

HEMISPHERX BIOPHARMA INC  
Form 10-Q  
November 16, 2015

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 September 30, 2015

Commission File Number: 1-13441

HEMISPHERX BIOPHARMA, INC.  
(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

52-0845822  
(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.

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).

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  Smaller reporting company

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

247,516,987 shares of common stock were outstanding as of November 1, 2015.

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## 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)

	September 30, 2015 (Unaudited)	December 31, 2014 (Audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$1,161	\$2,156
Marketable securities	11,214	13,952
Inventory-work in process	1,326	—
Prepaid expenses and other current assets	278	399
Total current assets	13,979	16,507
Property and equipment, net	11,501	4,601
Patent and trademark rights, net	883	861
Construction in progress	—	7,337
Other assets	134	134
Total assets	\$26,497	\$29,440
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$1,506	\$2,081
Accrued expenses	1,818	2,333
Current portion of capital lease	3	22
Total current liabilities	3,327	4,436
Commitments and contingencies (Note 6)	—	—
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 247,557,287 and 204,004,818, respectively	248	204
Additional paid-in capital	313,185	302,729
Accumulated other comprehensive loss	(401	) (160
Accumulated deficit	(289,862	) (277,769
Total stockholders' equity	23,170	25,004
Total liabilities and stockholders' equity	\$26,497	\$29,440

See accompanying notes to consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Revenues:				
Clinical treatment programs	\$23	\$45	\$106	\$157
Total revenues	23	45	106	157
Costs and expenses:				
Production	353	306	1,232	923
Research and development	1,968	1,894	7,081	6,550
General and administrative	1,685	2,174	5,600	7,210
Total costs and expenses	4,006	4,374	13,913	14,683
Operating loss	(3,983	) (4,329	) (13,807	) (14,526
Interest expense	(1	) (3	) (3	) (9
Interest and other income/expense	181	130	343	414
Redeemable warrants valuation adjustment	—	—	—	1
Gain from sale of income tax net operating losses	—	—	1,374	1,126
Net loss	(3,803	) (4,202	) (12,093	) (12,994
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	(215	) (169	) (241	) —
Net comprehensive loss	\$(4,018	) \$(4,371	) \$(12,334	) \$(12,994
Basic and diluted loss per share	\$(0.02	) \$(0.02	) \$(0.05	) \$(0.07
Weighted average shares outstanding, basic and diluted	246,774,460	190,677,576	232,307,548	184,434,475

See accompanying notes to consolidated financial statements.

## HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

## Consolidated Statement of Changes in Stockholders' Equity

For the Nine Months Ended September 30, 2015

(in thousands except share data)

(Unaudited)

	Common Stock Shares	Common Stock \$0.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre- hensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2014	204,004,818	\$204	\$302,729	\$ (160 )	\$ (277,769 )	\$25,004
Shares to settle accounts payable	2,558,779	3	669	—	—	672
Equity-based compensation	—	—	148	—	—	148
Shares sold at the market	40,993,690	41	9,639	—	—	9,680
Net comprehensive loss	—	—	—	(241 )	(12,093 )	(12,334 )
Balance at September 30, 2015	247,557,287	\$248	\$313,185	\$ (401 )	\$ (289,862 )	\$23,170

See accompanying notes to consolidated financial statements.

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## HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

## Consolidated Statements of Cash Flows

For the Nine Months Ended September 30, 2015 and 2014

(in thousands)

(Unaudited)

	2015		2014	
Cash flows from operating activities:				
Net loss	\$(12,093	)	\$(12,994	)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation of property and equipment	663		500	
Amortization and abandonment of patent and trademark rights	166		414	
Redeemable warrants valuation adjustment	—		(1	)
Equity-based compensation	148		260	
Change in assets and liabilities:				
Inventories	(1,326	)	—	
Prepaid expenses and other current assets	121		123	
Accounts payable	97		1,214	
Accrued expenses	(515	)	553	
Net cash used in operating activities	(12,739	)	(9,931	)
Cash flows from investing activities:				
Purchase of property, equipment and construction in progress	(226	)	(386	)
Additions to patent and trademark rights	(188	)	(187	)
Deposits on capital leases refunded	—		2	
Sales and maturities of short-term and long-term marketable securities	2,497		1,222	
Net cash provided by investing activities	2,083		651	
Cash flows from financing activities:				
Payments on capital leases	(19	)	(24	)
Proceeds from sale of stock, net of issuance costs	9,680		9,763	
Net cash provided by financing activities	9,661		9,739	
Net (decrease) increase in cash and cash equivalents	(995	)	459	
Cash and cash equivalents at beginning of period	2,156		803	
Cash and cash equivalents at end of period	\$1,161		\$1,262	
Supplemental disclosures of non-cash investing and financing cash flow information:				
Issuance of common stock for accounts payable	\$672		\$38	
Supplemental disclosure of cash flow information:				
Cash paid for interest expense	\$(3	)	\$(9	)

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 (collectively, “Hemispherx”, “Company”, “we or “us”). 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 also has a foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., which was established in Belgium in 1998. All significant intercompany balances and transactions have been eliminated in consolidation.

