N Injection(R) currently competes with Schering's injectable recombinant alpha interferon product (INTRON(R) A) for the treatment of genital warts. 3M Pharmaceuticals also received FDA approval for its immune-response modifier,

Aldara(R), a self-administered topical cream, for the treatment of external genital and perianal warts. ALFERON N Injection(R) also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of ALFERON N Injection(R). If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our potential competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. In the United States, three recombinant forms of beta interferon have been approved for the treatment of relapsing-remitting multiple sclerosis. There can be no assurance that, if we are able to obtain regulatory approval of ALFERON N Injection(R) for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than ALFERON N Injection(R). Currently, our wholesale price on a per unit basis of ALFERON N Injection(R) is higher than that of the competitive recombinant alpha and beta interferon products.

General. Other companies may succeed in developing products earlier than we do, obtaining approvals for such products from the FDA more rapidly than we do, or developing products that are more effective than those we may develop. While we will attempt to expand our technological capabilities in order to remain competitive, there can be no assurance that research and development by others or other medical advances will not render our technology or products obsolete or non-competitive or result in treatments or cures superior to any therapy we develop.

Possible side effects from the use of Ampligen(R) or ALFERON N Injection(R) could adversely affect potential revenues and physician/patient acceptability of our product.

Ampligen(R). We believe that Ampligen(R) has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heart beat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of "feeling hot," sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by slowing the infusion rate. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, transient visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months. One or more of the potential side effects might deter usage of Ampligen(R) in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

ALFERON N Injection(R). At present, ALFERON N Injection(R) is only approved for the intralesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with ALFERON N Injection(R), patients did not experience serious side effects; however, there can be no assurance that

unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of ALFERON N Injection(R) which could threaten or limit such product's usefulness.

We may be subject to product liability claims from the use of Ampligen(R), Alferon N Injection(R), or other of our products which could negatively affect our future operations.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen(R) or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure. Although we currently maintain product liability insurance coverage, there can be no assurance that this insurance will provide adequate coverage against Ampligen(R) and/or Alferon N Injection(R) product liability claims. A successful product liability claim against us in excess of Ampligen(R)'s $1,000,000 in insurance coverage; $3,000,000 in aggregate, or in excess of Alferon N Injection(R)'s $5,000,000 in insurance coverage; $5,000,000 in aggregate; or for which coverage is not provided could have a negative effect on our business and financial condition.

The loss of Dr. William A. Carter's services could hurt our chances for success.

Our success is dependent on the continued efforts of Dr. William A. Carter because of his position as a pioneer in the field of nucleic acid drugs, his being the co-inventor of Ampligen(R), and his knowledge of our overall activities, including patents and clinical trials. The loss of Dr. Carter's services could have a material adverse effect on our operations and chances for success. We have secured key man life insurance in the amount of $2,000,000 on the life of Dr. Carter and we have an employment agreement with Dr. Carter that, as amended, runs until May 8, 2008. However, Dr. Carter has the right to terminate his employment upon not less than 30 days prior written notice. The loss of Dr. Carter or other personnel, or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

Uncertainty of health care reimbursement for our products.

Our ability to successfully commercialize our products will depend, in part, on the extent to which reimbursement for the cost of such products and related treatment will be available from government health administration authorities, private health coverage insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and from time to time legislation is proposed, which, if adopted, could further restrict the prices charged by and/or amounts reimbursable to manufacturers of pharmaceutical products. We cannot predict what, if any, legislation will ultimately be adopted or the impact of such legislation on us. There can be no assurance that third party insurance companies will allow us to charge and receive payments for products sufficient to realize an appropriate return on our investment in product development.

There are risks of liabilities associated with handling and disposing of hazardous materials.

Our business involves the controlled use of hazardous materials, carcinogenic chemicals, flammable solvents and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with the standards prescribed by applicable regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident or the failure to comply with applicable regulations, we could be held liable for any damages that result, and any such liability could be significant. We do not maintain insurance coverage against such liabilities.

Risks Associated With and Investment in Our Common Stock

We reported material weaknesses in our internal control over financial reporting that, if not remedied, could adversely affect our internal controls.

We have assessed the effectiveness of our internal control over financial reporting as of December 31, 2005. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control--Integrated Framework (COSO). Based on this assessment, management has identified the following material weaknesses as of December 31, 2005. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The restatements made to the financial statements for the three and nine months ended September 30, 2004 and 2005 reflect weaknesses in disclosure controls and internal control over financial reporting that existed as of the date of this report. Specifically,

1. Financial Statement Close and Reporting Process - We did not maintain effective controls over the financial statement close and reporting process because we lacked a complement of personnel able to devote sufficient time and adequate financial reporting expertise commensurate with quarterly and year-end financial statement close requirements, which include the financial statement preparation and disclosures. Additionally, we had inadequate policies and procedures providing for a detailed comprehensive review of the underlying information supporting the amounts including in our annual and interim consolidation financial statements and disclosures.

2. We did not maintain effective controls over the initial recording of our convertible debentures that contained beneficial conversion features (including incorrect recording of investment banking fees incurred and subsequent conversion price resets) and the accounting for warrants and options issued to non-employees. Our interpretation and application of EITF No. 00-27, FASB Statement 133, EITF 98-5 and EITF 00-19 was not correct at the time the convertible debentures were initially recorded (2003 through July 2004), and our interpretation and application of FASB statement No. 123 was not correct in recording certain warrant and option issuances to non-employees. These control deficiencies resulted in the restatement of the 2004 and 2003 annual consolidated financial statements as well as to the unaudited consolidated interim financial statements for each of the three years in the period ended December 31, 2005.

The result of applying the proper accounting treatment increased our net loss applicable to common stockholders by $0.01, from $0.42 per share to $0.43 per share, for the year ended December 31, 2003, decreased our net loss

applicable to common stockholders by $0.07, from $0.53 per share to $0.46 per share, for the year ended December 31, 2004, and decreased our net loss per share applicable to common stockholders by $.00, $.01 and $.01 from $.07 per share to $.07 per share, $.08 per share to $.07 per share and $.06 per share to $.05 per share for the first, second and third quarters of 2005, respectively.

