HEMISPHERX BIOPHARMA INC
Form 10-Q
August 08, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q
Quarterly Report Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the Quarterly Period Ended June 30, 2014

Commission File Number: 1-13441

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 500, Philadelphia, PA 19103
(Address of principal executive offices) (Zip Code)

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

(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.
x Yes ¨ No

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

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

¨ Large accelerated filer	¨ Accelerated filer
¨ Non-accelerated filer	x Smaller reporting company

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

189,997,547 shares of common stock were outstanding as of August 1, 2014.

PART I - FINANCIAL INFORMATION

ITEM 1: Financial Statements

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(in thousands, except for share and per share amounts)

	June 30, 2014 (Unaudited)	December 31, 2013 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$2,617	$803
Marketable securities	17,595	17,391
Prepaid expenses and other current assets	246	358
Total current assets	20,458	18,552
Property and equipment, net	4,845	5,053
Patent and trademark rights, net	924	1,080
Construction in progress	7,188	7,046
Other assets	134	136
Total assets	$33,549	$31,867
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$1,471	$1,271
Accrued expenses	2,659	1,228
Current portion of capital lease	31	33
Total current liabilities	4,161	2,532
Long-term liabilities		
Long-term portion of capital lease	7	23
Redeemable warrants	13	14
Total liabilities	4,181	2,569
Commitments and contingencies (Notes 6, 8, 10)		
Stockholders' equity:		
Preferred stock, par value $0.01 per share, authorized 5,000,000; issued and outstanding; none	—	—
Common stock, par value $0.001 per share, authorized 350,000,000 shares; issued and outstanding 189,498,664 and 168,660,370, respectively	189	168
Additional paid-in capital	298,236	289,563
Accumulated other comprehensive income (loss)	54	(114)
Accumulated deficit	(269,111)	(260,319)
Total stockholders' equity	29,368	29,298
Total liabilities and stockholders' equity	$33,549	$31,867

See accompanying notes to consolidated financial statements.

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

	Three months ended June 30, 2014	Three months ended June 30, 2013	Six months ended June 30, 2014	Six months ended June 30, 2013
Revenues:				
Clinical treatment programs	$36	$36	$112	$78
Total revenues	36	36	112	78
Costs and expenses:				
Production/cost of goods sold	294	635	617	826
Research and development	2,330	2,318	4,656	4,654
General and administrative	2,497	1,817	5,036	3,894
Total costs and expenses	5,121	4,770	10,309	9,374
Operating loss	(5,085)	(4,734)	(10,197)	(9,296)
Interest expense	(3)	(5)	(6)	(10)
Interest and other income	131	354	284	535
Gain from sale of income tax net operating losses	—	—	1,126	686
Redeemable warrants valuation adjustment	1	102	1	191
Net loss	(4,956)	(4,283)	(8,792)	(7,894)
Other Comprehensive Income (Loss):				
Unrealized gain (loss) on marketable securities	147	(1,005)	168	(960)
Reclassification adjustments for impairment losses included in net loss	—	(76)	—	(85)
Net comprehensive loss	$(4,809)	$(5,364)	$(8,624)	$(8,939)
Basic and diluted loss per share	$(0.03)	$(0.03)	$(0.05)	$(0.05)
Weighted average shares outstanding, basic and diluted	185,749,722	167,202,512	181,265,253	167,005,714

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Stockholders' Equity
For the Six Months Ended June 30, 2014
(in thousands except share data)
(Unaudited)

	Common Stock Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2013	168,660,370	$168	$289,563	$(114)	$(260,319)	$29,298
Stock issued for settlement of accounts payable	153,273	—	38	—	—	38
Equity-based compensation	—	—	198	—	—	198
Shares sold at the market	20,685,021	21	8,437	—	—	8,458
Net comprehensive loss	—	—	—	168	(8,792)	(8,624)
Balance at June 30, 2014	189,498,664	$189	$298,236	$54	$(269,111)	$29,368

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
For the Six Months Ended June 30, 2014 and 2013
(in thousands)
(Unaudited)

	2014	2013
Cash flows from operating activities:		
Net loss	$(8,792)	$(7,894)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	332	350
Amortization and abandonment of patent and trademark rights	276	87
Redeemable warrants valuation adjustment	(1)	(191)
Equity-based compensation	198	219
Change in assets and liabilities:		
Inventories	—	453
Prepaid expenses and other current assets	112	(37)
Accounts payable	238	(1,026)
Accrued expenses	1,431	(1,590)
Net cash used in operating activities	(6,206)	(9,629)
Cash flows from investing activities:		
Purchase of property, equipment and construction in progress	(266)	(534)
Additions to patent and trademark rights	(120)	(122)
Deposits on capital leases refunded	2	3
Deposit paid on office lease	—	(74)
Maturities of short-term and long-term marketable securities	—	9,479
Purchase of short-term and long-term marketable securities	(36)	—
Net cash provided by (used in) investing activities	(420)	8,752

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows (Continued)
For the Six Months Ended June 30, 2014 and 2013
(in thousands)
(Unaudited)

	2014	2013
Cash flows from financing activities:		
Payments on capital leases	$(18)	$(29)
Proceeds from sale of stock, net of issuance costs	8,458	—
Net cash provided by (used in) financing activities	8,440	(29)
Net increase (decrease) in cash and cash equivalents	1,814	(906)
Cash and cash equivalents at beginning of period	803	2,212
Cash and cash equivalents at end of period	$2,617	$1,306
Supplemental disclosures of non-cash investing and financing cash flow information:		
Issuance of common stock for accounts payable	$38	$164
Unrealized gain (loss) on marketable securities	$168	$(1,044)
Supplemental disclosure of cash flow information:		
Cash paid for interest expense and capitalized construction interest	$(9)	$(98)

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 consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has three domestic subsidiaries: BioPro Corp., BioAegean Corp. and Core Biotech Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., established in Belgium in 1998, has minimal activity. All significant intercompany balances and transactions have been eliminated in consolidation. Certain items in these financial statements have been reclassified to conform to the current year presentation.

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 the Company's annual consolidated financial statements and notes thereto.

These consolidated financial statements should be read in conjunction with the Company's consolidated financial statements for the years ended December 31, 2013 and 2012, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants which amounted to 62,575,159 and 37,071,415 shares for the six months ended June 30, 2014 and 2013, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive.

Note 3: Equity-Based Compensation

The fair value of each option and equity warrant award is estimated on the date of grant using a Black-Scholes-Merton option pricing valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option and equity warrant. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. There were 855,000 options or equity warrants granted in the six months ended June 30, 2014. The fair values of the options and equity warrants granted in the six months ended June 30, 2014 and 2013, were estimated based on the following weighted average assumptions:

	Six Months Ended June 30,	
	2014	2013
Risk-free interest rate	1.66%	0.14% - 1.01%
Expected dividend yield	—	—
Expected lives	5 years	1 year to 5 years
Expected volatility	92.631%	89.727% - 118.222%
Weighted average grant date fair value for options and equity warrants issued	$0.23 per option/warrant for 855,000	$0.12 per option/warrant for 2,520,000

	options/warrants	options/warrants

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Stock option for employees' activity during the six months ended June 30, 2014 is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2014	10,611,480	$1.73	4.92	$—
Granted	855,000	0.36	9.92	—
Forfeited	(200,000)	0.43	8.00	—
Outstanding June 30, 2014	11,266,480	$1.66	4.77	$—
Vested and expected to vest June 30, 2014	11,266,480	$1.66	4.77	$—
Exercisable June 30, 2014	10,457,730	$1.73	4.25	$—

855,000 options to purchase shares were granted to employees during the six months ended June 30, 2014.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2014	525,000	$0.29	8.38	$—
Granted	855,000	0.36	9.92	—
Vested	(571,250)	0.28	9.18	—
Forfeited	—	—	—	—
Outstanding June 30, 2014	808,750	$0.37	9.11	$—

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2014	4,128,432	$1.48	5.01	$—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(200,000)	2.97	3.56	—
Outstanding June 30, 2014	3,928,432	$1.40	4.56	$—
Vested and expected to vest June 30, 2014	3,928,432	$1.40	4.56	$—
Exercisable June 30, 2014	3,807,599	$1.65	4.43	$—

No options to purchase shares were granted to non-employees during the six months ended June 30, 2014.

Unvested stock option activity for non-employees during the year:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2014	470,833	$0.25	9.61	$—
Options granted	—	—	—	—
Options vested	(350,000)	0.25	9.11	—
Options forfeited	—	—	—	—
Outstanding June 30, 2014	120,833	$0.25	9.11	$—

The impact on the Company’s results of operations of recording equity-based compensation for the six months ended June 30, 2014 and 2013 was to increase general and administrative expenses by approximately $198,000 and $219,000, respectively. There was no impact on basic and fully diluted earnings per share for the six months ended June 30, 2014 and 2013.

As of June 30, 2014 and 2013, respectively, there was $348,000 and $278,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan.

Note 4: 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) June 30, 2014	December 31, 2013
Inventory work-in-process, January 1	$—	$453
Production	—	5
Spoilage	—	(458)
Inventory work-in-process, end of period	$—	$—

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® Active Pharmaceutical Ingredient (“API”), which would need to be released by the FDA before those materials could be used in commercial product. After conducting all of the appropriate tests on samples of the inventory during 2013, the Company concluded that it could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection®. Accordingly, these lots were not be submitted to the FDA to request release for commercial sale and their remaining dollar value was written-off in 2013.

Note 5: Marketable Securities

Marketable securities consist of equity securities. As of June 30, 2014, it was determined that none of the marketable securities had other-than-temporary impairments. At June 30, 2014, all securities were classified as available for sale investments and were measured as Level 1 instruments of the fair value measurements standard (see "Note 10: Fair Value").

Securities classified as available for sale consisted of:

June 30, 2014
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$17,541	$77	$(23)	$17,595	$17,595	$—
Totals	$17,541	$77	$(23)	$17,595	$17,595	$—

December 31, 2013
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$17,505	$115	$(229)	$17,391	$17,391	$—
Totals	$17,505	$115	$(229)	$17,391	$17,391	$—

Unrealized losses on investments

Investments with continuous unrealized losses for less than 12 months and 12 months or greater and their related fair values were as follows:

June 30, 2014
(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in loss position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	2	$10,492	$(23)	$—	$—	$10,492	$(23)
Totals	2	$10,492	$(23)	$—	$—	$10,492	$(23)

December 31, 2013
(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in loss position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$12,460	$(229)	$—	$—	$12,460	$(229)
Totals	1	$12,460	$(229)	$—	$—	$12,460	$(229)

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	June 30, 2014	December 31, 2013
Compensation	$1,928	$378
Professional fees	172	270
Other expenses	536	529
Accrued Alferon production costs	23	51
	$2,659	$1,228

Note 7: Property and Equipment

	(in thousands)	
	June 30, 2014	December 31, 2013
Land, buildings and improvements	$4,209	$4,209
Furniture, fixtures, and equipment	5,218	5,093
Leasehold improvements	85	85
Total property and equipment	9,512	9,387
Less: accumulated depreciation and amortization	(4,667)	(4,334)
Property and equipment, net	$4,845	$5,053

Property and equipment are recorded at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets, ranging from five to thirty-nine years.

Construction in progress consists of funds used for the construction and installation of property and equipment within the Company's New Brunswick, NJ facility. As of June 30, 2014, construction in progress is reported as $7,188,000 as compared to $7,046,000 as of December 31, 2013. The Company capitalized $143,000 of interest charges through December 31, 2013 related to the construction in progress.

Note 8: Margin Account Loan

A “Margin Account” loan was established with Wells Fargo Advisors for which the proceeds of this flexible form of indebtedness effectively serves the Company as a line of credit to finance the capital improvement project underway at the New Brunswick, New Jersey Manufacturing facility. In order to maintain this Margin Account, established on July 26, 2011, the Company needs to pledge, restrict from sale and segregate to a dedicated Margin Account its marketable securities at an approximate ratio of two to one of security collateral to debt undertaken. With the exception of collateral requirements, the Company maintains all the rights and benefits of ownership including receipt of interest, dividends or proceeds from the securities. While this Margin Account has no material establishment or maintenance fees, it currently carries an effective interest rate of approximately 2.5% per annum applied against the “Margin Debit Balance” (i.e., those funds withdrawn and outstanding), based on the prevailing “Wells Fargo Base Rate” less 2.75%. As of June 30, 2014 and December 31, 2013, the principal loan balance of the Margin Account was $0. For the year ended December 31, 2013, the interest charge was approximately $130,000 which has been capitalized along with the other costs related to the capital improvement project.