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, 2014 and 2013, contained in the Company’s Annual Report on Form 10-K for the year ended December 31, 2014.

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 of 14,845,888 and warrants of 2,232,392 which totaled 17,078,280 shares and equivalent common shares consisting of stock options of 14,959,480 and warrants of 8,535,422 which totaled 23,494,902 shares for the nine months ended September 30, 2015 and 2014, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive, due to the net loss of the Company.

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 800,000 and 955,000 options or equity warrants granted in the nine months ended September 30, 2015 and 2014, respectively.

Stock option for employees' activity during the nine months ended September 30, 2015 is as follows:

Stock option activity for employees:

Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual	Aggregate Intrinsic Value
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			Term (Years)	
Outstanding January 1, 2015	11,287,888	\$1.64	4.61	\$—
Granted	800,000	0.25	—	—
Forfeited	(565,000 )	1.75	—	—
Outstanding September 30, 2015	11,522,888	\$1.54	4.45	\$—
Vested and expected to vest September 30, 2015	11,522,888	\$1.54	4.45	\$—
Exercisable September 30, 2015	10,929,674	\$1.58	4.05	\$—

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## Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Unvested January 1, 2015	710,594	\$1.38	8.76	\$—
Granted	800,000	0.25	—	—
Vested	(917,380 )	0.96	—	—
Forfeited	—	—	—	—
Unvested September 30, 2015	593,214	\$0.50	8.69	\$—

## 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, 2015	3,800,000	\$1.36	4.75	\$—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(477,000 )	1.83	—	—
Outstanding September 30, 2015	3,323,000	\$1.29	4.57	\$—
Vested and expected to vest September 30, 2015	3,323,000	\$1.29	4.57	\$—
Exercisable September 30, 2015	3,323,000	\$1.29	4.57	\$—

## 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
Unvested January 1, 2015	33,333	\$2.60	9.08	\$—
Options granted	—	—	—	—
Options vested	(33,333 )	2.60	—	—
Options forfeited	—	—	—	—
Unvested September 30, 2015	—	\$—	0.00	\$—

The impact on the Company's results of operations of recording equity-based compensation for the nine months ended September 30, 2015 and 2014 was to increase general and administrative expenses by approximately \$148,000 and \$260,000, respectively, which had no impact on earnings per share.

As of September 30, 2015 and 2014, respectively, there was \$231,000 and \$301,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan. Generally, the Company's stock options will become recognizable within a 12 month period.

## Warrants:

The Company has 2,232,392 warrants outstanding as of September 30, 2015. The Company has not issued any warrants for the nine months ended September 30, 2015 and 2014.

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## 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)	
	September 30, 2015	December 31, 2014
Inventory work-in-process, January 1	\$—	\$—
Production <sup>(1)</sup>	1,326	—
Spoilage	—	—
Inventory work-in-process, end of period	\$1,326	\$—

(1) Commercial sales of Alferon® will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We are continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application (“BLA”) for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. The Company will also need the FDA’s approval to release commercial product once it has submitted satisfactory stability and quality release data.

## Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the nine months ended September 30, 2015, it was determined that some of the Marketable Securities had other than temporary impairments of approximately \$54,000. There were no other than temporary impairments of Marketable Securities for the nine months ended September 30, 2014. At September 30, 2015 and December 31, 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 12: Fair Value").

Securities classified as available for sale consisted of:

September 30, 2015  
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	\$11,615	\$—	\$(401)	) \$11,214	\$11,214	\$—
Totals	\$11,615	\$—	\$(401)	) \$11,214	\$11,214	\$—

December 31, 2014  
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	\$14,112	\$—	\$(160)	) \$13,952	\$13,952	\$—
Totals	\$14,112	\$—	\$(160)	) \$13,952	\$13,952	\$—

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:

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September 30, 2015

(in thousands)

	Total number in loss position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Securities							
Mutual Funds	2	\$5,330	\$(194 )	\$5,884	\$(207 )	\$11,214	\$(401 )
Totals	2	\$5,330	\$(194 )	\$5,884	\$(207 )	\$11,214	\$(401 )

December 31, 2014

(in thousands)

	Total number in loss position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Securities							
Mutual Funds	2	\$5,928	\$(106 )	\$8,024	\$(54 )	\$13,952	\$(160 )
Totals	2	\$5,928	\$(106 )	\$8,024	\$(54 )	\$13,952	\$(160 )

## Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	September 30, 2015	December 31, 2014
Compensation	\$973	\$1,806
Professional fees	301	404
Other expenses	524	123
Other liabilities	20	—
	\$1,818	\$2,333

The Company maintained a balance of legal fees from a law firm of \$587,000 which the Company agreed to pay with the issuance of 2,105,982 shares of the Company's common stock. The Company agreed to use the Company's share price of \$0.27 as of May 6, 2015 to settle the balance due; however, the Company agreed to pay the difference if the law firm receives less from the sale of the Company's common stock than the balance due within sixty days after the sale of shares is completed. The Company's share price was \$0.17 as of September 30, 2015. As a result of the drop in share price, the Company accrued an additional \$211,000 which has been included within the accrual for professional fees above.

## Note 7: Property and Equipment

	(in thousands)	
	September 30, 2015	December 31, 2014
Land, buildings and improvements	\$11,603	\$4,209
Furniture, fixtures, and equipment	5,476	5,307
Leasehold improvements	85	85
 Total property and equipment	 17,164	 9,601
Less: accumulated depreciation and amortization	(5,663	) (5,000 )
 Property and equipment, net	 \$11,501	 \$4,601

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.

As of February 28, 2015, the Company had completed and put into service the construction and installation of property and equipment within its New Brunswick, NJ facility. All amounts within construction in progress were reclassified to property and equipment during the current period. As of December 31, 2014, construction in progress was \$7,337,000.

## Note 8: Stockholders' Equity

The Equity Incentive Plan of 2009 ("2009 Plan"), 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 2009 Plan. In September 2015, the Company's shareholders approved the following amendments to the 2009 Plan: (1) increased the number of shares authorized to be issued under the Equity Incentive Plan from 15,000,000 to 22,000,000; (2) required a gradual vesting period of options issued under the Equity Incentive Plan over a three year period; (3) revised the definition of "change in control" to make it less "liberal" by amending the provision that a change in control occurs upon stockholder approval of a merger, consolidation or sale or disposition by the Company of all or substantially all of its assets (a "Business Combination") to state that such a change in control occurs upon the consummation of the Business Combination; and (4) clarified that the definition of change in control has a double trigger – For a Participant to get the benefit resulting from a change in control, such Participant must have been terminated other than for cause within a two year period. Unless sooner terminated, the 2009 Plan will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2015 and 2014, there were 800,000 and 955,000 options granted by the Company, respectively.

On July 23, 2012, the Company entered into a Equity Distribution Agreement (the "EDA") with Maxim Group LLC ("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 EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the 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 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 EDA or terminate the EDA. Up until August 4, 2015, the shares were 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. Since August 4, 2015, 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 August 4, 2015 (the "2015 Universal Shelf"). 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 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 EDA. On December 23, 2013, the Company filed an updated Prospectus Supplement with the Securities and Exchange Commission to revise the EDA for an aggregate of 90,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the EDA. On March 6, 2015, the Company filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus

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to 117,600,000 shares. On August 5, 2015, the Company filed an updated Prospectus Supplement to reflect that sales under the EDA are now being conducted pursuant to the 2015 Universal Shelf.

For the nine months ended September 30, 2015, the Company had sold 40,993,690 shares of the EDA that resulted in net cash proceeds of approximately \$9,680,000 after direct expenses along with commissions paid to Maxim for approximately \$299,000.

The Company's stockholders approved an amendment to the Company's corporate Charter at the Annual Shareholder Meeting held in Philadelphia, PA that concluded on December 8, 2011. This amendment increased the Company's authorized shares from 200,000,000 to 350,000,000 with specific limitations and restrictions on the usage of 75,000,000 of the 150,000,000 newly authorized shares. In the event that the issuance of any Restricted Shares for a purpose prohibited by the above mentioned limitations are in the Company's best interests, our Board is required to seek stockholder approval before we could use such shares for that purpose. Our Board is required to specify to stockholders the use of proceeds for the sale of such shares, why the use of the shares for that purpose is necessary and the number of authorized shares that would be needed. On September 16, 2015, the Company's stockholders approved up to an additional 60,000,000 of the remaining Restricted Shares for use in capital raising transactions.

The Company plans to allocate the net proceeds from the offering towards research and development, operations and general and administrative purposes related to the commercialization of Ampligen® and Alferon® related products, including, but not limited to, the following: (1) Costs to finalize the upgrade of the Alferon N Injection® manufacturing facility and to prepare for the FDA pre-approval inspections of the Ampligen® facility, (2) Manufacture of commercial product, (3) Potential new preclinical and/or clinical studies in order to gain commercial approval for Ampligen® and broader approvals for Alferon® and Alferon LDO®, (4) 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, (5) Pursuit of potential partnering opportunities for Ampligen®, (6) Potential establishment of sales and marketing capabilities, as well as consideration towards the expansion of our manufacturing capacity, and (7) working capital for general and administrative expenses.