Although the recording of the convertible debentures occurred during the periods from March 2003 through July 2004, and we have not issued any debentures since July 2004, we have taken and plan to take, during 2006, additional steps to remediate these internal control weaknesses. We have subscribed to CCH's "Accounting Research Manager," a recognized on-line service in order to maintain up-to-date accounting guidance to enhance internal control over both financial reporting and disclosure requirements. In addition, we have established policies and procedures to include a detailed comprehensive review of the underlying information supporting the amounts included within our consolidated financial statements and disclosures including to assist in ensuring: 1) clerical accuracy within our financial statements and disclosures, 2) financial statement groupings within our financial statements are accurate, 3) support utilized in preparation of the consolidated statement of cash flows is accurate, and 4) equity transactions during the reporting period are complete and accurate. We also engaged an additional accounting consultant in April 2006 to assist in initiating the implementation of these policies and procedures on a going forward basis. Notwithstanding the foregoing, and the measures we have taken and any future measures we may take to remediate the reported internal control weaknesses, we may not be able to maintain effective internal controls over financial reporting in the future. In addition, deficiencies in our internal controls may be discovered in the future. Any failure to remediate the reported material weaknesses, or to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any such failure also could affect the ability of our management to certify in our 2006 Forms 10-K and 10-Q that our internal controls are effective when it provides an assessment of our internal control over financial reporting, and could affect the results of our independent registered public accounting firm's related attestation report regarding our management's assessment. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

The market price of our stock may be adversely affected by market volatility.

The market price of our common stock has been and is likely to be volatile. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency concerns regarding the safety or effectiveness of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;

- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries; new accounting standards; and
- the occurrence of any of the risks described in these "Risk Factors."

Our common stock is listed for quotation on the American Stock Exchange. For the 12-month period ended September 30, 2005, the price of our common stock has ranged from $1.25 to $2.50 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly. Our relatively low average volume and low average number of transactions per day may affect the ability of our stockholders to sell their shares in the public market at prevailing prices and a more active market may never develop.

In the past, following periods of volatility in the market price of the securities of companies in our industry, securities class action litigation has often been instituted against companies in our industry. If we face securities litigation in the future, even if without merit or unsuccessful, it would result in substantial costs and a diversion of management attention and resources, which would negatively impact our business.

Our stock price may be adversely affected if a significant amount of shares are sold in the public market.

As of November 1, 2005, approximately 1,132,457 shares of our common stock, constituted "restricted securities" as defined in Rule 144 under the Securities Act of 1933, 402,798 of which are registered for public sale. Also, we have registered 21,106,907 shares issuable (i) to Fusion Capital pursuant to the common stock purchase agreement with Fusion Capital; (11) upon conversion of approximately 135% of Debentures that we issued in 2003 and 2004; (iii) as payment of 135% of the interest on all of the Debentures; (iv) upon exercise of 135% of the certain Warrants; and (v) upon exercise of certain other warrants. In addition we will be registering an aggregate of 1,224,983 shares representing 135% of shares issuable upon exerice of the October 2009 Warrants and as additional interest shares (resulting from the amendment to the Debentures. Registration of the shares permits the sale of the shares in the open market or

in privately negotiated transactions without compliance with the requirements of Rule 144. To the extent the exercise price of the warrants is less than the market price of the common stock, the holders of the warrants are likely to exercise them and sell the underlying shares of common stock and to the extent that the conversion price and exercise price of these securities are adjusted

pursuant to anti-dilution protection, the securities could be exercisable or convertible for even more shares of common stock. We also may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or directors. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock. Sales of substantial amounts of our common stock in the public market could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

The sale of our common stock to Fusion Capital may cause dilution and the sale of the shares of common stock acquired by Fusion Capital could cause the price of our common stock to decline.

The sale by Fusion Capital of our common stock will increase the number of our publicly traded shares, which could depress the market price of our common stock. Moreover, the mere prospect of resales by Fusion Capital could depress the market price for our common stock. The issuance of shares to Fusion Capital under the common stock purchase agreement dated July 8, 2005, will dilute the equity interest of existing stockholders and could have an adverse effect on the market price of our common stock.

The purchase price for the common stock to be sold to Fusion Capital pursuant to the common stock purchase agreement will fluctuate based on the price of our common stock. All shares sold to Fusion Capital are freely tradable. Fusion Capital may sell none, some or all of the shares of common stock purchased from us at any time. We expect that the shares will be sold over a period of in excess of 25 months from the date theprospectus was filed. Depending upon market liquidity at the time, a sale of shares under this offering at any given time could cause the trading price of our common stock to decline. The sale of a substantial number of shares of our common stock under this offering, or anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Provisions of our Certificate of Incorporation and Delaware law could defer a change of our management which could discourage or delay offers to acquire us.

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, in November 2002, we adopted a stockholder rights plan and, under the Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to

stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one unit of preferred stock for $30.00. The

Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock. However, for Dr. Carter, our chief executive officer, who already beneficially owns 10.3% of our common stock, the Plan's threshold will be 20%, instead of 15%. The Rights will expire on November 19, 2012, and may be redeemed prior thereto at $.01 per Right under certain circumstances.

Because the risk factors referred to above could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements made by us, you should not place undue reliance on any such forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made and we undertake no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for us to predict which will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Our research in clinical efforts may continue for the next several years and we may continue to incur losses due to clinical costs incurred in the development of Ampligen(R) for commercial application. Possible losses may fluctuate from quarter to quarter as a result of differences in the timing of significant expenses incurred and receipt of licensing fees and/or cost recovery treatment revenues in Europe, Canada and in the United States.