Note 9: Stockholders’ Equity

The Equity Incentive Plan of 2009, effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 15,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. Unless sooner terminated, the Equity

Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date. For the six months ended June 30, 2014, the Company issued 855,000 options to some employees to purchase shares of common stock.

On July 23, 2012, the Company entered into a new Equity Distribution Agreement (the "New EDA") with Maxim pursuant to which the Company may sell up to $75,000,000 worth of its shares of Common Stock from time to time through Maxim, as sales agent. Under the New EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the New EDA, up to aggregate gross proceeds of $10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the New EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the New EDA or terminate the New EDA. The Shares are being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, the Company filed a Prospectus Supplement with the SEC increasing the number of shares covered by the Prospectus from 12,000,000 to 20,000,000 shares under the New EDA. On October 5, 2012, the Company filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus to 40,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the New EDA. On December 23, 2013, the Company filed an updated Prospectus Supplement with the Securities and Exchange Commission to revise the New EDA for an aggregate of 90,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the New EDA.

For the six months ended June 30, 2014, the Company had sold 20,685,021 shares of the New EDA that resulted in net cash proceeds of approximately $8,458,000 after direct expenses along with commissions paid to Maxim for approximately $262,000.

The Company plans to use the net proceeds from the offering as follows: (1) Costs to upgrade the Alferon N Injection® manufacturing facility and to prepare for the FDA pre-approval inspections, (2) Potential new preclinical or clinical studies in order to gain commercial approval for Ampligen® and broader approvals for Alferon® and Alferon LDO®, (3) Working capital to build and maintain sufficient inventory by procuring raw materials, supplies and other items for the New Brunswick manufacturing facility, as well as to remunerate outside contractors for necessary services, such as, final filling and finishing operations in order to meet any anticipated demand from normal operations as well as through the possible pursuit of other disease areas and/or geographic regions that may present themselves, (4) Pursuit of potential partnering opportunities for Ampligen®, (5) Potential establishment of sales and marketing capabilities, as well as consideration towards the expansion of the Company's manufacturing capacity.

Note 10: Fair Value

The Company is required under U.S. Generally Accepted Accounting Principles ("GAAP") to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's Consolidated Balance Sheets.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items.

The Company also has certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction. The fair value recalculation of the Liability resulting from the issuance of the Warrants ("Call") and existence of the Fundamental Transaction ("Put") related to the May 2009 issuance, are calculated using a Monte

Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the Fair Value of the Warrants. As an additional factor to determine the Fair Value of the Put's Liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation. The Company recomputes the fair value of the Warrants at the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different. The remaining redeemable warrants expire in November 2014 and there was no change in the assumptions utilized to estimate the fair value as of June 30, 2014. The balance of the redeemable warrants was approximately $13,000 and $14,000 as of June 30, 2014 and December 31, 2013, respectively.

Fair value at June 30, 2014, was estimated using the following assumptions:

Underlying price per share	$0.19 - $0.27
Exercise price per share	$1.31 - $1.65
Risk-free interest rate	0.06% - 0.23%
Expected holding period	0.38 - 1.64 yrs.
Expected volatility	69.74% - 113.56%
Expected dividend yield	None

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input may change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants was approximately $13,000 and $14,000 at June 30, 2014 and December 31, 2013, respectively. There were no other financial instruments at June 30, 2014.

On January 1, 2008, the Company adopted new accounting guidance (codified at FASB ASC 820 and formerly Statement No. 157 Fair Value Measurements) that defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The guidance does not impose any new requirements around which assets and liabilities are to be measured at fair value, and instead applies to asset and liability balances required or permitted to be measured at fair value under existing accounting pronouncements. The Company measures its warrant liability for those warrants with a cash settlement feature at fair value. As of June 30, 2014, the Company had no other derivative assets or liabilities.

FASB ASC 820-10-35-37 (formerly SFAS No. 157) establishes a valuation hierarchy based on the transparency of inputs used in the valuation of an asset or liability. Classification is based on the lowest level of inputs that is significant to the fair value measurement. The valuation hierarchy contains three levels:

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.
- Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation.

As of June 30, 2014 and 2013, the Company has classified the Warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing these Warrants.

The table below presents the balances of assets and liabilities measured at fair value on a recurring basis by level within the hierarchy as of June 30, 2014:

	(in thousands)			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities-unrestricted	$17,595	$17,595	$—	$—
Liabilities:				
Warrants	$(13)	$—	$—	$(13)

The changes in Level 3 Liabilities measured at fair value on a recurring basis are summarized as follows:

	Fair Value of Redeemable Warrants (in thousands)	
	2014	2013
Balance at January 1	$14	$295
Fair value adjustment at March 31	—	(89)
Balance at March 31	$14	$206
Fair value adjustment at June 30	(1)	(102)
Balance at June 30	$13	$104

Note 11: Cash And Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents.

Note 12: Recent Accounting Pronouncements

In 2014, the FASB issued Accounting Standards Updates (“ASU”) 2014-1 through 2014-12. These updates did not have a significant impact on the financial statements.

Note 13: Funds Received From Sale Of Income Tax Net Operating Losses

As of December 31, 2013, the Company has approximately $134,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2033) available to off-set future federal taxable income. The Company also had approximately $37,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2019 through 2033) and approximately $25,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2019 through 2020) available to off-set future state taxable income.

In February 2014, the Company effectively sold $13,900,000 of its approximately $25,000,000 of New Jersey state net operating loss carryforwards (for the year 2012) for approximately $1,126,000. The utilization of certain state net operating loss carry-forwards may be subject to annual limitations. With no tax due for the foreseeable future, the Company has determined that the accounting for interest or penalties related to the payment of tax is not necessary at this time.

Note 14: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued and determined that no subsequent event constituted a matter that required adjustment to the financial statements for the six months ended June 30, 2014.

On July 8, 2014, the Company's Board of Directors approved the recommendation of the Compensation Committee for the Company to enter into an Employment Agreement with Mr. Pascale. The Compensation Committee noted that Mr. Pascale has recently assumed the role of Chief Accounting Officer. Based upon his performance and continued commitment to the Company, the Committee has determined that his base pay be set at $154,000 per annum and issue him 50,000, 10-year options that vest one year after issuance. Other provisions within the agreement included Company paid health insurance premiums attributed to his spouse.
On June 25, 2014, we concluded strategic discussions in Johannesburg with Bioclones (Pty) Ltd. ("Bioclones"), a leading South African biotechnology company, with three principle goals; 1) initiating studies utilizing Ampligen(R)

as a potential adjuvant enhancement of Bioclones' therapeutic cancer vaccine, currently in clinical trials in Cape Town, including pre-clinical studies followed, potentially, by a Phase 1 clinical trial; 2) seeking South African Medicine's Control Council approval to conduct trials using Alferon(R) to eradicate the HIV virus in patients highly responsive to anti-retroviral therapy (HAART); and 3) initiating a joint effort to obtain commercial registration of both Ampligen(R) and Alferon(R) in the South African markets.

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

Special Note Regarding Forward-Looking Statements

Certain statements in this report, including statements under “Item 1. Legal Proceedings” and “Item 1A. Risk Factors” in Part II, contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements reflect our current views with respect to future events are based on assumptions and are subject to risks, uncertainties and other important factors. We discuss many of these risks, uncertainties and other important factors in greater detail under “Item 1A. Risk Factors” in Part II in this Report. Because the risk factors referred to above and in our Annual Report on Form 10-K for our most recent fiscal year filed with the Securities and Exchange Commission 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, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. You should carefully read this Report completely and with the understanding that our actual future results may be materially different from what we expect. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our business, results of operations and financial condition. 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. 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. Any statements in this Report about our expectations, beliefs, plans, objectives, assumptions or future events or performance that are not historical facts are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as “believe”, “may”, “could”, “will”, “estimate”, “continue”, “anticipate”, “inte “seek”, “plan”, “expect”, “should”, or “would,” and similar expressions intended to identify forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance or our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to the improvements and construction at of our New Brunswick, New Jersey facility. We have disclosed that in February 2013, we received a Complete Response from the FDA declining to approve our Ampligen® New Drug Application (“NDA”) for Chronic Fatigue Syndrome Treatment ("CFS") stating that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Accordingly, the remaining steps to potentially gain FDA approval of the Ampligen® NDA, the final results of these and other ongoing activities could vary materially from our expectations and could adversely affect the chances for approval of the Ampligen® NDA. These activities and the ultimate outcomes are subject to a variety of risks and uncertainties, including but not limited to risks that (i) the FDA may ask for additional data, information or studies to be completed or provided; and (ii) the FDA may require additional work related to the commercial manufacturing process to be completed or may, in the course of the inspection of manufacturing facilities, identify issues to be resolved. With regard to our New Drug Application (“NDA”) for Ampligen® to treat Chronic Fatigue Syndrome (“CFS”), we note that there are additional steps which the FDA has advised Hemispherx to take in our seeking approval. The final results of these and other ongoing activities, and of the FDA review, could vary materially from Hemispherx' expectations and could adversely affect the chances for approval of the Ampligen® NDA. Any failure to satisfy the FDA's requirements could significantly delay, or preclude outright, approval of our drugs for commercial sale. While facility upgrades are being undertaken for the Alferon® manufacturing process, this project has not impacted our capability to manufacture the Ampligen® drug substance intermediates needed for the final production steps of that product. The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete. While the facility is approved by FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced product. Once we begin commercial scale production of Alferon® Active Pharmaceutical Product ("API"), we will need the FDA to reaffirm our BLA status via a pre-approval inspection and also gain their approval to allow commercial sales to resume once we have submitted satisfactory stability and quality release data. We anticipate that it will take approximately 14 months before we have newly produced Alferon® API ready for submission to the FDA for review and approval. 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. We cannot provide any guarantee that the facility will necessarily pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex.

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

General

We are a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and 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 certain chronic diseases. We have three domestic subsidiaries BioPro Corp., BioAegean Corp., and Core BioTech Corp., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. established in Belgium in 1998, which has minimal activity. All significant intercompany balances and transactions have been eliminated in consolidation.

Our flagship products include Alferon N Injection® and the experimental therapeutic Ampligen®. Alferon N Injection® is approved for a category of STD infection, and Ampligen® represents an experimental RNA being developed for globally important viral diseases and disorders of the immune system. Hemispherx' platform technology includes components for potential treatment of various severely debilitating and life threatening diseases. Alferon® LDO (Low Dose Oral) is a formulation under development targeting influenza.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ to produce Alferon® and Ampligen® and are in the final stages of our facility enhancement project which includes the Installation and Operation Qualification phase for Alferon® production. Approximately $7,188,000 has been spent on the project through June 30, 2014, which was mainly financed through a Margin Account with an effective interest rate of approximately 2.50%. The Margin Account was paid off utilizing approximately one half of our marketable securities in October 2013. While facility upgrades are being undertaken for the Alferon® manufacturing process, this project has not impacted our capability to manufacture the Ampligen® drug substance intermediates needed for the final production steps of that product. The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete. While the facility is approved by FDA under the Biological License Application (“BLA”) for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced product. Once we begin commercial scale production of Alferon® Active Pharmaceutical Product (“API”), we will need the FDA to reaffirm our BLA status via a pre-approval inspection and also gain their approval to allow commercial sales to resume once we have submitted satisfactory stability and quality release data. We anticipate that it will take approximately 14 months before we have newly produced Alferon® API ready for submission to the FDA for review and approval. 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. We cannot provide any guarantee that the facility will necessarily pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex.