#### Note 9: 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 10: Recent Accounting Pronouncements

In 2015, the FASB issued Accounting Standards Updates ("ASU") 2015-01 through 2015-16. These updates did not have a significant impact on the financial statements.

#### Note 11: Funds Received From Sale Of Income Tax Net Operating Losses

As of December 31, 2014, the Company had approximately \$151,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2034) available to off-set future federal taxable income. The Company also had approximately \$36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2034) and approximately \$28,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2033 through 2034) available to off-set future state taxable income.

In January 2015, the Company effectively sold \$14,291,000 of its approximately \$28,000,000 of New Jersey state net operating loss carryforwards (for the year 2013) for approximately \$1,374,000. 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 12: 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.

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.

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 had certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction which are measured at fair value. 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 recomputed 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 redeemable warrants expired in May and November 2014. The balance of the redeemable warrants was \$0 as of September 30, 2015 and December 31, 2014.

Fair value at September 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).

As of September 30, 2014, 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 September 30, 2015:

(in thousands)

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	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities-unrestricted	\$11,214	\$11,214	\$—	\$—

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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)	
	2015	2014
Balance at January 1	\$—	\$14
Fair value adjustment at March 31	—	—
Balance at March 31	\$—	\$14
Fair value adjustment at June 30	—	\$(1
Balance at June 30	\$—	\$13
Fair value adjustment at September 30	—	\$—
Balance at September 30	\$—	\$13

#### Note 13: Agreements

On March 9, 2015, the Company executed an agreement with Emerge Health Pty Ltd. ("Emerge") to seek approval of Ampligen® for CFS in Australia and New Zealand and to commence distribution of Ampligen® in both countries on a named-patient basis, where deemed appropriate. The parties intend to collaborate on seeking regulatory approval from Australia's Therapeutic Goods Administration ("TGA") and New Zealand's Medicines and Medical Devices Safety Authority ("Medsafe"). Under this five year exclusive license to sell, market, and distribute Ampligen in Australia and New Zealand to treat CFS, Emerge will implement regulatory-compliant programs to educate physicians about Ampligen® for CFS and seek orphan drug designation and approval of Ampligen® to treat CFS. Hemispherx will support these efforts and will supply Ampligen® at a predetermined transfer price. The Company has the right to buy out of the agreement at a price equal to three times Ampligen® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

On August 3, 2015, the Company executed a multi-year agreement with Impatiens, N.V., a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program ("EAP") in Europe and Turkey (the "Territory") related to Chronic Fatigue Syndrome. MyTomorrows, as Hemispherx' exclusive service provider and distributor in the Territory, will perform EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. Hemispherx will support these efforts and will supply Ampligen to myTomorrows at a predetermined transfer price. In the event that the Company receives Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. The parties will establish a Joint Steering Committee composed of representative of both parties to oversee the EAP.

On August 6, 2015, the Company executed an agreement with Emerge to seek approval of Alferon N Injection® in Australia and New Zealand and to commence distribution of Alferon® in both countries on a named-patient basis, for treating genital warts and other infections and diseases to which patients in Australia and New Zealand have become refractory to recombinant interferon. Hemispherx and Emerge will collaborate on seeking regulatory approval from Australia's TGA and New Zealand's Medsafe. Under a five year exclusive license to sell, market, and distribute Alferon N Injection® in Australia and New Zealand, Emerge will implement regulatory-compliant programs to educate physicians about Alferon®. Hemispherx will support these efforts and will supply Alferon® at a predetermined transfer price. We have the right to buy out of the agreement at a price equal to three times Alferon® sales for the

preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

On September 28, 2015, the Company and William A. Carter, M.D., agreed to extend the period for notice of non-renewal to December 1, 2015 as provided within the June 11, 2010 Amended and Restated Engagement Agreement entered into between the Company and Dr. Carter related to patent development. The agreement terminates on December 31, 2015; however, the Agreement automatically renews for a successive one year period after the termination date unless written notice of refusal to renew is given by either party at least 90 days prior to the termination date or the expiration of any renewal period.

#### 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 nine months ended September 30, 2015.

#### 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 and 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”, “intend”, “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: our ability to adequately fund our projects, 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 of 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 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 NDA for Ampligen® to treat 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.