NEW ACCOUNTING PRONOUNCEMENTS

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 123 (revised 2004) (FASB 123R), Shared-Based Payment. FASB 123R will require the Corporation to expense share-based payments, including employee stock options, based on their fair value. The Corporation is required to adopt the provisions of FASB 123R effective as of the beginning of its next fiscal year that begins after June 15, 2005. FASB 123R provides alternative methods of adoption, which include prospective application and a modified retroactive application. The Corporation is currently evaluating the financial impact, including the available alternative of adoption of FASB 123R.

Disclosure About Off-Balance Sheet Arrangements

Prior to our annual meeting of stockholders in September 2003, we had a limited number of shares of Common Stock authorized but not issued or reserved for issuance upon conversion or exercise of outstanding convertible and exercisable securities such as debentures, options and warrants. Prior to the meeting, to permit consummation of the sale of the July 2003 Debentures and the related warrants, Dr. Carter agreed that he would not exercise his warrants or options unless and until our stockholders approve an increase in our authorized shares of common stock. For Dr. Carter's waiver of his right to exercise certain options and warrants prior to approval of the increase in our authorized shares, we have agreed to compensate Dr. Carter. See Note 9 in the accompanying financial statements for more information concerning this transaction.
In connection with the Debenture agreements, we have outstanding letters of credit of $1,000,000 as additional collateral.

Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our significant accounting policies are described in Notes to the Consolidated Financial Statements. The significant accounting

policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

Revenue

Revenues for non-refundable license fees are recognized under the Performance Method-Expected Revenue. This method considers the total amount of expected revenue during the performance period, but limits the amount of revenue recognized in a period to total non-refundable cash received to date. This limitation is appropriate because future milestone payments are contingent on future events.

Upon receipt, the upfront non-refundable payment is deferred. The non-refundable upfront payments plus non-refundable payments arising from the achievement of defined milestones are recognized as revenue over the performance period based on the lesser of (a) percentage of completion or (b) non-refundable cash earned (including the upfront payment).

This method requires the computation of a ratio of cost incurred to date to total expected costs and then apply that ratio to total expected revenue. The amount of revenue recognized is limited to the total non-refundable cash received to date.

Revenue from the sale of Ampligen(R) under cost recovery clinical treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

Revenues from the sale of product are recognized when the product is shipped, as title is transferred to the customer. We have no other obligation associated with our products once shipment has occurred.

Patents and Trademarks

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight-line method over the estimated useful life of 17 years. We review our patents and trademark rights periodically to determine whether they have continuing value. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential on an undiscounted cash basis to support the realizability of our respective capitalized cost. In addition, management's review addresses whether each patent continues to fit into our strategic business plans.

Concentration of Credit Risk

Financial instruments that potentially subject us to credit risks consist of cash equivalents and accounts receivable.

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At times, we have bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables consist principally of amounts due from wholesale drug companies as of September 30, 2005.

Convertible Debentures

The March 2003, July 2003, October 2003, January 2004 and July 2004 Debenture issuances and related embedded conversion features and warrants issuances were accounted for in accordance with EITF 98-5: Accounting for convertible securities with beneficial conversion features or contingency adjustable conversion and with EITF No. 00-27: Application of issue No. 98-5 to certain convertible instruments. We determined the fair values to be ascribed to detachable warrants issued with the convertible debentures utilizing the

Black-Scholes method. Discounts derived from determining the beneficial conversion feature and fair value of the warrants based on the relative fair value of the proceeds are amortized to financing costs over the remaining life of the debenture in accordance with the effective interest method of accounting. The unamortized discount upon the conversion of the debentures is expensed to financing cost on a pro-rata basis.

RESULTS OF OPERATIONS

Three months ended September 30, 2004 versus Three months ended September 30, 2005

Net Loss Applicable to Common Stockholders

Our net loss applicable to common stockholders of $2,643,000 for the three months ended September 30, 2005 was down $3,185,000 or 55% compared to the same period in 2004. The reduction was primarily due to $415,000 in lower costs associated with non-cash financing charges related to our convertible debentures and related warrants as well as a deemed dividend of $1,676,000 recorded upon the issuance of warrants to our debenture holders as incentive to exercise prior warrant issuance. In addition, expenditures for manufacturing/production were down $606,000 in 2005 reflecting the decrease in non-recurring expenses associated with the ramping up of the New Brunswick facility for further production of Alferon N Injection(R) in the third quarter of 2004.

Net losses applicable to common stockholders were $(.05) per share for current period versus $(.12) per share in the same period 2004.

Revenues

Revenues for the three months ended September 30, 2005 were $271,000 as compared to revenues of $258,000 for the same period in 2004. Alferon N Injection(R) sales were down $6,000 or 3% while Ampligen(R) sold under the cost recovery clinical program was up $19,000 or 53%. Ampligen(R) sold under the cost recovery clinical program is a product of physicians and ME/CFS patients applying to us to enroll in the program. After screening the patient's enrollment records, we ship Ampligen(R) to the physician. A typical six-month treatment therapy costs the patient about $7,200 for Ampligen(R). This program has been in effect for many years and is offered as a treatment option to patients severely affected by ME/CFS. As the name "cost recovery" implies, we have no gain or profit on these sales. The benefits to us include 1) physicians and patients becoming familiar with Ampligen(R) and 2) collection of clinical data relating to the patients' treatment and results.

We continue our efforts to establish an internal marketing and sales infrastructure to support the sales of Alferon N Injection(R) in the United States. We continually search for qualified sales managers to increase sales

coverage in all major US markets. Our sales force will introduce Alferon N Injection(R) and promote Alferon N Injection(R) to OB GYN's, dermatologists, and infectious disease physicians and particularly STD Clinics, who are involved in the treatment of patients with refractory or recurring external genital warts, as well as physicians about the growing problem and the risks of HPV. We also intend to expand our marketing/sales programs on an international basis with our primary focus on Europe. This program is being designed to engage European pharmaceutical distributors to market and distribute Alferon N Injection(R).