On February 1, 2013, we received a Complete Response Letter (“CRL”) from the FDA declining to approve our NDA for Ampligen® for Chronic Fatigue Syndrome ("CFS"). Please see the discussion in "Our Products - Ampligen®" below for more detail.

OUR PRODUCTS

Our primary pharmaceutical product platform consists of our experimental compound, Ampligen®, our FDA approved natural interferon product, Alferon N Injection®, and our experimental liquid natural interferon for oral administration, Alferon® LDO (Low Dose Oral).

Ampligen®

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of CFS. As noted above and discussed below, the FDA in its recent CRL declined to approve our NDA for the treatment of CFS with Ampligen®. Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Treatment IND (e.g., treatment investigational new drugs, or "Emergency" or "Compassionate" use authorization) with Cost Recovery Authorization (FDA) and "promising" clinical outcome recognition based on the evaluation of certain summary clinical reports ("AHRQ" or Agency for Healthcare Research and Quality). Ampligen® represents the first drug in the class of large (macromolecular) RNA (nucleic acid) molecules to apply for NDA review. Based on the results of published, peer reviewed pre-clinical studies and clinical trials, we believe that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties.

We believe that nucleic acid compounds represent a potential new class of pharmaceutical products as they are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which compromise the body's immune system. RNA directs the production of proteins and regulates certain cell activities including the activation of an otherwise dormant cellular defense against viruses and tumors. Our drug technology utilizes specifically-configured RNA. Our double-stranded RNA drug product, trademarked Ampligen®, is an experimental, unapproved drug, that would be administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I) poly(C_{12}U).

Clinical trials of Ampligen® already conducted by us include studies of the potential treatment of CFS, Hepatitis B, HIV and cancer patients with renal cell carcinoma and malignant melanoma. All of these potential uses will require additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval.

In May 1997, the FDA approved an open-label treatment protocol, ("AMP 511"), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP 511 protocol through a consortium group with active clinical sites in New York City, NY, Charlotte, NC, Miami, FL, Incline Village, NV and Salt Lake City, UT, provide safety information regarding the use of Ampligen® in patients with CFS. As of June 30, 2014, there were thirty-three patients participating in this open label treatment protocol with twenty-five taking treatment and eight on drug holiday. We are establishing an enlarged data base of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen® and/or the design of future clinical studies.

On February 1, 2013, we received a CRL from the FDA declining to approve our New Drug Application ("NDA" for Ampligen® for CFS. In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. The additional clinical study should address, among other things, Ampligen®'s efficacy in treating CFS patients, be of sufficient size and duration to assess the safety of Ampligen® and be sufficient to determine appropriate dosing. The FDA set forth the reasons for this action and provided recommendations to address certain of the outstanding issues. The FDA stated that the submitted data does not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data does not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data. In addition to the safety and effectiveness issues recommended to be addressed in at least one additional clinical trial, the CRL states that Hemispherx should conduct complete rodent carcinogenicity studies in two species prior to approval and also conduct additional animal toxicology studies providing more comprehensive evaluation of Ampligen® fragments and degradation products. The CRL also requests evaluation of variation between lots of Ampligen® tested in the development process and recommends tighter control of the Ampligen® manufacturing process.

In response to the CRL, we continue to plan to avail ourselves of the opportunity for an “end-of-review” meeting with representatives of the Office of Drug Evaluation II which issued the CRL, in order to clarify and seek to narrow the outstanding issues regarding the further development of Ampligen® for the treatment of CFS.

FDA regulations provide a formal dispute resolution process to obtain review of any FDA decision, including a decision not to approve an NDA, by raising the matter with the supervisor of the FDA office that made the decision. The formal dispute resolution process exists to encourage open, prompt discussion of scientific (including, medical) disputes and procedural (including, administrative) disputes that arise during the drug development, new drug review, and post-marketing oversight processes of the FDA. Depending on the outcome of a number of initiatives in the CFS community, including the FDA’s Patient Focused Drug

Development Initiatives, forthcoming drug guidance and other scientific initiatives by the Institute of Medicine, Center for Disease Control and National Institute of Health, we will continue to examine the opportunity for an “end-of-review” meeting. Depending on the results of these initiatives, we may request an "end-of-review" conference with the FDA as a precursor to a possible submission of a formal appeal to the Office of New Drugs within the FDA's Center for Drug Evaluation and Research regarding the FDA's decision. Please see “Risks Associated With Our Business” in Item 1A. Risk Factors below.

Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. Industry norms suggest that it will require three to six months to initiate the study, one to two years to accrue and test patients, three to six months to close-out the study and file the necessary documents with the FDA. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations. We anticipate that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. Please see "Part I; Item 1A, Risk Factors: "We may require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding".

On July 12, 2012, we filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT’s Orphan Drug regulations. We believe that the approval of Ampligen® as an Orphan Drug may allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for CFS.

On October 2, 2011, the Company finalized their Fourth Amendment to a Supply Agreement, effective through March 11, 2014, with Jubilant Hollister-Stier Laboratories LLC of Spokane, Washington (“Hollister-Stier”), pursuant to which Hollister-Stier would formulate and package Ampligen® from the key raw materials that Hemispherx would supply to them. This Supply Agreement expired March 11, 2014. The Company is working towards an amendment to the existing Supply Agreement which may contain additional fees as part of entering into the extension.

On May 13, 2014, the United States Patent Office issued patent U.S. 8,722,874 titled “Double-Stranded Ribonucleic Acids with Rugged Physiochemical Structure and Highly Specific Biologic Activity” to inventors Carter, et al. and assignee Hemispherx Biopharma, Inc. The patent claims a novel form of rugged dsRNA. Rugged dsRNA are nucleic acids with a unique composition and physical characteristic identified with high specificity of binding to Toll-Like Receptor 3 (TLR3), thereby conveying an important range of therapeutic opportunities. The newly discovered form of dsRNA has increased bioactivity and binding affinity to the TLR 3 receptor because of its reduced tendency to form branched dsRNA which can inhibit receptor binding. Pharmaceutical formulations containing the newly discovered nucleic acid as active ingredients and methods of treatment, with those formulations are also described in the issued patent. The issuance of U.S. Patent 8,722,874 will help ensure that Hemispherx Biopharma retains patent protection for novel formulations of Ampligen® products until at least 2029.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which is approved by the FDA in 1989 for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. Certain types of human papilloma viruses (“HPV”) cause genital warts, a sexually transmitted disease (“STD”). The U.S. Centers for Disease Control and Prevention (“CDC”) estimates that “approximately twenty million Americans are currently infected with HPV with another six million becoming newly infected each year. HPV is so common that at least 50% of sexually active men and women get it at some point in their lives.” Although they do not usually result in death, genital warts recurrence is common, cause significant morbidity and entail substantial health care costs.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection® contains a multi-species form of alpha interferon. The world-wide market for injectable alpha interferon-based products has experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide. Alpha interferons are manufactured commercially in three ways: by genetic engineering, by cell culture, and from human white blood cells. All three of these types of alpha interferon are or were approved for commercial sale in the U.S. Our natural alpha interferon is produced from human white blood cells.

The potential advantages of natural alpha interferon over recombinant (synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which we believe may account for its higher activity in laboratory studies. Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently U.S. marketed recombinant alpha interferons. We believe that the absence of glycosylation may be, in part, responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from our natural alpha interferon.

Alferon N Injection® [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year, probably due to neutralizing antibody formation. Neutralizing antibody formation has not been reported with the use of Alferon N Injection®.

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API and is completed for the related Final Lot Release Test. To formulate, fill, finish and package (“fill and finish”) Alferon N Injection® Drug Product, we require a FDA approved third party Contract Manufacturing Organization (“CMO”). In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. (“Althea”) of San Diego, CA, regarding the fill and finish process for Alferon N Injection®.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® API, which would need to be released by the FDA before those materials could be used in commercial product. As of December 31, 2012, all of our existing lots of Alferon® Work-In-Process Inventory had completed the fill, finish and packaging process. After conducting all of the appropriate tests on samples of the inventory during 2013, we concluded that we could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection®. Accordingly, these lots will not be submitted to the FDA to request release for commercial sale and their remaining dollar value has been written-off (see "Note 4: Inventory" for greater details).

Commercial sales of Alferon® will not resume until new batches of API can be produced and released by the FDA. We are currently in the Installation and Operation Qualification phase for Alferon® production of the enhancement project. The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete. While the facility is approved by FDA under the BLA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. We anticipate that it will take until at least 14 months before we will have newly produced Alferon® API ready for submission to the FDA for review and approval. 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. We cannot provide any guarantee that the facility will necessarily pass a FDA pre-approval inspection for Alferon® manufacture.

In January 2012, the ANMAT approved the sale and distribution of Alferon N Injection® (under the brand name "Naturaferon") in Argentina. In June 2010, Hemispherx agreed to provide GP Pharm an option to market Alferon N Injection®, its FDA-approved natural interferon, in Argentina and other Latin American countries. The receipt of the ANMAT approval for HPV is the first step of a regulatory process towards the commercial sales of Naturaferon. On September 20, 2012, we filed with ANMAT an amended NDA for the use of Alferon N Injection® in patients with chronic hepatitis C who have become refractory to recombinant interferon as a result of the appearance of neutralizing antibodies against recombinant interferon. On February 6, 2013, we received the ANMAT approval for the treatment of refractory Hepatitis C with Naturaferon in Argentina.

Alferon® LDO (Low Dose Oral)

Alferon® LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection®, should not cause antibody formation, which is a problem

with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon could be economically feasible for patients and logistically manageable globally for development programs for prevention and, or treatment of pandemic influenza, seasonal influenza and other emerging viruses. Oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, no production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment or prevention for viral diseases.
Hemispherx currently has an FDA authorized protocol to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Our Phase II study has continued to be delayed as we have redirected many of our resources to complete the upgrades in the New Brunswick facility.

Other Diseases

In July 2011, we received FDA authorization to proceed with the initiation of a new clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. On April 16, 2012, a clinical trial was initiated in which Ampligen® is being nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert, Associate Professor of Medicine in the Division of Infectious Diseases and Director of the Alabama Vaccine Research Clinic. This study is a first use of Ampligen® with a seasonal vaccine in humans to assess the safety of Ampligen® when nasally delivered as a vaccine adjuvant. Another objective of this study is to determine the extent to which Ampligen® mobilizes potential protections against pandemic influenza by utilization of a seasonal flu vaccine. The study will evaluate the potential immunologic enhancement of Ampligen® by comparing immune parameters in the group receiving Ampligen® plus FluMist® with another group receiving FluMist® plus placebo. We intend to conduct a broad array of immune tests to compare the immune response for both its magnitude and breadth. It is our objective to qualify and enroll 72 patients for this clinical trial. On December 9, 2013, we announced that enrollment in this study was being expanded based on an analysis of safety results to date conducted by both the FDA and a Data Monitoring Committee, the latter group comprised of a team of independent clinical, basic research, and statistical professionals. Enrollment of additional subjects into Stage 2 began in March 2014. Twenty-five patients have been enrolled; 12 in Stage 1 and 13 patients in Stage 2.

In August 2011, a study utilizing Ampligen® was initiated by investigators from the Tumor Vaccine Group (“TVG”) at the University of Washington in Seattle, WA. As of June 30, 2014, 50 patients were enrolled in this ninety-eight patient Phase I-II Study of HER2 vaccination with Ampligen® as an adjuvant in optimally treated breast cancer patients. The goal of this study is to see how well the combination works in treating patients with Stage II-IV human epidermal growth factor receptor 2 (“HER2”)-positive breast cancer. Vaccines made from synthetic HER2/neu peptides may help the body build an effective immune response to kill tumor cells that express HER-2/neu. The TVG has developed vaccines against several cancer proteins, and in this study, they are researching a new approach in an attempt to make the immune response to the vaccine even better. Compounds that specifically stimulate TLR receptors are promising immune stimulators, and Ampligen® has the potential to provide a profile of immune stimulation that could be clinically beneficial. Data from these patients was evaluated and the Company elected to, at this time, to redirect resources to other projects.