We recently completed installation of the \$8 million in equipment at the core of our facility enhancement project which should provide for a higher capacity and more cost effective manufacturing process for the production of Alferon N Injection®. Commercial sales of Alferon and Alferon API internationally are projected to begin as early as next quarter. However, commercial



sales of Alferon® in the USA will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We are continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application (“BLA”) for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. We will also need the FDA’s approval to release commercial product once we have submitted satisfactory stability and quality release data. We had anticipated that it would take approximately until at least the 2nd half of 2015 before we would have Alferon® approved for commercial sales; however, during the final stage of the manufacturing process we encountered issues regarding a change in both the contract supplier of leukocytes and the long term supply availability related to a stockpiled (2 year) reagent used in the formulation of Alferon®. We have substantially resolved these issues. However, due to the interruption of the required flow of leukocytes, production ceased, causing parts to malfunction in the upstream process when the system was restarted for testing. We are working diligently to make the necessary repairs within the coming months to be able to restart the validation process; however, we have yet to obtain exact time estimates for the repairs which vendors have roughly estimated at 2-3 months. 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. 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. Please see “Risks Associated With Our Business” in Part II. Item 1A. Risk Factors below - 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®.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen® in the United States and abroad as well as to widen existing commercial therapeutic indications of Alferon N Injection® presently approved in the United States and Argentina. In addition, we have formed collaborations with multiple research laboratories around the world to examine Ampligen®, an experimental therapeutic, and Alferon N, an FDA-approved commercial product (for refractory venereal warts (HPV)) as potential preventatives for, and treatments of, Ebola Virus Disease (EVD). Our ability to commercialize our products, widen commercial therapeutic indications of Alferon N Injection® and/or capitalize on our collaborations with research laboratories to examine our products as potential preventatives for, and treatments of, EVD are subject to a number of significant risks and uncertainties including, but not limited to our ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

We outsource certain components of our manufacturing, quality control, marketing and distribution while maintaining control over the entire process through our quality assurance and regulatory groups. We cannot provide any guarantee that the facility or our contract manufacturer will necessarily pass an FDA pre-approval inspection for Alferon® manufacture.

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

Hemispherx Biopharma, Inc. and its subsidiaries (collectively, “Hemispherx”, “Company”, “we” or “us”) 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

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. which was established in Belgium in 1998. 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.

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We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ to produce Alferon® and Ampligen®, and recently completed our \$8 million facility enhancement project which should provide for a higher capacity, more cost effective manufacturing process for the production of Alferon N Injection®. Please see "Manufacturing" section below for more information on the recommencement of commercial sales of Alferon®. 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.

We have executed an agreement with Impatients ("myTomorrows") on a collaboration to provide access to our natural alpha interferon for patients that have become intolerant to treatment with recombinant interferon or where such treatment fails in South America and Europe. We currently have inventory available for sale comprising of approximately 1,200 vials of clinical grade natural interferon Alpha-n3. We are currently working to sell this inventory of clinical grade natural interferon Alpha-n3 through our Early Access Program ("EAP") in South America and Europe. We are reviewing the possibility of also selling the remaining work-in-process inventory through the EAP; however, this inventory has yet to go through the fill and finish process. Sales are anticipated to start in early 2016. See "Marketing/Distribution" sections below for more details on the marketing/distribution of Ampligen®. On September 16, 2015, the Board appointed Mr. Peter Rodino as Lead Director. In addition, Mr. Rodino and William Mitchell, M.D., Ph.D. were each appointed to the Compensation Committee and Corporate Governance and Nominating Committee. Mr. Rodino, Dr. Mitchell and Iraj E. Kiani were each appointed to the Audit Committee. Our principal executive office is located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is 215-988-0080.

#### 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 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(C12U).

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 authorized 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 of clinical sites provide safety information regarding the use of Ampligen® in patients with CFS. As of September 30, 2015, there were 23 patients participating in this open label treatment protocol taking treatment. 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

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of new data and information, will ultimately support our future filings for Ampligen® and/or the design of future clinical studies. In 1997, we calculated the cost per dose (400mg) of Ampligen® to be \$150 per dose consistent with the regulatory guidelines; however, we recently engaged an independent certified public accountant to recalculate the cost per dose consistent with the current guidelines, utilizing the costs to produce a vial in 2015. The independent analysis disclosed a cost per 400mg dose of Ampligen® of \$400, \$200 per vial. We plan to implement the new cost in conjunction with an updated patient consent form during the first half of 2016. Existing patients utilizing Ampligen® may be qualified for a "Patient Assistance Program" for the CFS open label study to help mitigate the increase in cost. 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 Part II. 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, 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 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".

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.

In January 2015, we reported that we have conducted new in vitro studies of natural killer (NK) cells obtained from CFS patients in conjunction with a comprehensive review of the medical literature to determine the relative incidence of NK cell functional deficiencies in CFS disease. This review indicates that low NK cell cytotoxicity (NKCC) has been consistently reported in CFS patients compared to normal controls. In the new laboratory studies, Ampligen® was found to increase in vitro NK activity utilizing cells from CFS patient donors. The authors of the new report are all affiliated with Hemispherx.