Human papillomavirus (HPV) is one of the most common causes of sexually transmitted infection in the world. Experts estimate that there are more cases of genital HPV infection than of any other sexually transmitted disease (STD) in the United States. The Centers for Disease Control and the National Institute of Health, report that approximately 20 million people are presently infected with HPV. Roughly 6.2 million Americans get a new genital HPV infection each year. While the market for drugs treating HPV is extremely large, there are many competing drugs.

Production costs/cost of goods sold

Our costs for production/cost of goods sold were down $606,000 for the three months ended September 30, 2005 compared to the same period in 2004. A decrease in production costs of approximately $590,000 is primarily due to expenses incurred in the third quarter of 2004 related to preparing the New Brunswick facility for the production of Alferon N Injection(R). There were no such costs for Alferon N Injection(R) in the current quarter. We are now concentrating on the completion of the construction and consolidation of the raw material manufacturing within our own facility in New Brunswick for Ampligen(R). This installation and consolidation will increase production capacity, improve efficiency and assure compliance procedures with worldwide drug manufacturing standards.

Cost of goods sold for the three months ended September 30, 2004 and 2005 were $109,000 and $93,000, respectively. Since acquiring the right to manufacture and market Alferon N Injection(R) in March 2003, we have focused on converting the work-in-progress inventory into finished goods. This work-in-progress inventory included three production lots totaling the equivalent of approximately 55,000 vials (doses) at various stages of the manufacturing process. Approximately 34,000 vials have been produced. In August 2004, we released most of the second lot of product to Hospira (formerly Abbott Laboratories) for bottling and realized approximately 12,000 vials of Alferon N Injection(R). Some 3,000 of the remaining vials within this lot were held back to be utilized in the development of a more compatible vial size for manufacturing of Alferon N Injection(R). Hospira is in the process of completing the labeling and packaging of these approximately 12,000 vials of Alferon N Injection(R) work-in-progress inventory and we anticipate that these vials will be released into finished goods inventory by mid-November 2005. Hospira is ceasing the labeling and packaging of Alferon N Injection(R) as they are seeking larger production runs for cost efficiency purposes. We have identified five new potential contract manufacturers to replace Hospira, obtained proposals from all five, and have audited two concerning the future formulation and packaging of Alferon N Injection(R). We are in the process of reviewing these proposals. If we are unable to secure a new facility within a reasonable period of time to formulate and package Alferon N Injection(R) at an acceptable cost, our ability to sell Alferon N Injection(R) and to generate profits therefrom will be adversely affected.

We plan on initiating the process of converting the third lot of

approximately 13,000 vials of Alferon N Injection(R) from work-in-progress to finished goods inventory in the first half of 2006. We elected to delay the process of converting this third lot as a result of two factors: 1) we are concentrating on the relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen(R) raw materials and 2) Alferon N Injection(R) inventory on hand is sufficient to meet current demand. Approximately 2,000 vials were abstracted from the third lot for research and development purposes during the fourth quarter 2004. Our production and quality control personnel in our New Brunswick, NJ facility are involved in the extensive process of manufacturing and validation required by the FDA.

The installation of an Ampligen(R) raw material production line within our New Brunswick facility should be completed by year end 2005. The transfer of Ampligen(R) raw materials manufacture to our own facilities has obvious advantages with respect to overall control of the manufacturing procedure of Ampligen(R)'s raw materials, keeping costs down and controlling regulatory compliance issues (other parts of the 43,000 sq. ft. wholly owned facility are FDA approved for Alferon N Injection(R) manufacture). This will also allow us to obtain Ampligen(R) raw materials on a more consistent manufacturing basis. In May 2005, we committed to purchase equipment related to the manufacture of Ampligen(R) raw material in the amount of approximately $628,000. We estimate the total cost of establishing this production line to be some $1,800,000, including modifications to our New Brunswick facility.

Research and Development costs

Overall research and development direct costs for the three months ended September 30, 2004 and 2005 were $974,000 and $987,000, respectively. These costs in 2005 reflect the direct costs associated with our effort to develop our lead product, Ampligen(R), as a therapy in treating chronic diseases and cancers as well as on-going clinical trials involving patients with HIV. In addition, these costs reflect direct costs incurred relating to the development of Alferon LDO (low dose oral interferon alfa-N3, human leukocyte derived). We have over approximately 150,000 doses on hand of Alferon LDO which have been prepared for use in clinical trials treating patients affected with the SARS, Avian Flu or other potentially emerging infectious diseases.

During 2005, we increased our clinical staff by employing several highly trained individuals to focus on the preparation of our Ampligen(R) NDA filing. The NDA filing is a very complex document and we are being meticulous in the preparation of the document. Our clinical monitors and research assistants are in the process of visiting the multiple clinical study sites around the country and are collecting and auditing data generated at each of these sites. All data must be reviewed and checked to clarify any inconsistencies or inaccuracies that turn up. Due to the human factor, these types of problems occur in all clinical trials. These gaps and inconsistencies in data must be resolved with the respective clinical investigators, while maintaining a clear record of events which allows the FDA to conduct a meaningful audit of these records.

We believe that our recently completed AMP 516 ME/CFS Phase III clinical trial for use of Ampligen(R) in the treatment of ME/CFS is the most comprehensive study ever conducted in ME/CFS. This Phase III clinical trial, which was conducted over a six-year period, involved an enrollment of more than 230 severely debilitated ME/CFS patients and was conducted at twelve medical centers throughout the United States. The study is serving as the basis for us to file a new drug application with the FDA.

We had originally targeted a late 2004 filing date for this NDA for Ampligen(R). In order to respond to recent changes in the regulatory environment that place a greater emphasis on the safety and efficacy of all new experimental drug candidates, we are now incorporating a larger sample of data from our previous trials. The NDA filing will now include data accumulated from 40,000 administrations of the studied drug to approximately 700 ME/CFS patients.

The clinical development of the experimental therapeutic, Ampligen(R) for ME/CFS was initiated approximately 16 years ago. To date federal health agencies have yet to reach a consensus regarding various aspects of ME/CFS, including parameters of "promising therapies" for ME/CFS and which aspects of ME/CFS are anticipated to be "serious or life-threatening".