On January 7, 2014, we announced publication of an article entitled “Emergence of a novel drug resistant H7N9 influenza virus: Evidence based clinical potential of a natural IFN-áalpha for infection control and treatment” in Expert Review of Anti-infective Therapy early online edition pages 1-5, 2014. H7N9 is a recently identified virus associated with high mortality in humans with the potential to emerge as an agent for a global pandemic. New cases of H7N9 have been very recently reported in China, Hong Kong and Taiwan. In vitro tests reported in the new article demonstrated that both oseltamivir (Tamiflu®) and Alferon N have significant inhibitory effect on a neuraminidase inhibitor sensitive H7N9 influenza virus. In contrast, Alferon N, but not Tamiflu®, had an inhibitory effect on the neuraminidase resistant Shanghai/1/H7N9 virus. The research was conducted under the supervision of Juergen Richt, DVM, PhD, Director of the U.S. Department of Homeland Security Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD), The Regents Distinguished Professor at Kansas State University, and an Eminent Scholar of Kansas Bioscience Association (KBA). Professor Richt is recognized as an expert on zoonotic agents and has published extensively on the monitoring of the mutations and the basic events leading to cross-species transmission and the opportunities to adapt to human hosts, with the potential to cause a pandemic. According to the peer reviewed article “The novel avian H7N9 influenza virus has caused more than 130 human infections with 43 deaths (as of September, 2013) in China. Because of the lack of existing immunity against H7 subtype influenza viruses in the human population and the absence of a licensed commercial vaccine, antiviral drugs are critical tools for the treatment of infection with this novel H7N9. Both M2-ion channel blockers and neuraminidase inhibitors are used as antiviral drugs for influenza infections of humans. The emerging H7N9 viruses are resistant to the M2-ion channel blockers because of a S31N mutation in the M2 protein; additionally, some H7N9 isolates have gained neuraminidase R292K substitution resulting in broad resistance to neuraminidase inhibitors. In this study we report that Alferon N can inhibit wild type and 292K H7N9 virus replication in vitro.

On December 2, 2013, we announced that we are supporting the University of Pittsburgh's National Institutes of Health funded study (grant 1PO1CA132714) currently underway as part of the University's Chemokine Modulation Research initiative which includes Ampligen® as an adjuvant. As part of this collaboration, Hemispherx has supplied clinical grade Ampligen® (rintatolimod) to the University. The study, under the leadership of professor of surgery Pawel Kalinski, M.D., Ph.D. and involves the Chemokine Modulatory regimen developed by Dr. Kalinski's group, has successfully completed the lowest tier of dose escalation in patients with resectable colorectal cancer under the clinical leadership of Dr. Amer Zureikat, an assistant professor of surgery. In addition, the University has initiated enrollment in an additional cancer study.

On April 8, 2014, we announced a new publication which enlarged the understanding of Ampligen's® safety profile across diverse animal species and focuses on the unique TLR-3 Receptor/Ampligen® Interaction. The peer-reviewed publication titled "Discordant Biological and Toxicological Species Responses to TLR-3 Activation" in the current issue of the American Journal of Pathology Vol. 184 (Mitchell, W.M., C.F. Nicodemus, W.A. Carter, J.C. Horvath, and D.R. Strayer, pages 1062-1072), 2014, disclosed markedly diminished pro-inflammatory responses observed in both non-human primates and in patients with Chronic Fatigue Syndrome (CFS). Toll-like receptors (TLR) are multiple proteins of the innate immune system that trigger upon activation cascades (release) of disease fighting molecules, which include enhancement of the body's immunity and interruption of the replication cycles of many different viruses. Ampligen®, an experimental therapeutic, initiates its pharmacological effects by binding TLR-3 selectively. The selectivity/ specificity of Ampligen® was first fully described by the late Nobel Laureate in Medicine, Professor Ralph Steinman of the Rockefeller University. The biological significance of the extraordinary specificity of Professor Steinman's findings is illustrated in the current manuscript. For example, all other TLR stimulators thus far studied clinically (e.g., CpG, Flagellins, etc.) trigger more pro-inflammatory cascades, which may lead to a significant side effect profile in patients. In contrast, Ampligen®, an experimental therapeutic, displayed a discordance between the rodent and human inflammatory responses. Systemic inflammatory cytokines, observed in rats, were correlated with significant acute and chronic in vivo toxicities at Ampligen® doses that elicited no detectable systemic inflammatory cytokines and minimal toxicities in primates. The lack of systemic cytokine detection is consistent with the observed minimal toxicity in primates, in contrast to the significant toxicities observed in non-primates. Rat toxicity correlates with systemic cytokine levels, and the lack of primate toxicity similarly is correlated with the lack of significant systemic inflammatory cytokine levels. Inflammatory cytokines observed in the systemic circulation in rats are associated with toxicity and are analogous to the toxicity seen in humans with lethal viral infections, such as highly pathogenic avian influenza and severe acute respiratory syndrome-CoV associated with inflammatory cytokine storms. Cytokine responses from baseline in seventy-six (76) patients with CFS enrolled in two clinical trials of Ampligen® were also examined at 32 weeks post-treatment with only one patient exhibiting a relatively high systemic TNF-á (Tumor Necrosis Factor Alpha) level. TNF-á is a cytokine with high inflammatory activity. In summary, primates including humans display a relatively down-regulated inflammatory cytokine induction pathway with TLR-3 receptor stimulation secondary to Ampligen® administration. This down regulatory effect may contribute to the favorable safety profile observed clinically with Ampligen®, an experimental therapeutic.

On May 5, 2014, we announced that one of our advanced stage biological products, Alferon(R) N, significantly inhibited the replication of the MERS virus in vitro. MERS-CoV is a recently emerged human coronavirus responsible for the lethal pulmonary syndrome known as MERS (Middle East Respiratory Syndrome). Recent testing in laboratories of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, has revealed that Alferon(R) N was inhibitory to MERS-CoV both when used before test cells were exposed to MERS-CoV, as well as after the cells were exposed to the deadly virus. NIAID researchers led the Alferon(R) N MERS-CoV experiments. They treated monkey kidney cells with Alferon(R) N either 18 hours prior to infection with MERS-CoV ("pre-treatment") or 1 hour following infection with MERS-CoV ("post-treatment"). At Day 1 and Day 3, supernatants were collected from cells and virus titers were thereafter measured. In both cases, Alferon(R) N showed significant dose-dependent inhibitory effects, thus suggesting the potential of Alferon(R) N both as a preventive and a potential treatment. Laboratory (in vitro) studies of potential antiviral agents are not necessarily predictive of clinical benefits. The Company was not involved in the conduct of the experimentation. The results were forwarded to Hemispherx at the conclusion of the experiments and formal publication is pending.

On June 3, 2014, we announced that we have confirmed that Alferon(R) N inhibits replication of the MERS virus in vitro. Chien-Te (Kent) Tseng, Ph.D., Associate Professor, Microbiology & Immunology at the University of Texas Medical Branch at Galveston, led the Alferon(R) N MERS-CoV experiments. Calu-3 cells were treated with Alferon(R) N 24 hours prior to infection with MERS-CoV. At 36 hours, supernatants were collected from cells and the virus titers were thereafter measured. Alferon(R) N showed significant dose-dependent inhibitory effects, thus suggesting the potential of Alferon(R) N as a preventative. Laboratory (in vitro) studies of potential antiviral agents are not necessarily predictive of clinical benefits. The Company supplied the Alferon N, but was not directly involved in the conduct of the experimentation. The results were forwarded to Hemispherx at the conclusion of the experiments for its review and formal publication is pending.

On June 25, 2014, we concluded strategic discussions in Johannesburg with Bioclones (Pty) Ltd. ("Bioclones"), a leading South African biotechnology company, with three principle goals; 1) initiating studies utilizing Ampligen(R) as a potential adjuvant enhancement of Bioclones' therapeutic cancer vaccine, currently in clinical trials in Cape Town, including pre-clinical studies followed, potentially, by a Phase 1 clinical trial; 2) seeking South African Medicine's Control Council approval to conduct trials using Alferon(R) to eradicate the HIV virus in patients highly responsive to anti-retroviral therapy (HAART); and 3) initiating a joint effort to obtain commercial registration of both Ampligen(R) and Alferon(R) in the South African markets. The first clinical program builds on the Bioclones patented (US Patent 7,981,673 entitled "Process for the maturation of dendritic cells and a vaccine") therapeutic human dendritic cell (DC) cancer vaccination approach. This invention provides a method of producing mature DCs in vitro, which comprises the step of culturing the immature DCs, thereafter exposing said cells to tumor antigens before administration to patients. The team has successfully obtained the necessary Ethics approval to use Ampligen(R) as an adjuvant in the Bioclones pre-clinical cancer immunotherapy program utilizing patient derived samples. Pre-clinical studies will be directed towards the potential treatment of breast cancer in particular, followed by prostate cancer. These studies are part of the effort to develop patient-specific DC immunotherapy vaccines against breast cancer and prostate cancer, which elicit an immune response that will target and kill cancer cells. Human DCs matured with Ampligen(R) and transfected with autologous tumor-specific mRNA are designed to elicit a potent and autologous tumoricidal antigen-specific cytotoxic response to the cancer.

Biosecurity / Biodefense

On September 9, 2013, we announced at the Rodman and Renshaw Conference in New York City a major new initiative in the BioSecurity field involving both Alferon N Injection® and Ampligen®. Our Chief Executive Officer, Dr. William Carter, MD, highlighted the broad anti-viral effect of both agents along with the Company’s strategy to undertake major programs in the biosecurity field, specifically with respect to the potential prevention or treatment of pandemic flu virus, H7N9, MERS (Middle East Respiratory Syndrome) and alpha viruses such as VEE (Venezuelan Equine Encephalomyelitis). With all three classes of viruses, researchers have now confirmed significant bioactivity with Ampligen® or Alferon N Injection®, or both, in either in vitro and/or in vivo non-human studies. Alferon N Injection® has been found to be highly active against SARS virus (a close relative of MERS) by the Singapore Genome Institute in laboratory studies. Dr. Carter highlighted that the results of the recent Kansas State University experiments, coupled with Dr. Richt’s work on influenza virus reassortment (mixing of genetic material) and other published studies, sets the stage for evaluating the possibility that mutational changes and reassortment could be prevented in animals by the use of type I interferon (á/ß) and/or a type I interferon inducer. Moreover, previous research suggested that Alferon® may be active against a range of viruses existing in animal populations even in the low dose oral (LDO) formulation referred to as Alferon® LDO.

401(k) Plan

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. The 6% Company matching contribution was terminated as of March 15, 2008 and then was reinstated effective January 1, 2010. For the six months ended June 30, 2014, the Company contributions towards the 401(k) Plan were approximately $72,000.

New Accounting Pronouncements

See “Note 12: Recent Accounting Pronouncements”.

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Part I; Item 2: “Management's Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies” contained in our Annual Report on Form 10-K for the year ended December 31, 2013.

RESULTS OF OPERATIONS

Three months ended June 30, 2014 versus three months ended June 30, 2013

Net Loss

Our net loss was approximately $4,956,000 for the three months ended June 30, 2014, an increase in loss of approximately $673,000 or 16% when compared to the same period in 2013. This increase in loss for these three months was primarily due to the following:

1) an increase in General and Administrative expenses of approximately $680,000 or 37%;
2) a decrease in interest and other income of $223,000 or 63%;
3) a decrease in the value of the redeemable warrant liability of $101,000 or 99%; offset by
4) a decrease in Production Costs of approximately $341,000 or 54%;

Net loss per share was $(0.03) and $(0.03) for the three months ended June 30, 2014 and 2013, respectively. The weighted average number of shares of our common stock outstanding as of June 30, 2014 was 185,749,722 as compared to 167,202,512 as of June 30, 2013.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $36,000 for the three months ended June 30, 2014 and 2013, respectively. As of June 30, 2014, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the FDA approved open-label treatment protocol, (“AMP 511”), that allows patient access to Ampligen® for treatment in an open-label safety study.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $294,000 and $635,000, respectively, for the three months ended June 30, 2014 and 2013. This decrease of approximately $341,000 or 54% was primarily due to the write off of inventory of $458,000 incurred during the three months ended June 30, 2013 offset by an increase in testing and pre-production costs of $123,000 related to the initiation of potential manufacturing of Alferon N Injection®.