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See "Manufacturing" and "Marketing/Distribution" sections below for more details on the manufacture and marketing/distribution of Ampligen®.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon, which was 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 commonly recur, causing 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 neutralizing antibodies observed against Alferon N Injection® 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.

See "Manufacturing" and "Marketing/Distribution" sections below for more details on the manufacture and marketing/distribution of Alferon N Injection®.

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 preventative 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 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.

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### 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. Twenty-five subjects have been enrolled; 12 in Stage 1 and 13 subjects in Stage 2. The safety data on these 25 subjects will be reviewed by the Data Monitoring Committee in the near future. As of September 30, 2015, there are no active subjects receiving study drug.

In December 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. To date, 13 patients have been treated in this study. In addition, the University has initiated enrollment in an additional cancer study of peritoneal surface malignancies which includes Ampligen® as an adjuvant. To date, 26 patients have been treated.

In May 2014, we announced that one of our advanced stage biological products, Alferon® 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® 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® N MERS-CoV experiments. They treated monkey kidney cells with Alferon® 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® N showed significant dose-dependent inhibitory effects, thus suggesting the potential of Alferon® 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.

In June 2014, we announced that we have confirmed that Alferon® 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® N MERS-CoV experiments. Calu-3 cells were treated with Alferon® 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® N showed significant dose-dependent inhibitory effects, thus suggesting the potential of Alferon® 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.

In July 2015, we submitted an application for orphan drug designation to the European Medicines Agency (EMA) for Alferon® N to treat MERS. The EMA has accepted the application and the Committee for Orphan Medicinal Products (COMP) has initiated the official review process. It is anticipated that the COMP will give an opinion on the application within the next 90 days.

In June 2014, we concluded strategic discussions with Bioclones in Johannesburg with three principle goals; 1) initiating studies utilizing Ampligen® 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® and/or Ampligen® to eradicate latent HIV in patients highly responsive to anti-retroviral therapy; and 3) initiating a joint effort to obtain commercial registration of both Ampligen® and Alferon® 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. Our efforts were mainly directed towards the Ebola virus disease as well as the recent developments on our CFS initiatives which have required our personnel to devote more of our time and resources towards these initiatives. Previously, we informed Bioclones of our intention to put on hold any formal agreement until such time Bioclones would be able to obtain funding to initiate these HIV initiatives and that we would provide Ampligen® on an as needed basis for their clinical programs as long as adequate supply exists. We have determined that the Company will not move forward with these initiatives due to a lack of funding from Bioclones.

Ebola

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We announced, in September 2014, a series of collaborations designed to determine the potential effectiveness of Alferon® N and Ampligen® as potential preventative and/or therapeutic treatments for Ebola related disorders. Our two platform drugs Alferon® N and Ampligen®, have certain unique structural attributes and developmental histories which suggest potential incremental value with respect to inclusion in various Ebola therapeutic cocktails under development. These collaborations have resulted in the following reports being issued:

\* November 2014 - We received a report from the United States Army Medical Research Institute of Infectious Diseases ("USAMRIID") scientists that they have in-vitro data indicating that Alferon®, the only multi-species, natural alpha interferon commercially approved in the U.S., successfully protected human cells against the Ebola virus (EBOV).

\* November 2014 - We announced that we had received a new research report from Professor Tramontano in the Department of Life and Environmental Sciences, University of Cagliari, Italy. The biochemical study demonstrates Ampligen® can successfully bind to the lethal Ebola Virus protein designated VP35. VP35 protein normally inactivates a patient's immune/antiviral system by binding to viral dsRNA thereby sequestering a critical antiviral/immune activator of the body, which leads to high morbidity and death rates. Ampligen® competes with viral dsRNA for VP35 binding and this finding is consistent with recent studies at USAMRIID demonstrating that Ampligen® inhibits Ebola virus infectivity in vitro.

\* December 2014 - We announced that we received a new research report from researchers at Howard University, Washington DC. The report describes a study in which Ampligen® strongly inhibited the Ebola minigenome in the human embryonic kidney cell system.

\* February 2015 - We announced results of a new efficacy study of Ampligen® in a mouse model of EBOV infection performed by scientists at the USAMRIID. Ampligen® was utilized with a mouse adapted Ebola virus using multiple groups of mice with varying dosages of Ampligen® given every other day. The most effective dose, resulting in 100% percent survival at Day 21, corresponded to a human dose of approximately 400 mg, which has been used clinically approximately 50,000 times and has been generally well-tolerated when administered twice weekly. When higher doses of Ampligen® were used in the Ebola-infected mice, the survival rate dropped to 90%. The Ebola-infected mice treated with placebo had a 100% death rate by Day 7 post-infection. The EBOV data obtained from the in vitro and mouse infection studies using Ampligen® suggest a potential prophylactic and/or early onset therapeutic role in EVD. Previously published experimental results of animal studies using models of other lethal viral infections indicate possible similar applications to other lethal viral diseases. However, in vitro and animal testing is no assurance of human safety or efficacy for viral diseases. Clinical studies would be necessary to establish human efficacy and safety of Ampligen® for any treatment and/or prevention indication.