Over its developmental history, Ampligen(R) has received various designations, including Orphan Drug Product Certification (FDA), Emergency (compassionate) Cost Recovery Sales Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ, Agency Health Research Quality). However to date, the FDA has determined it has yet to receive sufficient information to support the potential of Ampligen(R) to treat a serious or life threatening aspect of ME/CFS. The definition of the "seriousness of a condition", according to Guidance for Industry documents published in July, 2004 is "a matter of judgment, but generally based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one". The FDA has recently requested a "complete and audited report of the Amp 516 study to determine whether Ampligen(R) has a clinically meaningful benefit on a serious

or life threatening aspect of ME/CFS in order to evaluate whether the Amp 516 study results do or do not support a "fast track designation". The FDA has also invited us to include a schedule for completion of all ME/CFS studies as well as a proposed schedule for our NDA submission. Because we believe our ME/CFS studies are complete, we intend to request a pre-NDA meeting to obtain advice on preparing and submitting our NDA. At the same time we will continue with our existing ongoing efforts to prepare a complete and audited report of our various studies, including the well-controlled Amp 516 study. We are using our best efforts to complete the requisite reports including the hiring of new staff and various recognized expert medical/regulatory consultants, but can provide no assurance as to whether the outcome of this large data collection and filing process (approximately 750 patients, treated more than 45,000 times) will be favorable or unfavorable, specifically with respect to the FDA's perspective. Also, we can provide no guidance as to the tentative date at which the compilation and filing of such data will be complete, as significant factors are outside our control including, without limitation, the ability and willingness of the independent clinical investigators to complete the requisite reports at an acceptable regulatory standard, the ability to collect overseas generated data, and the ability of Hollister-Stier facilities (or the facilities of such other manufacturer as we may retain in the event that we do not come to definitive terms with Hollister-Stier) to interface with our own New Brunswick staff/facilities to meet the manufacturing regulatory standards.

The timing of the FDA review process of the NDA is subject to the control of the FDA and result in one of the following events; 1) approval to market Ampligen(R) for use in treating ME/CFS patients, 2) require more research, development, and clinical work, 3) approval to market as well as conduct more testing, or 4) reject our application ("NDA"). Given these variables, we are unable to project when material net cash inflows are expected to commence from the sale of Ampligen(R).

Ampligen(R) is currently in two Phase IIb studies for the treatment of HIV to overcome multi-drug resistance, virus mutation and toxicity associated with current HAART therapies. One study, the AMP-719, is a Salvage Therapy, conducted in the U.S. and evaluating the potential synergistic efficacy of Ampligen(R) in multi-drug resistant HIV patients for immune enhancement. The second study, the AMP-720, is a clinical trial designed to evaluate the effect of Ampligen(R) under Strategic Treatment Intervention and is also conducted in the U.S. Enrollment in the AMP 719 study is presently on hold as we focus our efforts on ramping up the AMP 720 study.

The Amp 720 HIV study is a treatment using a Strategic Treatment Interruption (STI). The patients' antiviral HAART regimens are interrupted and Ampligen(R) is substituted as mono-immunotherapy. Ampligen(R) is an experimental immunotherapeutic designed to display both antiviral and immune enhancing characteristics. Prolonged use of Highly Active Antiretroviral Therapy (HAART) has been associated with long-term, potentially fatal, toxicities. The clinical study AMP 720 is designed to address these issues by evaluating the administration of our lead experimental agent, Ampligen(R), a double stranded RNA drug acting potentially both as an immunomodulator and antiviral. Patients, who have completed at least nine months of Ampligen(R) therapy, were able to stay off HAART for a total STI duration with a mean time of 29.0 weeks whereas the control group, which was also taken off HAART, but not given Ampligen(R), had earlier HIV rebound with a mean duration of 18.7 weeks. Thus, on average, Ampligen(R) therapy spared the patients excessive exposure to HAART, with its inherent toxicities, for more than 11 weeks. We enrolled two new patients in this study in the third quarter. 41 HIV patients have already participated in this 64 week study. It is difficult to estimate the duration or projected costs of this clinical trial due to the many variables involved, i.e.: patient drop out rate, recruitment of clinical investigators, etc. The length of the study and costs related to our clinical trials cannot be determined at this time as

such will be materially influenced by (a) the number of clinical investigators needed to recruit and treat the required number of patients, (b) the rate of accrual of patients and (c) the retention of patients in the studies and their adherence to the study protocol requirements. Under optimal conditions, the cost of completing the studies could be approximately $2.5 to $3.0 million if the target of 120 patients is achieved. The rate of enrollment depends on patient availability and on other products being in clinical trials for the treatment of HIV, as there is competition for the same patient population. At present, more than 18 FDA approved drugs for HIV treatment may compete for available patients. The length, and subsequently the expense of these studies, will also be determined by an analysis of the interim data, which will determine when completion of the ongoing Phase IIb is appropriate and whether a Phase III trial will be conducted or not. In case a Phase III study is required; the FDA might require a patient population exceeding the current one which will influence the cost and time of the trial. Accordingly, the number of "unknowns" is sufficiently great to be unable to predict when, or whether, we may obtain revenues from our HIV treatment indications.

With the threat of an avian influenza pandemic rising and health officials warning that the virus could develop resistance to current flu treatments, the pursuit of a cost-effective and complementary treatment to existing antivirals and vaccines has become critical. This combination may permit the use of lower dosages and fewer injections of the antivirals and vaccines used to combat avian flu, thereby decreasing the cost of both immunization programs and treatment programs for the full-blown disease.

In antimicrobial (antibacterial) therapy, which is the best-studied clinical model, synergistic drug combinations may result in curative conditions/outcomes, often not observed when the single drugs are given alone. In the case of avian influenza where global drug supplies are presumptively in very limited supply relative to potential needs, therapeutic synergistic combinations could not only affect the disease outcome, but also the number of individuals able to access therapies.