Research and Development Costs

Overall Research and Development (“R&D”) costs for the three months ended June 30, 2014 were approximately $2,330,000 as compared to $2,318,000 for the same period a year ago, reflecting a slight increase of approximately $12,000. Research and development costs represent efforts regarding Ampligen® research and development, stability tests and polymer production as well as Alferon® related costs associated with cGMP compliance testing, environmental studies at our New Brunswick manufacturing facility, and clinical research.

General and Administrative Expenses

General and Administrative (“G&A”) expenses for the three months ended June 30, 2014 and 2013, were approximately $2,497,000 and $1,817,000, respectively, reflecting an increase of approximately $680,000 or 37%. The rise in G&A expenses in 2014 are due to: 1) higher legal fees of $322,000 (see "Part II - Other Information; Item 1: Legal Proceedings" for details), and 2) higher salaries and wages of $238,000 associated with incentive compensation and bonuses awarded to executives.

Interest and Other Income

Interest and other income for the three months ended June 30, 2014 and 2013 were approximately $131,000 and $354,000, respectively, representing a decrease of approximately $223,000 or 63%. The cause for the decrease in investment income in 2014 was primarily due to a greater value of funds available for investment purposes in the prior period as well as lower fund performance as compared to the prior period.

Redeemable Warrants

The quarterly fiscal revaluation of certain redeemable warrants for the three months ended June 30, 2014 resulted in non-cash adjustment of $1,000 in the valuation of the redeemable warrants liability versus an approximate $102,000 gain for the same period in the prior year (see “Note 10: Fair Value” for the various factors considered in the valuation of redeemable warrants).

Six months ended June 30, 2014 versus six months ended June 30, 2013

Net Loss

Our net loss was approximately $8,792,000 for the six months ended June 30, 2014, an increase in loss of approximately $898,000 or11% when compared to the same period in 2013. This increase in loss for the six months was primarily due to the following:

1) an increase in General and Administrative expenses of approximately $1,142,000 or 29%;
2) a decrease in Production Costs of approximately $209,000 or 25%;
3) a decrease in interest and other income of $251,000 or 47%;
4) a decrease in the value of the redeemable warrant liability of $190,000 or 99%; offset by
5) the sale of New Jersey State Net Operating Loss carryforwards (for the year 2012) for approximately $1,126,000, representing an increase in cash gain of $440,000 or 64% in 2014 as compared to the same period in the prior year.

Net loss per share was $(0.05) and $(0.05) for the three months ended June 30, 2014 and 2013, respectively. The weighted average number of shares of our common stock outstanding as of June 30, 2014 was 181,265,253 as compared to 167,005,714 as of June 30, 2013.

Revenues

Revenues from our Ampligen® Cost Recovery Program increased approximately $34,000, or 44%, for the six months ended June 30, 2014 as compared to the same time period of 2013 due to the number of patients increasing 29% in the six months ended June 30, 2014. As of June 30, 2014, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the FDA approved open-label treatment protocol, (“AMP 511”), that allows patient access to Ampligen® for treatment in an open-label safety study.

Production/Cost of Goods Sold

Production/Cost of Goods Sold was approximately $617,000 and $826,000, respectively, for the six months ended June 30, 2014 and 2013. This decrease of approximately $209,000 or 25% was primarily due to a write off of inventory of $458,000 incurred during the three months ended June 30, 2013 offset by an increase in testing and pre-production costs of $249,000 related to the initiation of potential manufacturing of Alferon N Injection®.

Research and Development Costs

Overall Research and Development (“R&D”) costs for the six months ended June 30, 2014 were approximately $4,656,000 as compared to $4,654,000 for the same period a year ago, reflecting a slight increase of approximately $2,000. Research and development costs represent efforts regarding Ampligen® research and development, stability tests and polymer production as well as Alferon® related costs associated with cGMP compliance testing, environmental studies at our New Brunswick manufacturing facility, and clinical research.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the six months ended June 30, 2014 and 2013, were approximately $5,036,000 and $3,894,000, respectively, reflecting an increase of approximately $1,142,000 or 29%. The rise in G&A expenses in 2014 are due to: 1) higher legal fees of $820,000 (see "Part II - Other Information; Item 1: Legal Proceedings" for details), and 2) higher salaries and wages of $569,000 associated with incentive compensation and bonuses awarded to executives. ; offset by 1) a decrease in consulting fees of $109,000 related to governmental affairs, and 2) a decrease in fees incurred from the Sage Group of $48,000.

Interest and Other Income

Interest and other income for the six months ended June 30, 2014 and 2013 were approximately $284,000 and $535,000, respectively, representing a decrease of approximately $251,000 or 47%. The cause for the decrease in investment income in 2014 was primarily due to a greater value of funds available for investment purposes in the prior period as well as lower fund performance as compared to the prior period..

Redeemable Warrants

The quarterly fiscal revaluation of certain redeemable warrants for the three months ended June 30, 2014 resulted in non-cash adjustments of $1,000 in the valuation of the redeemable warrants liability versus an approximate $191,000 gain for the same period in the prior year (see "Note 10: Fair Value" for the various factors considered in the valuation of redeemable warrants).

Sale of New Jersey Tax Net Operating Loss

In February 2014, we effectively sold $13,900,000 of our approximately $25,000,000 of New Jersey state net operating loss carryforwards (for the year 2012) for approximately $1,126,000. In January 2013, we effectively sold $8,500,000 of our approximately $17,000,000 of New Jersey State Net Operating Loss carryforwards (for the year 2011) for approximately $686,000, representing a increase in cash gain of $440,000 or 64% (see "Note 13: Funds Received From Sale of Income Tax Net Operating Losses") for the six months ended June 30, 2014 as compared to the same period in 2013.

Liquidity and Capital Resources

Cash used in operating activities for the six months ended June 30, 2014 was approximately $6,206,000 compared to approximately $9,629,000 for the same period in 2013, a decrease of $3,423,000 or 36%. Excluding the proceeds from the sale of New Jersey Net Operating Loss carry-forwards, cash used in operating activities for the six months ended June 30, 2014 decreased by approximately $2,983,000 or 29% over the comparable period in 2013. The primary reason for this decrease in 2014 was due to the January 2013 payout of 2012 employee and strategic consultant bonuses for approximately $2,196,000 reflected in accrued expenses and a decrease in accounts payable of approximately $1,026,000 during the six months ended June 30, 2013. This was offset by the write off of inventory valued at $453,000 during the six months ended June 30, 2013.

As of June 30, 2014, we had approximately $20,212,000 in cash, cash equivalents and marketable securities inclusive of approximately $17,595,000 in Marketable Securities, or an increase of approximately $2,018,000 from December 31, 2013. The primary reason for the increase in cash, cash equivalents and marketable securities was due to shares sold pursuant to the ATM during the six months ended June 30, 2014 (see below and "Note 9: Stockholders' Equity"). However, if we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. However, there is no assurance that such financing will be available.

In its February 1, 2013 CRL, the FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Please see “Part II; Item 1A. Risk Factors; “We may require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding”. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. We anticipate that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the study plan, the final design of an acceptable Phase III clinical study protocol, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations which may require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding.

On July 23, 2012, we entered into a new EDA with Maxim (the New EDA") pursuant to which we may sell up to $75,000,000 worth of our shares of common stock from time to time through Maxim, as sales agent. Under the New EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the New EDA, up to aggregate gross proceeds of $10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the New EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. We have no obligation to sell any of the Shares and may at any time suspend offers under the New EDA or terminate the New EDA. The Shares are being sold pursuant to our Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. On September 14, 2012, we filed a Prospectus Supplement with the SEC increasing the number of shares covered by the Prospectus from 12,000,000 to 20,000,000 shares under the New EDA. On October 5, 2012, we filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus to 40,000,000 shares. On December 23, 2013, we filed an updated Prospectus Supplement with the Securities and Exchange Commission to revise the New EDA for an aggregate of 90,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the New EDA. For the six months ended June 30, 2014, we sold an aggregate of approximately 20,685,021 shares that resulted in net cash proceeds of approximately $8,458,015 after commissions paid to Maxim for approximately $261,588 (see "Note 9: Stockholders' Equity"). The impact of 2014 and 2013's fund raising effort through the New EDA, which was limited in 2013, is reflected in the "Consolidated Statements of Cash Flow" Statement comparing the various financing activities for the six months ended June 30, 2014 to the same period in 2013.

There can be no assurances that, if needed, we will be able to raise adequate funds from these or other sources or enter into licensing, partnering or other arrangements to advance our business goals. Our inability to raise such funds or enter into such arrangements, if needed, could 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. 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. We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. 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, acquisitions of intellectual property or assets, enhancements to the manufacturing process, competitive and technological advances, the regulatory processes including the commercializing of Ampligen® products or new utilization of Alferon® products. See Part II, ITEM 1A. Risk Factors; "We may require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding."

The proceeds from our financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development along with our efforts regarding the Ampligen® NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility. There can be no assurances that, if needed, 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 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $20,212,000 in cash, cash equivalents and marketable securities at June 30, 2014 as compared to $18,194,000 at December 31, 2013.

To the extent that our cash and cash equivalents exceed our near term funding needs, we intend to invest the excess cash in money market accounts, high-grade corporate bonds or fixed-income type bond funds. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

ITEM 4: Controls and Procedures

Our Chairman of the Board (serving as the principal executive officer) and the Chief Financial Officer performed an evaluation of the effectiveness of our disclosure controls and procedures, which have been designed to permit us to effectively identify and timely disclose important information. In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and Management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of June 30, 2014, to ensure that material information was accumulated and communicated to our Management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

During the six months ended June 30, 2014, we have made no change in our internal controls over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Part II – OTHER INFORMATION

ITEM 1: Legal Proceedings

Except as set forth below, there have been no material developments in litigation from that disclosed in our Annual Report Form 10-K for the fiscal year ended December 31, 2013, Note 16 - Contingencies:

(a) Stephanie A. Frater v. Hemispherx Biopharma, Inc., William A. Carter, David Strayer and Wayne Pambianchi, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:12-cv-07152-WY.

(b) Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William M. Mitchell, Richard C. Piani, David Strayer and Charles T. Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:13-cv-00243-WY.

(c) Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, March 2013 Term, No. 110.

(d) Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, April 2013 Term, No. 3458.

(e) Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Richard C. Piani, William M. Mitchell, Iraj E. Kiani and Robert E Peterson, Chancery Court of the State of Delaware , June 18, 2013, Case No. 8657.

(f) Charles T. Bernhardt III v. Hemispherx Biopharma, Inc., Dr. William A. Carter, Thomas K. Equels, Esquire, Dr. Iraj Eqhbal Kiani, Dr. William M. Mitchell and Peter W. Rodino; Court of Common Pleas of Philadelphia County, Philadelphia, PA; Case: February Term, 2014 No. 000784.

On December 21, 2012, a putative Federal Securities Class Action Complaint was filed against the Company and three of its Officers in the United States District Court for the Eastern District of Pennsylvania. This action, Stephanie A. Frater v. Hemispherx Biopharma, Inc., et al., was purportedly brought on behalf of a putative class of Hemispherx investors who purchased the Company's publicly traded securities between March 14, 2012 and December 17, 2012. The Complaint generally asserted that Defendants made material misrepresentations and omissions regarding the status of the Company's New Drug Application for Ampligen®, which had been filed with the United States Food and Drug Administration, in alleged violation of Section 10(b) of the Securities Exchange Act of 1934 (“Exchange Act”), Rule 10b-5 promulgated thereunder, and Section 20(a) of the Exchange Act. On March 14, 2013, the Court appointed

Hemispherx Investor Group as Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995 (“PSLRA”), 15 U.S.C. § 78u-4. Pursuant to the Court's March 29, 2013 scheduling order, Lead Plaintiff filed a Consolidated Amended Class Action Complaint (“Amended Complaint”) on May 20, 2013, and in its Amended Complaint, dropped Thomas K. Equels and Charles T. Bernhardt as Defendants and added David R. Strayer, M.D. and Wayne Pambianchi, an outside consultant, as Defendants. The Amended Complaint alleges an expanded Class Period of March 14, 2012 to December 20, 2012, which period encompasses statements made in the Company's 2011 Form 10-K filed on March 14, 2012, and at the FDA Advisory Committee Meeting on December 20, 2012. On July 19, 2013, Defendants filed a motion to dismiss the Amended Complaint. Lead Plaintiff filed its brief in opposition to Defendants' motion to dismiss is September 17, 2013, and Defendants filed their reply brief on October 17, 2013. On January 24, 2014, the court entered an order denying defendants' motion to dismiss the Amended Complaint, and on February, 20, 2014, entered a scheduling order imposing, inter alia, a March 31, 2015 deadline for the completion of all fact discovery. On February 25, 2014, defendants filed an answer and affirmative defenses to the Amended Compliant. Also on February 25, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery.