Positive results from a non-human primate ("NHP") study in all probability may be required before initiation of human clinical testing of Ampligen® in patients with Ebola Virus Disease ("EVD"). Clinical studies would also be necessary to establish human safety and efficacy of Ampligen® for either treatment and/or prevention of EVD. Clinical safety and tolerability data obtained for one indication, for example, CFS, may be different for another disorder like EVD. Currently, because of increased demand and the limited number of facilities that can conduct EBOV studies in NHP, the scheduling of a NHP study may be delayed; however, the Company is actively seeking such a study.

Our European subsidiary, Hemispherx Biopharma Europe N.V./S.A., has been formally notified of a positive opinion regarding its Orphan Medicinal Product Application for Ampligen®, an experimental therapeutic, to treat EVD. The EU final decision designates Ampligen as an Orphan Medical Product for treatment of EVD.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen® in the United States and abroad as well as to widen existing commercial therapeutic indications of Alferon® N Injection presently approved in the United States and Argentina. Laboratory experiments do not necessarily indicate clinical benefit. Some of the research both past and present has been, and may in the future be, sponsored in part by contracts or grants from us to various independent research entities.

#### Biosecurity / Biodefense

Our efforts in the biosecurity/biodefense have been redirected towards the Ebola virus disease. We have entered into material transfer and research agreements with multiple research laboratories around the world to examine whether

Ampligen® and/or Alferon® exhibit antiviral activity against the Ebola virus (See "Ebola" section above).

**Manufacturing**

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

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may contain additional fees as part of entering into the extension. In October 2014, we entered into a purchase commitment with Hollister-Stier for approximately \$700,000 for the manufacture of clinical batches of Ampligen®. We recently completed installation of the \$8 million in equipment at the core of our facility enhancement project which should provide for a higher capacity and more cost effective manufacturing process for the production of Alferon N Injection®. Commercial sales of Alferon and Alferon API internationally are projected to begin as early as next quarter. However, commercial sales of Alferon® in the USA will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We are continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application (“BLA”) for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. We will also need the FDA’s approval to release commercial product once we have submitted satisfactory stability and quality release data. We had anticipated that it would take approximately until at least the 2nd half of 2015 before we would have Alferon® approved for commercial sales; however, during the final stage of the manufacturing process we encountered issues regarding a change in both the contract supplier of leukocytes and the long term supply availability related to a stockpiled (2 year) reagent used in the formulation of Alferon®. We have substantially resolved these issues. However, due to the interruption of the required flow of leukocytes, production ceased, causing parts to malfunction in the upstream process when the system was restarted for testing. We are working diligently to make the necessary repairs within the coming months to be able to restart the validation process, however, we have yet to obtain exact time estimates for the repairs which vendors have roughly estimated at 2-3 months.

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 November 2014, we entered into a purchase commitment with Althea for approximately \$622,000 for the production of validation batches of Alferon® N Injection for emergency use and/or commercial sale. The Company has paid approximately \$210,000 to Althea with regard to this open purchase commitment as of September 30, 2015 and has recorded this amount within work-in-process inventory.

#### Marketing/Distribution

Our marketing strategy for Ampligen® reflects the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems. We expect that, subject to receipt of FDA, ANMAT and/or other regulatory approval, Ampligen® may be utilized in four medical arenas: physicians’ offices; clinics; hospitals; and the home treatment setting. In preparation for the FDA’s consideration of our Ampligen® NDA, we undertook early stage development of pre-launch and launch driven marketing plans focusing on audience development, medical support and payer reimbursement initiatives which could facilitate product acceptance and utilization at the time of regulatory approval, if obtained. Similarly, we continued to consider distribution scenarios for the Specialty Pharmacy/Infusion channel which could provide market access, offer 3PL (third party logistics) capabilities and provide the requisite risk management control mechanisms. It is our intent to utilize third party service providers to execute elements of both the marketing/sales and distribution plans. As a possible option, we considered a plan to utilize a small group of Managed Market account managers to introduce the product to payor, employer and government account audiences. We believe that this approach could establish a market presence and facilitate the generation of revenue without incurring the substantial costs associated with a traditional sales force. Furthermore, Management believes that any approach considered should enable us to retain multiple options for future marketing strategies.