We recently announced that true therapeutic synergy had been observed in the interaction between Ampligen(R) and Tamiflu in the inhibition of the avian influenza virus. Cell destruction was measured in vitro using different drug combinations. True therapeutic synergy is defined by mathematical equations which indicate that the therapeutic effect observed is in fact greater than the expected arithmetic sum of the two drugs working independently, and is referred to by pharmacologists as the "Chou/Talalay" equations developed at Johns Hopkins University.

In a recently reported study from a vaccine group in Japan, the incorporation of poly I: poly C (dsRNA) into a nasal administration of a killed influenza A preparation converted a poorly immunogenic response into a highly efficacious vaccine in protection of mice from lethal infection from human influenza A. Ampligen is a dsRNA which currently is undergoing testing in the animal model.

A preclinical study was initiated in June 2005, to determine if Ampligen(R) enhances the effectiveness of different drug combinations on avain influenza. The preclinical study suggests a new, and potentially pivotal role of double-stranded RNA ("dsRNA") therapeutics in improving the efficiacy of the present standards in care in both influenza prevention and treatment of acute disease. The preclinical study is being conducted by research affiliates of the National Institutes of Health at Utah State University to examine potential therapeutic synergies with different drug combinations. The ongoing research is comparing the relative protection conveyed by Tamiflu (oseltamivir, Roche) and Ampligen(R) (dsRNA), alone and in combination, against the avian flu virus (H5N1). Cell destruction was measured in vitro using different drug combinations. Both drugs, given alone, were effective in inhibiting cell destruction by avian influenza, but viral suppression with the combination was greater than either drug alone. The overall assessment is that there was improvement in cell protection when Ampligen(R) was combined with oseltamivir carboxylate (Tamiflu). Further immediate experimental tests are planned.

Recently, Japanese researchers (Journal of Virology page 2910, 2005) have found that dsRNAs increase the effectiveness of influenza vaccine by more than 300% and may also convey "cross-protection ability against variant viruses" (mutated strains of influenza virus). In October 2005, we signed a research agreement with the National Institute of Infectious Diseases, in Tokyo, Japan. The collaboration, by Hideki Hasegawa, M.D., Ph.D., Chief of the Laboratory of Infectious Disease Pathology, will assess Hemispherx' experimental therapeutic Ampligen(R) as an adjuvant to the Institution's nasal flu vaccine.

In October 2005, we also engaged the Sage Group, Inc., a health care, technology oriented, strategy and transaction advisory firm, to assist us in obtaining a strategic alliance in Japan for the use of Ampligen(R) in treating Chronic Fatigue Syndrome or CFS. In the past year leaders in the Japanese medical community have established the Japanese Society of the Fatigue Science and the Osaka City University Hospital opened the Fatigue Clinical Center as the initial step in their Fatigue Research Project.

A clinical study has been approved by the Clinical Research Ethics Committee of the Kowloon West Cluster at the Princess Margaret Hospital in Hong Kong to evaluate the use of Alferon LDO (Low Dose Oral Interferon Alfa-N3, Human Leukocyte Derived) in normal volunteers and/or asymptomatic subjects with exposure to a person known to have SARS.

A clinical study to evaluate the use of Alferon LDO in HIV infected volunteers was initiated during the second quarter 2005 in Philadelphia, PA. The study is currently being conducted at two sites, Drexel University and Philadelphia FIGHT, a comprehensive AIDS service organization providing primary care, consumer education, advocacy and research on potential treatments and vaccines. The study is designed to determine whether Alferon LDO can resuscitate the broad-spectrum antiviral and immunostimulatory genes. The initial patient enrolled in this study in July 2005 and, as of October 2005, five patients have completed dosing. The trial methodology may have implications for treating other emerging viruses such as avian influenza (bird flu). Present production methods for vaccines involve the use of millions of chicken eggs and would be slow to respond to an outbreak according to a recently convened World Health Organization (WHO) expert panel in November 2004. Health officials are also concerned that bird flu could mutate to cause the next pandemic and render present vaccines under development ineffective.

In September 2004, we commenced a clinical trial using Alferon N Injection(R) to treat patients infected with the West Nile Virus. The infectious Disease section of New York Queens Hospital and the Weill Medical College of Cornell University are conducting this double-blinded, placebo controlled trial. This study plans to enroll 60 patients as they become available. As of October 2005, nine patients have entered this study. The CDC reports that 1,804 cases of West Nile Virus have been reported in the US as of September 27, 2005, including 52 deaths.

We have completed the transfer and consolidation of our Rockville Quality Assurance Lab and equipment into our New Brunswick facility. We believe this newly consolidated lab will provide more efficiencies with regard to the quality assurance needs for both Ampligen(R) and Alferon N Injection(R).

In connection with settling various manufacturing infractions previously noted by the FDA, Schering-Plough ("Schering") entered into a "Consent Decree" with the FDA whereby, among other things, it agreed to discontinue various contract (third party) manufacturing activities at various facilities including its San Juan, Puerto Rico, plant. Ampligen(R) (which was not involved in any of the cited infractions) was produced at this Puerto Rico plant from year 2000-2004. Operating under instructions from the Consent Decree, Schering has advised us that it would no longer manufacture Ampligen(R) in this facility beyond 2004 and would assist us in an orderly transfer of said activities to other non Schering facilities.

On September 9, 2005, we signed a Letter of Intent ("LOI") with Hollister-Stier Laboratories LLC of Spokane, Washington ("Hollister-Stier"), for the contract manufacturing of Ampligen(R). In November 2005, we paid $100,000 upon executing the LOI in order to initiate the manufacturing project. The LOI shall remain in full force and effect for 90 calendar days or until a definitive agreement is reached. The achievement of the initial objectives described in the LOI, in combination with our polymer production facility under construction in New Brunswick, N.J., may enable us to manufacture the raw materials for approximately 10,000 doses of Ampligen(R) per week. Based on the LOI, Hollister-Stier has agreed to formulate and bottle Ampligen(R) using raw materials received from us. We have an executed confidentiality agreement in

place and; therefore, have commenced the preliminary transfer of our manufacturing technology to Hollister-Stier. Our decision to transfer relevant manufacturing technology absent of an executed agreement, was done in part to expedite the eventual manufacture of Ampligen(R) by Hollister-Stier. If we are unable to negotiate and finalize an agreement with Hollister-Stier, in a timely manner our plans to file an NDA for Ampligen(R) and, eventually, to market and sell Ampligen(R) will be delayed.