On January 15, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the United States District Court for the Eastern District of Pennsylvania. Purporting to assert claims on behalf of the Company, the Complaint in this action, Mark Zicherman v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On February 22, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On July 3, 2013, Plaintiff filed an Amended Complaint, adding David R. Strayer, M.D., as a Defendant. On July 18, 2013, the Court entered an order staying the case as against Dr. Strayer pending the outcome of the motion to dismiss the securities class action. On January 24, 2014, the Court denied the defendants' motion to dismiss the securities class action. On March 26, 2014, the Court entered an order to continue the temporary stay, and on March 27, 2014, the Court entered an order placing the action in the Civil Suspense File. On April 11, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery.

On March 4, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, Michael Desclos v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On April 10, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On January 24, 2013, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the court entered an order consolidating this action with the shareholder derivative action, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., described below. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery.

On April 23, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On May 10, 2013, the Court entered an order staying this case pending the outcome of the ruling on the Federal Securities Class Action Defendants' motion to dismiss. On January 24, 2014, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the Court entered an order consolidating this action with the shareholder derivative action, Michael Desclos v. Hemispherx Biopharma, Inc., et al., described above. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery.

On June 18, 2013, a Stockholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the Court of Chancery of the State of Delaware. The Complaint in this action, Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., et al., alleges breaches of fiduciary duties, waste of corporate assets and unjust enrichment. The Company's Board of Directors has appointed a Special Litigation Committee (“SLC”) to review the allegations set forth in the Complaint. On September 10, 2013, the Court entered a Stipulation and Order staying all proceedings in this action pending the SLC’s review and recommendation concerning the allegations contained in the Complaint. On December 20, 2013, the SLC issued its Report, in which it concluded that dismissing the Complaint is in the best interests of Hemispherx and its stockholders. On January 20, 2014, the SLC moved to dismiss the Complaint. Since the SLC filed its motion to dismiss, plaintiffs have served document requests on the SLC, noticed the depositions of the SLC members (on dates to be mutually agreed-upon following document production), and served a subpoena on the SLC's counsel McCarter & English LLP. The SLC responded to plaintiffs’ document requests on March 6, 2014, and produced responsive documents the same day. McCarter & English responded to plaintiff's subpoena and produced responsive documents on March 20, 2014, and produced additional responsive documents on April 7, 2014 and June 23, 2014. On June 25, 2014, plaintiffs served document requests on the Company, to which the Company responded on July 25, 2014. The deposition of McCarter & English, tentatively scheduled for April 15, 2014, has been postponed indefinitely. On July 3, 2014, the Company amended its bylaws to (a) provide for fee shifting to stockholders who engage in unsuccessful stockholder litigation against Hemispherx and/or its officers, directors, or stockholders; and (b) require certain stockholders who engage in stockholder litigation to post security to cover the estimated expenses of litigation should the stockholder be unsuccessful. Counsel for Hemispherx notified plaintiffs of the amendment by letter on July 18, 2014, and on July

21, 2014, plaintiffs filed a motion to invalidate the bylaw, or in the alternative, to dismiss the action. The Court has scheduled a conference on August 15, 2014 to discuss plaintiffs' motion.

On February 7, 2014, Charles T. Bernhardt III ("Bernhardt") filed a Complaint in the Philadelphia Court of Common Pleas asserting that under an employment agreement dated December 6, 2011, the Company currently owes Bernhardt certain wages, fringe benefits and severance payments by reason of his resignation from employment as Chief Financial Officer from the Company. The claims against the Company included breach of contract, violation of the Pennsylvania Wage Protection Collection Law ("WPCL") and anticipatory breach of the employment agreement. The suit also asserts claims against Dr. William A. Carter, Thomas K. Equels, Esquire, Dr. Iraj Eqhbal Kiani, Dr. William M. Mitchell and Peter W. Rodino, in their capacity as corporate officers and/or directors of the Company, for violation of the WPCL and for anticipatory breach of the employment agreement. In addition to compensatory damages on all counts, Bernhardt's claim includes a demand for attorneys' fees and liquidated damages under the WPCL. On February 27, 2014, the Defendants filed preliminary objections to Bernhardt's Complaint challenging the legal sufficiency of the Complaint for various reasons including that the Complaint did not properly state claims under the WPCL, nor did it assert a right to severance benefits. The preliminary objections further sought to strike certain improper allegations contained in the Complaint. Bernhardt filed an Amended Complaint supplementing and changing the allegations of the Complaint. The Company filed Preliminary Objections to the Amended Complaint asserting that the Amended Complaint contained legal deficiencies. On April 25, 2014, Bernhardt filed a Second Amended Complaint. On July 23, 2014, the Company answered and asserted its defenses to the Second Amended Complaint, and also asserted counterclaims against Bernhardt on behalf of the Company and the individual defendants named in the Complaint. These counterclaims included claims against Bernhardt for breach of contract, corporate defamation/false light and defamation. In addition, the Company has asserted a claim for the return of corporate property which Bernhardt is believed to have taken at the time of his departure. Discovery in the matter is ongoing. The Company intends to vigorously defend against the allegations of the Second Amended Complaint, and to strongly pursue the affirmative claims of the Company and those of the other defendants. At this time no reasonable judgment can be made as to the likely outcome of the matter.

The Company believes it has meritorious defenses and is vigorously defending against these claims by Bernhardt as unjustifiable. There is currently no projection as to the likely outcome of the case.

The Company intends to vigorously defend these actions. The potential impact of these actions, which seek unspecified damages, equitable relief, attorneys' fees and expenses, is uncertain. There can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on the Company's business, results of operations and financial condition.

(g) Hemispherx Biopharma, Inc. v. Johannesburg Consolidated Investments, et al., U.S. District Court for the Southern District of Florida, Case No. 04-10129-CIV.

In December 2004, the Company filed a multi-count complaint in U.S, Federal Court (Southern District of Florida) which was granted by the Court in August 2010 whereby Hemispherx was awarded $188 million, plus interest against Johannesburg Consolidated Investments ("JCI") and former JCI officers R.B. Kebble and H.C. Buitendag. The Company attempted to domesticate the Final Judgment in South Africa. The action to domesticate had been filed in South Africa. As required by South African law, on October 11, 2011, Hemispherx posted security bond of $66,873 related to the JCI proceedings and a second bond of $25,200 was posted in July 2012 related our proceedings against the Estate of Kebble. Hemispherx and the other parties to the domestication action convened an arbitral panel in South Africa to decide the domestication issue in Johannesburg on May 5 through 9, 2014. After deliberation, the panel declined to domesticate the U.S. judgment in South Africa. In all probability, the entire amount of the security bonds stated above will be forfeited.

(h) MidSouth Capital, Inc. v. Hemispherx Biopharma, Inc., Civil Action No. 1:09-CV-03110-CAP.

After remand to the United States District Court, Northern District of Georgia, a Scheduling Order proposed by the parties was entered by the Court on October 17, 2012. The Company deposed representatives of two more of the investors to preserve their testimony for trial. Neither witness testified that MidSouth's activity significantly influenced the decision to invest. The parties have submitted a proposed pretrial Order. The Company has also filed a Motion to Reopen Discovery for a limited purpose, a Motion in Limine to exclude five categories of evidence and a Request for a Special Setting. The Court held a Pretrial Conference on October 3, 2013. The Court denied the Motion to Reopen Discovery, stated that the case will be number one on a published calendar for trial after the first of the year, and took all other matters under advisement. On March 3, 2014, the jury in the MidSouth Capital, Inc. v. Hemispherx Biopharma, Inc. case returned a verdict in favor of the Company and against MidSouth on all claims. The time within which MidSouth could have appealed from the judgment in favor of the company has expired, and the judgment is now final. The company sought and received a judgment in its favor for its fees and expenses incurred amounting to approximately $19,000 in the litigation from the opposing parties and their counsel. This case is now concluded.

(i) Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 09-549-GMS.

The Parties had a Non-Jury trial on March 4, 5 and 6, 2013 before the United States District Court for the District of Delaware. On April 22, 2013 the Parties submitted Proposed Findings of Fact and Conclusions of Law, and on April 26, 2013, submitted hyperlinked copies to the Court pursuant to the Court's Order. In February and March of 2014, the Company’s counsel advised the Court that certain rulings in a similar matter undercut certain factual and legal arguments advanced by the Plaintiff at, and subsequent to the trial. There can be no estimate of when the Court may rule on the case.

As of March 13, 2014, no informed judgment can be made as to the likely outcome and Counsel is unable to provide an estimate of the merits or probability of success of the Cato claims or a range of potential recovery or loss.

(j) Summation.

In reference to Contingencies identified, there can be no assurance that an adverse result in these proceedings would not have a potentially material adverse effect on our business, results of operations, and financial condition. The Company believes it has meritorious defenses and is vigorously defending against the claims identified. There is currently no projection as to the likely outcome of the cases and the Company has not recorded any gain or loss contingencies as a result of the above matters for the six months ended June 30, 2014 and for the year ended December 31, 2013. Also with regards to Contingency (a), (b), (c), (d) and (e), the Company maintains insurance coverage which is expected to respond to certain claims and expenses.

ITEM 1A: Risk Factors

The following cautionary statements identify important factors that could cause our actual results to differ materially from those projected in the forward-looking statements made in this Form 10-Q. Among the key factors that have a direct bearing on our results of operations are:

Risks Associated With Our Business

No assurance of successful product development.

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® 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 investigational 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® 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. (Please see the next Risk Factor and Part 1, Item II Business, “Our Products” “Ampligen®” above for more information).

Alferon N Injection®. Although Alferon N Injection® 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. (Please see the next Risk Factor and Part 1, Item II Business, “Our Products” “Alferon N Injection®” above for more information).

Our drug and related technologies are investigational and subject to regulatory approval. If we are unable to obtain regulatory approval in a timely manner, or at all, our operations will be materially harmed and our stock adversely affected.

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for commercial distribution and sale and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® 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® for other indications will require regulatory approval.

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the United States ("U.S.") and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch ("HPB") of Canada, the Agency for the European Medicines Agency ("EMA") in Europe and the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT") in Argentina. 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® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe and efficacious. While Ampligen® is authorized for use in clinical trials in the U.S., 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. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

On February 1, 2013, we received a CRL from the FDA declining to approve our Ampligen® NDA for the treatment of CFS. The FDA communicated that we should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analysis. For more detailed information about the current status of our Ampligen® NDA please see "Our Products; Ampligen®" in Part 1, Item II. Business above.

The FDA's regulatory review and approval process is extensive, lengthy, expensive and inherently uncertain. To receive approval for a product candidate, we must, among other things, demonstrate to the FDA's satisfaction with substantial evidence from well-controlled pre-clinical and clinical trials that the product candidate is both safe and effective for each indication for which approval is sought. Before we can sell Ampligen® for any use, or Alferon® for any use other than as Alferon N Injection® for treatment of refractory or recurring genital warts, we will need to file the appropriate NDA with the FDA in the U.S. and the appropriate regulatory agency outside of the U.S. where we intend to market and sell such products. At present the only NDA we have filed with the FDA is the NDA for the use of Ampligen® to treat CFS. As discussed in the prior paragraph, the FDA declined to approve this NDA and indicated that we needed to conduct additional work. Therefore, ultimate FDA approval, if any, may be delayed by several years and may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict if or when we might receive regulatory approval for the use of Ampligen® to treat CFS or for the use of any other products. Even if regulatory approval from the FDA is received for the use of Ampligen® to treat CFS or eventually, for the use of any other product, any approvals that we obtain could contain significant limitations in the form of narrow indications, patient populations, warnings, precautions or contra-indications or other conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues from such products could be greatly reduced and our business could be harmed.