We have identified two other capable cGMP facilities in the US for the manufacture of Ampligen(R) and obtained proposals from both. If either of these two facilities are acceptable, we would be able to maintain a minimum of two independent production sites. We are in the process of reviewing these other proposals.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2004 and 2005 were approximately $1,299,000 and $1,384,000, respectively. The increase in G&A expenses of $85,000 during this period is primarily due to stock compensation of $53,000 and higher public accounting and other professional fees.

Interest and Other Income

Interest and other income for the three months ended September 30, 2004 and 2005 totaled $32,000 and $250,000, respectively. The increase in interest and other income during the current quarter can primarily be attributed to the maturing of marketable securities during the 2005 period. All funds in excess of our immediate need are invested in short-term high quality securities.

Interest Expense and Financing Costs

Interest and Expense non-cash financing costs were approximately $700,000 for the three months ended September 30, 2005 versus $1,097,000 in charges for the same three months a year ago. Non-cash financing costs consist of the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our debentures and the relative fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." The main reason for the decrease in financing costs of $397,000 can be attributed to the aggregate total of these charges being reduced since 2004 due to decreased amortization charges as well as charges related to the conversion of debentures. Please see Note 8 in the consolidated financial statements contained herein for more details on these transactions.

Deemed Dividend

Deemed dividend for the three months ended Septemeber 30, 2004 and 2005, was $1,676,000 and $0, respectively. This represents the fair value of the warrants issued to our debenture holders as incentive to exercise prior warrant issuances.

Nine months ended September 30, 2004 versus Nine months ended September 30, 2005

Net Loss Applicable to Common Stockholders

Our net loss applicable to common stockholders of $8,968,000 for the

nine months ended September 30, 2005 was down $9,063,000 or 50% compared to the same period in 2004. This reduction was primarily due to: 1) lower costs associated with non-cash financing charges related to convertible debentures. These lower non-cash financing costs of $1,999,000 represented 22% of the change in net loss from period to period, 2) production/costs of good sold expenditures were down $1,697,000 due to expenditures during the first three quarters of 2004 associated with ramping up of the New Brunswick facility for further production of Alferon N Injection(R), 3) lower non-cash stock compensation expenses of approximately $2,000,000 and 4) deemed dividend of $4,031,000 recorded upon the issuance of warrants to our debenture holders as incentive to exercise prior warrant issuances during the second and third quarters 2004. Net loss applicable to common stockholders was $(.18) per share for the current period versus $(.41) per share for the same period 2004.

Revenues

Revenues for the nine months ended September 30, 2005 were $829,000 as compared to revenues of $907,000 for the same period in 2004. Ampligen(R) sold under the cost recovery clinical program was up $16,000 (13%) and Alferon N Injection sales were down $94,000 (12%). For more information concerning revenue, see the revenue section contained in the results of operations for the three months ended September 30, 2004 versus three months ended September 30, 2005 discussed above.

Production costs/cost of goods sold

Production costs for the nine months ended September 30, 2004 were $1,641,000. These costs represented expenditures associated with preparing the New Brunswick facility for further production of Alferon N Injection(R) in the first three quarters of 2004. There were no production costs for Alferon N Injection(R) during the first nine months of 2005 as we concentrated on the completion of the consolidation of all raw material manufacturing and research and development activities within our facility in New Brunswick for Ampligen(R). This consolidation will improve production capacity, efficiency, and compliance procedures and bring the facility in line with worldwide drug manufacturing standards.

Cost of goods sold for the nine months ended September 30, 2004 and 2005 were $350,000 and $294,000, respectively. For more information concerning production/cost of goods sold, see the production/costs of goods sold section contained in the results of operations for the three months ended September 30, 2004 versus three months ended September 30, 2005 discussed above.

Research and Development costs

Overall research and development direct costs for the nine months ended September 30, 2004 and 2005 were $2,696,000 and $3,413,000, respectively. For more information on research and development activities, see the research and development section contained within the results of operations for the three months ended September 30, 2004 versus three months ended September 30, 2005 discussed above.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2004 and 2005 were approximately $5,229,000 and $3,933,000, respectively. The decrease in G&A expenses of $1,296,000 during this period is primarily due to a non-cash stock compensation charge of $1,769,000 resulting

from the issuance of 1,450,000 warrants to purchase common stock at $2.20 per share to Dr. Carter in 2003 that vested in the first quarter 2004. The warrants vested upon the second ISI asset closing which occurred on March 17, 2004. Higher professional fees, specifically legal costs, during the first nine months of 2005, slightly offset this decrease in G & A expenses, from period to period. The costs were associated with lawsuits we initiated seeking injunctive relief and damages against conspiratorial groups alleging that the conspiratorial group engaged in illegal activities to take over Hemispherx and enrich themselves at the expense of our shareholders. Please see Item 1. "Legal Proceedings" in Part II - Other Information, below for more information.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2004 and 2005 totaled $56,000 and $543,000, respectively. The increase in interest and other income during the current quarter can primarily be attributed to the maturing of marketable securities during the 2005 period.