Even if we believe that data collected from our preclinical studies and clinical trials of our product candidate are promising, these data have not been, and may not be in the future, sufficient to support marketing approval by the FDA, and regulatory interpretation of these data and procedures may continue to be unfavorable.

To the extent that we are required by the FDA pursuant to the Ampligen® NDA to conduct additional studies and take additional actions, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our applications approvable. If any of these outcomes occur, we may be forced to abandon one or more of our future applications for approval, which might significantly harm our business and prospects. As a result, we cannot predict when or whether regulatory approval will be obtained for any product candidate we develop.

Obtaining approval of a NDA by the FDA, or a comparable foreign regulatory authority, is inherently uncertain. Even after completing clinical trials and other studies, a product candidate could fail to receive regulatory approval for many reasons, including the following:

- not be able to demonstrate to the satisfaction of the FDA that our product candidate is safe and effective for any indication;
- the FDA may disagree with the design or implementation of our clinical trials or other studies;
- the results of the clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from clinical trials or other studies;

- the data collected from clinical trials and other studies of a product candidate may not be sufficient to support the submission of a NDA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA may not approve the proposed manufacturing processes and facilities for a product candidate.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® API, which would need to be released by the FDA before those materials could be used in commercial product. After conducting all of the appropriate tests on samples of the inventory during 2013, we concluded that we could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection®. Accordingly, these lots will not be submitted to the FDA to request release for commercial sale and their remaining dollar value has been written-off. In the absence of FDA approvals for product manufactured from existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale. (Please see Part I, Item II - "Business; Our Products; Alferon N Injection®" above for more information).

Alferon® LDO has been approved for pre-clinical testing for possible use as prophylaxis and treatment against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models 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 Alferon® as a possible treatment of influenza requires prior regulatory approval. In October 2009, we originally submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. In December 2010, the FDA authorized this Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Our Phase II study has been delayed. The outcome of this confirmatory study, if and when resumed, will allow us to better evaluate the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza. We are unable to provide any assurances that the Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken.

If we are unable to gain necessary FDA approvals related to Ampligen® and Alferon® on a timely basis, our operations most likely will be materially and/or adversely affected. Additionally, if we are unable to generate the additional data, successfully complete inspections or obtain approvals as required by the FDA on a timely manner, or at all, or determine that any of our clinical studies are not cost/justified to undertake or if, for that or any other reason, Ampligen®, Alferon® or one of our other products or production processes do not receive necessary regulatory approval in the U.S. or elsewhere:

- our ability to generate revenues to sustain our operations will be substantially impaired, which would increase the likelihood that we would need to obtain additional financing for our other development efforts;
- our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all; and
- our profitability would be delayed, our business will be materially harmed and our stock price may be adversely affected.

Biotechnology stock prices, including our stock price, have declined significantly in certain instances where companies have failed to meet expectations with respect to FDA approval or the timing for FDA approval.

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

We last reported net profit from 1985 through 1987. Since 1987, with a major emphasis on new drug diagnostic and development, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of June 30, 2014, our accumulated deficit was approximately $(269,111,000). 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 most likely will require additional financing which may not be available. The limitation on the number of shares of common stock available for financing without prior stockholder approval eventually may hinder our ability to raise additional funding.

The development of our products requires 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 June 30, 2014, we had approximately $20,212,000 in cash, cash equivalents and marketable securities (inclusive of approximately $17,595,000 in Marketable Securities). However, if we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted.

In its CRL, the FDA communicated that Hemispherx should conduct at least one additional clinical trial, complete various nonclinical studies and perform a number of data analyses. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations.

Given the challenging economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® along with the manufacturing, marketing and distribution of our products, including Alferon N Injection®. We may also need additional capital to eventually commercialize and sell Ampligen® or Alferon® LDO and/or recommence and increase sales of Alferon N Injection® or our other products. We anticipate considering multiple options in an attempt to secure funding, including but not limited to such methods as the sales of additional equity, licensing agreements, partnering with other organizations, debt financing or other sources of capital.

In this regard, on July 23, 2012, we entered into a New Equity Distribution Agreement with Maxim (the “New EDA”) pursuant to which we may sell up to $75,000,000 worth of our shares of Common Stock from time to time through Maxim, as sales agent (See Part I; Item II - “Management's Discussion and Analysis of Financial Condition and Results of Operations; Liquidity and Capital Resources”). We cannot assure how much funding will be obtained from the New EDA or whether it will be sufficient in conjunction with current financial resources to permit us to take all actions needed to obtain FDA approval for Ampligen® and manufacturing, commercialization, marketing and distribution of our products.

Our ability to raise additional funds from the sale of equity securities may be limited due to limitations on our ability to sell stock for funding purposes. Pursuant to our Amended and Restated Certificate of Incorporation, the purpose for which 75,000,000 of 150,000,000 of our authorized shares (the “Restricted Shares”) may be utilized is limited. Specifically, without stockholder approval, the Restricted Shares can only be issued where such issuance would be primarily in connection with strategic transactions or other non-fundraising purpose that met certain significant criteria. In this regard, 20,254,327 shares are authorized but unissued and unreserved at June 30, 2014 with an additional 75,000,000 of the Restricted Shares approved by Stockholders for certain generally defined business purposes.

There can be no assurances that we can obtain the requisite stockholder approval to use any additional Restricted Shares for funding purposes or raise adequate funds from other sources. If we are unable to obtain additional funding, through the New Maxim EDA or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

We have recently concluded talks to enter into a strategic alliance to develop multiple projects with Bioclones (Pty) Ltd. ("Bioclones"), a leading South African biotechnology company. If we are unable to finalize our arrangement with Bioclones, obtain regulatory approval for these projects, jointly obtain source funding through Bioclones to initiate the projects, and obtain positive test results at the conclusion of the projects, our operations may be materially harmed and our stock adversely affected.
On June 25, 2014, Bioclones and Hemispherx concluded strategic discussions in Johannesburg with three principle goals; 1) initiating studies utilizing Ampligen(R) as a potential adjuvant enhancement of Bioclones' therapeutic cancer vaccine, currently in trials in Cape Town, including pre-clinical studies followed, potentially, by a Phase 1 clinical trial; 2) seeking South African Medicine's Control Council approval to conduct trials using Alferon(R) to eradicate the HIV virus in patients highly responsive

to anti-retroviral therapy (HAART); and 3) initiating a joint effort to obtain commercial registration of both Ampligen(R) and Alferon(R) in the South African markets. This strategic alliance is subject to our entering into a formal agreement on any or all of the above points of understanding. We cannot assure you that we will enter into a formal agreement, that these clinical trial approvals will be authorized in South Africa, in a timely fashion or at all, or that Bioclones will complete these trials. We cannot assure you that Bioclones and the Company will be able to jointly raise the necessary resources to develop these projects and, even if we believe that data collected from these preclinical studies and clinical trials of these product candidates are promising, these data have not been, and may not be in the future, sufficient to support marketing approval by the appropriate regulatory body, and regulatory interpretation, safety and efficacy of these data and procedures may be determined to be unfavorable.

Our Alferon N Injection® Commercial Sales were halted due to lack of finished goods inventory. If we are unable to gain the necessary FDA approvals related to Alferon®, our operations most likely will be materially and/or adversely affected.

Commercial sales of Alferon N Injection® were halted in March 2008 when our finished goods inventory expired. The production of Alferon N Injection® from the Work-In-Process Inventory was restarted in May 2010, continued into January 2011 with its conversion into API.

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® API, which would need to be released by the FDA before those materials could be used in commercial product. After conducting all of the appropriate tests on samples of the inventory during 2013, we concluded that we could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection® and their remaining dollar value has been written-off. As we no longer have any existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale.

While our facility is FDA approved under the BLA by the FDA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's upgrades for Alferon®. We cannot provide any guarantee that the facility will necessarily pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex. Please see “There is no assurance that our manufacturing facility will again be granted a BLA certification by the FDA upon completion of the manufacturing enhancements or return to commercial, large-scale production” below for more information.

If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. For more information on Alferon N Injection® regarding potential commercial sales, please see PART I, Item II - "Business; Our Products; Alferon N Injection®”.

In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, 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 experimental drug, Ampligen®. We also have been issued patents on the use of Ampligen® 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® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers which we have sought to target.

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. In addition, Management's review addresses whether each patent continues to fit into our strategic business plans for Ampligen®, Alferon N Injection® and Alferon® LDO. One U.S. patent relating to our Alferon® product expired on April 2, 2013 (#5,503,828) (see discussion below on patent #5,503,828), while two other Alferon® patents expire on October 14, 2014 (#5,676,942) and December 22, 2017 (#5,989,441). In 2013, we were granted four new patents, one in Singapore for the use of Ampligen to initiate innate immunity and to treat or prevent viral infections and tumors, and three for the use of Alferon LDO to treat bacterial or protozoan infections in Australia, New Zealand and Singapore. In 2012, we were granted two new patents, one in Australia and the other in New Zealand, both for the use of Ampligen to initiate innate immunity and to treat or prevent viral infections and tumors. In December 2011, we were granted two new United States Patents for the use of Alferon® LDO for the treatment in a number of different human diseases. Alferon® composition patent #5,503,828, which expired in April 2013, relates to the manufacturing process for Alferon® Active Pharmaceutical Ingredient (“API”), a complex mixture of natural interferon species that is manufactured from human leukocytes obtained from human blood donors. In addition, while it is the current standard by the FDA to treat biological drug products like interferon as “Well Characterized” biologics, a process for which chemical entities can have their identity, purity, impurities, potency, and quality controlled by chemical testing, Alferon®, as a natural interferon, does not lend itself well to such testing. Moreover, FDA continues to require that each lot or Alferon we produce be tested and released by the FDA before it can be distributed for commercial sales. Because of the complexity of the Alferon manufacturing process and these additional regulatory requirements, we believe that potential manufacturers of generic, or so-called “bio-similar,” drug products are focused on developing recombinant interferon products, rather than natural interferon products. For these reasons, we believe the expiration of this Alferon® composition patent in April 2013 should have no or little impact on the Company. Additionally at the completion of the facility enhancement and receipt of the FDA certification for the revised Alferon® manufacturing process and techniques in New Brunswick, NJ, it is our intention to file for additional patent protection. Alferon® patent #5,676,942 relates to a manufacturing methodology which is no longer in use.

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 so. 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, process 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, process and technology 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 or process 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 all employees and certain 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.

We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future 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 in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen® for CFS, if and when it is approved for marketing and sale by the FDA, may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We continue to seek world-wide marketing partner(s), with the goal of having a relationship in place before approval is obtained. In parallel to partnering discussions, appropriate pre-marketing activities will be undertaken. It is our current intention to control manufacturing of Ampligen® on a world-wide basis.

Our commercialization strategy for Alferon N Injection® may include the utilization of internal functions and/or licensing/co-marketing agreements that would utilize the resources and capacities of one or more strategic partners. Accordingly, we have engaged Armada Healthcare to undertake the marketing, education and sales of Alferon N Injection® throughout the United States along with GP Pharm for both Ampligen® and Alferon® in Argentina along with other South and Latin American countries.

We cannot assure that our U.S. or foreign marketing strategy will be successful 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. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us. There can be no assurances that the approved Alferon N Injection® product will be returned to prior sales levels.

There are no long-term agreements with suppliers of required materials and services for Ampligen® and there are a limited number of raw material suppliers. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Ampligen®.

A number of essential raw materials are used in the production of Ampligen® as well as packaging materials utilized in the fill and finish process. We do not have, but continue to work towards having long-term agreements for the supply of such materials, when possible. There can be no assurance we can enter into long-term supply agreements covering essential materials on commercially reasonable terms, if at all.