Interest Expense and Financing Costs

Interest expense and non-cash financing costs were approximately $2,700,000 for the nine months ended September 30, 2005 versus $4,674,000 for the same nine months a year ago. Non-cash financing costs consist of the amortization of Original Issue Discounts and the amortization of costs associated with beneficial conversion features of our debentures and the relavtive fair value of the warrants relating to the Debentures. These charges are reflected in the Consolidated Statements of Operations under the caption "Financing Costs." The main reason for the decrease in financing costs of $1,974,000 can be attributed to the aggregate total of these charges being reduced since 2004 due to a decrease in amortization charges and additional financing costs during the first half of 2004 with regard to our January 2004 debenture and the impact of Section 713 of the American Stock Exchange Company Guide. Please see Note 8 "Section 713 of The American Stock Exchange Company Guide" in the consolidated financial statements contained herein for more details on these transactions and for details on our debenture and stock financings.

Deemed Dividend

Deemed dividend for the nine months ended September 30, 2004 and 2005 was $4,031,000 and $0, respectively. This represents the fair value of the warrants issued to our debenture holders as incentive to exercise prior warrant issuances.

Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2005 was $5,283,000. As of September 30, 2005, we had approximately $11,632,000 million in cash and short-term investments. These funds should be sufficient to meet our operating cash requirements including debt service for the near term. For detailed information on our debenture and equity financings during this period, please see Note 8 and 9 in the consolidated financial statements contained herein.

In May 2005, we committed to purchase lab equipment related to the manufacture of Ampligen(R) raw material ("polymers") in the amount of approximately $628,000. The overall cost of establishing the polymer production line at the New Brunswick facility is estimated at $1,800,000.

As of November 1, 2005, we have made aggregate installment payments of $2,389,000 and the investors have converted an aggregate $2,762,000 principal amount of debt from the Debentures noted below (in thousands):

Debenture	Original Principal Amount	Debt Conversion to Common Shares	Installment payments in Common Shares	Remaining Principal Amount	Common Sha issued f Conversi
October 2003	$ 4,142	$ 2,071	$ --	$ 2,071	1,025
January 2004	4,000	690	1,889	1,421	320
July 2004	2,000	--	500	1,500	--
Totals	$10,142	$ 2,762	$ 2,389	$ 4,992	1,345

On July 8, 2005, we entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"), pursuant to which Fusion Capital has agreed, under certain conditions, to purchase on each trading day $40,000 of our common stock up to an aggregate of $20.0 million over approximately a 25 month period, subject to earlier termination at our discretion. For detailed information on our equity financing, please see Note 9 in the consolidated financial statements contained here in.

Pursuant to our agreement with Fusion Capital, we have registered for public sale by Fusion Capital up to 10,795,597 shares of our common stock. However, in the event that we decide to issue more than 10,113,278, i.e. greater than 19.99% of the outstanding shares of common stock as of the date of the agreement, we would first seek stockholder approval in order to be in compliance with American Stock Exchange rules.

This funding arrangement with Fusion Capital plus our current cash position should be sufficient to meet our operating cash requirements for the next 30 months. However, we may need to raise additional funds through equity or debt financing or from other sources to the extent that we do not receive adequate funding from Fusion Capital (see "Risk Factors - We may require additional financing that may not be available") and to complete the regulatory processes including the commercialization of Ampligen(R) products. There can be no assurances that we will raise funds from these or other sources, which may have a material adverse effect on our ability to develop our products.

Effective October 6, 2005, the Company entered into a material definitive agreement with the debenture holders to 1) amend the remaining outstanding debentures that were to mature on October 31, 2005 (as amended, the "Series A Debenture") and the two traunches of outstanding debentures due to mature on January 31, 2006 (as amended, respectively, the "Series B and Series C Debentures"), to a maturity date of June 30, 2007, 2) to increase the interest rate from 6% per annum to 7% per annum. In consideration for extending the maturity date of the outstanding debentures, the Company issued an aggregate of 225,000 Warrants (the "October 2009 Warrants") to the debenture holders to acquire common stock at a price of $2.50 per share at any time from October 31, 2005 through October 31, 2009.

Also, because of our long-term capital requirements, we may seek to access the public equity market whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. Any additional funding may result in significant dilution and could involve the issuance of securities with rights, which are senior to those of existing stockholders. We

may also need additional funding earlier than anticipated, and our cash requirements, in general, may vary materially from those now planned, for reasons including, but not limited to, changes in our research and development programs, clinical trials, competitive and technological advances, the regulatory processes, including the commercializing of Ampligen products.

There can be no assurances that we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

Item 4: Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-QA was made under the supervision and with the participation of management, including our Chief Executive Officer and Chief Fincancial Officer. In connection with such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective based on the material weaknesses in internal control over financial reporting described in our Annual Report on Form 10-K/A for the period ended December 31, 2005.

Remediation of Material Weaknesses

During the second quarter of 2006, to remedy the material weakness in our internal control over financial reporting, we initiated the process of establishing procedures to enhance controls over the "financial statement close and disclosure" process which included subscribing to CCH's "Accounting Research Manager", a recognized on-line service in order to maintain up-to-date accounting and disclosure guidance. In addition, we have established policies and procedures to include a detailed comprehensive review of the underlying information supporting the amounts included within our consolidated financial statements and disclosures including documented reviews to assist in ensuring: 1) clerical accuracy within our financial statements and disclosures, 2) financial statement groupings within our financial statements are accurate, 3) support utilized in preparation of the consolidated statement of cash flows is accurate, and 4) equity transactions during the reporting period are completely and accurately recorded. We engaged an additional accounting consultant in April 2006 to assist in initiating the implementation of these policies and procedures during the second quarter 2006. The control deficiencies will be fully remediated when in the opinion of the Company's management, the revised control processes have been operating for a sufficient period of time to provide reasonable assurance as to their effectiveness. The Company believes it will be able to make this assessment by December 31, 2006.

Changes in Internal Controls

Other than as described above, there was no change in our internal controls over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this report that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II - OTHER INFORMATION

ITEM 6: Exhibits

(a) Exhibits

31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Executive Officer
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 from the Company's Chief Financial Officer

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.

HEMISPHERx BIOPHARMA, INC.

/S/ William A. Carter

William A. Carter, M.D.
Chief Executive Officer & President

/S/ Robert E. Peterson

Robert E. Peterson
Chief Financial Officer

Date: July 31, 2006