There are a limited number of suppliers in the United States available to provide the raw and packaging materials for use in manufacturing Ampligen®. At present, we do not have any agreements with third parties for the supply of any of these materials. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain a more consistent manufacturing basis in the quantities necessary for clinical testing. In September 2011 and similar to our prior agreements, Hollister-Stier has agreed to undertake the manufacturing sets to formulate, fill, finish and package Ampligen® from the key polymers that we would supply. Hollister-Stier would have the right of first refusal to manufacture certain Ampligen® related products. For more information on Ampligen®, please see Part I, Item II - "Business; Our Products; Ampligen®".

If we are unable to obtain or manufacture the required materials, and/or procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Ampligen®. The costs and availability of products and materials we need for the production of Ampligen® are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, ownership of intellectual property, FDA and other governmental regulations. 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 are a limited number of organizations in the United States available to provide the final manufacturing steps of formulation, fill, finish and packing sets for Alferon N Injection® and Ampligen®.

There are a limited number of organizations in the United States available to provide the final steps in the manufacturing for Alferon N Injection® and Ampligen®. To formulate, fill, finish and package our products ("fill and finish"), we require a FDA approved third party CMO.

In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea Technologies, Inc. regarding the fill and finish process for Alferon N Injection® (please see Part I, Item II - "Business; Our Products; Alferon N Injection®". As we no longer have any existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale.

Pursuant our Supply Agreement with Hollister-Stier, they will formulate, fill, finish and package Ampligen® from the key raw materials that we would supply. We are unable to provide any assurances that the FDA will approve the inventory manufactured by us or produced by Hollister-Stier. If this finish goods inventory is not granted approval by the FDA, our operations may be materially adversely affected. This Supply Agreement expired March 11, 2014. The Company is working towards an amendment to the existing Supply Agreement which may contain additional fees as part of entering into the extension.

If we are unable to procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Alferon N Injection® and/or Ampligen®. The costs and availability of products and materials we need for the production of Ampligen® and the commercial production of Alferon N Injection® 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. For more information on Ampligen® and Alferon N Injection®, please see Part I, Item II - "Business; Our Products; Ampligen® and Alferon N Injection®".

There is no assurance that our manufacturing facility will again be granted a BLA certification by the FDA upon completion of the manufacturing enhancements or return to commercial, large-scale production.

We are currently in the Installation and Operation Qualification phase for Alferon® production of the enhancement project. The production of new Alferon® API inventory will not commence until the validation phase is completed. While the facility is approved by FDA under the BLA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. We anticipate that it will take approximately sixteen months before we will have newly produced Alferon® API ready for submission to the FDA for review and approval. For more information, please see Part I, Item II - "Business; Our Products; Alferon N Injection®". There can be no assurance the BLA status will be recertified by the FDA upon the completion of the enhancement process or that the manufacturing facility will return to commercial, large-scale production for Alferon®. Additionally, there can be no assurance that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

Only if and when our BLA status is recertified by the FDA to produce new lots of Alferon® at our enhanced manufacturing facility can batches of Alferon® API be produced, formulated, filled, finished, packaged and then approved for release by the FDA. We are unable to provide any assurances that the FDA will approve our enhanced manufacturing process and/or newly created finish product lots. Without FDA approval, our Alferon N Injection® will not be considered suitable for commercial sales.

In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to commercial production or sale on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

Changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy. 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 may require additional management, technical personnel and capital to the extent such manufacturing is not handled by third parties. While we believe that the Company could successfully upgrade our production capability at our New Brunswick, NJ facility in a commercial scale-up of

Ampligen®, there can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

We have limited manufacturing experience for Ampligen® and Alferon®. We may not be profitable unless we can produce Ampligen®, Alferon® or other products in commercial quantities at costs acceptable to us.

Satisfactory inspection by the FDA of both our Ampligen® and Alferon® manufacturing process is required before commercial sale of project would be allowed. The CRL from the FDA on February 1, 2013, requests evaluation of variation between lots of Ampligen® tested in the development process and recommends tighter control of the Ampligen® manufacturing process. We cannot provide any guarantee that the facility will pass a FDA pre-approval inspection for Ampligen® or Alferon® manufacture, which are conducted in separately dedicated areas within the overall New Brunswick manufacturing complex. The failure to obtain FDA approval for either of our manufacturing process areas would most likely have a materially adverse impact upon us.

Ampligen® has been produced to date in limited quantities for use in our clinical trials, and we are dependent upon a qualified third party supplier for the manufacturing, filling, finish and packaging process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse effect on us.

In furtherance of the capital improvement program at our New Brunswick, NJ facility to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API, the validation phase of the Alferon® manufacturing project is currently underway as we undertake the Installation and Operation Qualification phase of the enhancement project. While the facility is approved by FDA under the BLA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. We anticipate that it will take at least 14 months before we will have newly produced Alferon® API ready for submission to the FDA for review and approval. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all. The failure to obtain FDA approval of any of our manufacturing process would most likely have a materially adverse impact upon us.

Also to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We believe, but cannot assure, that our enhancements to our manufacturing facilities will be adequate for our future needs for the production of our proposed products for large-scale commercialization. We intend to ramp up our existing facility and/or 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 cGMP requirements or maintaining our BLA status. 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 the production of our proposed products for large-scale commercialization or our long-term needs.

We have never produced Ampligen®, Alferon® 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® and/or Alferon®, or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. If and when the Ampligen® NDA is approved, we may need to find an additional vendor to manufacture the product for commercial sales. Also, each production lot of Alferon N Injection® 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, nor can we provide any assurance as to the receipt of FDA approval of our finished inventory product. There can be no assurances that the Ampligen® and/or Alferon® can be commercially produced at costs acceptable to us.

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®. 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 we do in preclinical 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 CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Pfizer, GlaxoSmithKline, Merck & Co., Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. 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® on the immune system, we cannot assure that we will be able to compete.

Alferon N Injection®. Our 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® currently competes with Merck's injectable recombinant alpha interferon product (INTRON® A) for the treatment of genital warts. In addition, other pharmaceutical firms offer self-administered topical cream, for the treatment of external genital and perianal warts such as Graceway Pharmaceuticals (Aldara®), Watson Pharma (Condylox®) and MediGene (Veregen®). Alferon N Injection® 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®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® 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®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products. Please see “We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents" above for additional information.

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® or Alferon N Injection® could adversely affect potential revenues and physician/patient acceptability of our product.

Ampligen®. We believe that Ampligen® 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 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heartbeat, 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 reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, 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.

The FDA in its February 1, 2013 CRL, set forth the reasons for not approving Ampligen® at this time and provided recommendations to address certain of the outstanding issues. The Agency stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of CFS and that the data do not provide sufficient information to determine whether the product is safe for use in CFS due to the limited size of the safety database and multiple discrepancies within the submitted data.

If approved, one or more of the potential side effects of the drug might deter usage of Ampligen® in certain clinical situations and therefore, could adversely affect potential revenues and physician/patient acceptability of our product.

Alferon N Injection®. At present, Alferon N Injection® 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®, 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® which could threaten or limit such product's usefulness.

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

We maintain Products Liability and Clinical Trial insurance coverage world-wide for Ampligen® and Alferon®. However even with retaining Products Liability and Clinical Trial insurance coverage for Ampligen®, Alferon N Injection® and Alferon® LDO, a claim against the products could have a materially adverse effect on our business and financial condition.

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen®, Alferon N Injection® 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.

The loss of services of key personnel including Dr. William A. Carter could hurt our chances for success.

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers along with 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®, and his knowledge of our overall activities, including patents and clinical trials. The loss of the services of Dr. Carter or other personnel key to our operations could have a material adverse effect on our operations and chances for success. As a cash conservation measure, we have elected to discontinue the Key Man life insurance on the life of Dr. Carter. An employment agreement continues to exist with Dr. Carter that, as amended, runs until December 31, 2016. 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 key 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.

A Securities Federal Class Action and Four Shareholder Derivative Actions Have Been Filed Against Us and We May Be Subject to Civil Liabilities.

As described above in Part II. Item 1. Legal Proceedings, paragraphs (a), (b), (c), (d) and (e), five actions have been filed against Hemispherx and certain of its Officers and Directors: a putative class action alleging violations of the federal securities laws and seeking monetary damages, costs, and attorneys' fees; and four shareholder derivative actions alleging various state law breach of fiduciary duty, waste of corporate assets and unjust enrichment claims along with seeking monetary damages, costs, attorneys' fees, and equitable and injunctive relief. Defending against these suits, even if meritless, can result in substantial costs to us and could divert the attention of our management.

The existence of these proceedings could have a material adverse effect on our ability to access the capital markets to raise additional funds. While Management believes that the lawsuits are without merit, we cannot predict or determine the timing or final outcomes of the lawsuits and are unable to estimate the amount or range of loss that could result from unfavorable outcomes.

Adverse results in some or all of these legal proceedings could be material to our results of operations, financial condition or cash flows.

Risks Associated With an Investment in Our Common Stock:

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. This is especially true given the current significant instability in the financial markets. 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;
- announcements of availability or projections of our products for commercial sale;
- announcements of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture 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;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE MKT non-compliance with requirements; and
- occurrence of any of the risks described in these "Risk Factors".

Our common stock is listed for quotation on the NYSE MKT. For the six month period ended June 30, 2014, the trading price of our common stock has ranged from $0.27 to $0.55 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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. In this regard, please see “A Securities Federal Class Action and Four Shareholder Derivative Actions Have Been Filed Against Us and We May Be Subject to Civil Liabilities" above.

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

In May 2009, we issued an aggregate of 25,543,339 shares and warrants to purchase an additional 14,708,687 shares under a Universal Shelf Registration Statement. 4,895,000 of these warrants have been exercised and 3,677,324 have expired as of June 30, 2014. Depending on market conditions, we may sell up to 6,136,363 shares pursuant to the exercise of these warrants before they expire in November 2014.

Additionally, we registered with the SEC on September 29, 2009, 1,038,527 shares issuable upon exercise of certain other warrants. To the extent the exercise price of our outstanding 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 exercise price of certain of these warrants are adjusted pursuant to anti-dilution protection, the warrants 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. In this regard, we have registered $150,000,000 of securities for public sale pursuant to a universal shelf registration statement and we have been selling shares under this shelf registration statement and the New EDA with Maxim. Through June 30, 2014, we had sold an aggregate of approximately 51,155,000 shares under the New EDA.

Pursuant to the New Maxim EDA, we may sell up to $75,000,000 worth of our shares of Common Stock from time to time through Maxim, as sales agent. While we have no obligation to sell any of the Shares and may at any time suspend offers under the New Maxim EDA or terminate the EDA, the sale of substantial numbers of Shares under the EDA may have an adverse impact on the trading value of the stock.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of substantial amounts of our common stock in the public market, including additional sale of securities pursuant to the New EDA with Maxim or otherwise under the universal shelf registration statement or upon exercise of outstanding options, 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.

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, on November 2, 2012, we amended and restated our Stockholder Rights Plan (“Rights Plan”) and, under the Rights 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-hundredth unit of preferred stock for $30.00 and may be redeemed prior to November 19, 2017, the expiration date, at $0.001 per Right under certain circumstances. 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. At June 30, 2014, for Dr. Carter, our Chief Executive Officer and President, who already beneficially owns approximately 4.96% of our common stock, the Rights Plan’s threshold will be 20%, instead of 15%.

Special Note Regarding Forward Looking Statements

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® 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 revenue.

ITEM 2: Unregistered Sales of Equity Securities and Use of Proceeds

We did not have any unregistered sales nor repurchase any of our securities during the six months ended June 30, 2014.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

None.

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.
101	The following materials from Hemispherx' Quarterly Report on Form 10-Q for the period ended June 30, 2014, formatted in eXtensible Business Reporting Language ("XBRL"): (i) Condensed Balance Sheets ; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

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/ Thomas K. Equels
Thomas K. Equels, Esq.
Executive Vice Chairman of the Board, Secretary,
General Counsel and Chief Financial Officer

Date: August 8, 2014