In January 2010, we engaged an Argentinean regulatory and business design entity to explore the possibility of initiating clinical trials of Alferon N Injection®, Ampligen® and Alferon® LDO during the influenza season in Argentina. On June 14, 2010, we executed a five year exclusive Sales, Marketing, Distribution and Supply Agreement for Argentina with GP Pharm Latinoamerica (“GP Pharm”), an affiliate company of Spanish GP Pharm SA. Under this Agreement, GP Pharm will be responsible for gaining regulatory approval in Argentina for Ampligen® to treat CFS in Argentina and for commercializing Ampligen® for this indication in Argentina. We granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving

certain performance milestones. We also granted GP Pharm an option to market Alferon N Injection® in Argentina and other Latin America countries. Under these agreements, we will manufacture and supply Ampligen® and Alferon N Injection® to GP Pharm. On November 15, 2010, we amended our June 15, 2010 agreement with GP Pharm to include Mexico in the Territory under the Sales, Marketing, Distribution and Supply Agreement. Under this Agreement, GP Pharm Mexico will be responsible for seeking regulatory approval in Mexico for Ampligen®, an experimental therapeutic, to treat CFS in Mexico and, if approval is obtained, for commercializing Ampligen® for this indication in Mexico. We have granted GP Pharm the right to expand rights to sell this experimental therapeutic into other Latin America countries based upon GP Pharm achieving certain performance milestones. We are currently working towards an amendment to this agreement with GP Pharma the agreement expired June 15, 2015. In January 2012, the ANMAT approved the sale and distribution of Alferon N Injection® (under the brand name “Naturaferon”) in Argentina. 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

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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 patients that failed or were intolerant to the treatment with Interferon recombinant with Naturaferon in Argentina.

On September 6, 2011, we executed an amended agreement with Armada Healthcare, LLC (“Armada”) to undertake the marketing, education and sales of Alferon N Injection® throughout the United States. This agreement also provides start-up along with ongoing sales and marketing support to the Company. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. We previously extended this agreement for the previous three years also under the same terms and conditions.

On September 6, 2011, we executed a new agreement with specialty distributor, BioRidge Pharma, LLC (“BioRidge”) to warehouse, ship, and distribute Alferon N Injection® on an exclusive basis in support of U.S. sales. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. We previously extended this agreement for the previous three years also under the same terms and conditions.

On March 9, 2015, we executed an agreement with Emerge Health Pty Ltd. (“Emerge”) to seek approval of Ampligen® for CFS in Australia and New Zealand and to commence distribution of Ampligen® in both countries on a named-patient basis, where deemed appropriate. The parties intend to collaborate on seeking regulatory approval from Australia's Therapeutic Goods Administration (“TGA”) and New Zealand's Medicines and Medical Devices Safety Authority (“Medsafe”). Under this five year exclusive license to sell, market, and distribute Ampligen in Australia and New Zealand to treat CFS, Emerge will implement regulatory-compliant programs to educate physicians about Ampligen® for CFS and seek orphan drug designation and approval of Ampligen® to treat CFS. Hemispherx will support these efforts and will supply Ampligen® at a predetermined transfer price. We have the right to buy out of the agreement at a price equal to three times Ampligen® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

On August 3, 2015, we executed a multi-year agreement with Impatients, N.V. (“Impatients”), a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to Chronic Fatigue Syndrome. MyTomorrows, as Hemispherx' exclusive service provider and distributor in the Territory, will perform EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. Hemispherx will support these efforts and will supply Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. The parties will establish a Joint Steering Committee composed of representative of both parties to oversee the EAP. On October 16, 2015, we amended the agreement with Impatients to include Alferon N® as part of the EAP as well as the inclusion of Brazil, Columbia and Chile within the definition of Territory which may provide access to our natural alpha interferon for patients that have become intolerant to treatment with recombinant interferon or where such treatment fails. We currently have inventory available for sale comprising of approximately 1,200 vials of clinical grade natural interferon Alpha-n3. We are currently working to sell this inventory of clinical grade natural interferon Alpha-n3 through the EAP in South America and Europe. We are reviewing the possibility of also selling the remaining work-in-process inventory through the EAP; however, this inventory has yet to go through the fill and finish process. We continue to test the stability characteristics of our products; the results of which are used to determine appropriate storage conditions and expiration dates. These tests are conducted routinely to extend the life of the product so long as the test results are positive. Negative results would result in discarding the product. Sales are anticipated to start in early 2016.

On August 6, 2015, we executed an agreement with Emerge to seek approval of Alferon N Injection® in Australia and New Zealand and to commence distribution of Alferon® in both countries on a named-patient basis, for treating genital warts and other infections and diseases to which patients in Australia and New Zealand have become refractory to recombinant interferon. Hemispherx and Emerge will collaborate on seeking regulatory approval from Australia's TGA and New Zealand's Medsafe. Under a five year exclusive license to sell, market, and distribute Alferon N Injection® in Australia and New Zealand, Emerge will implement regulatory-compliant programs to educate physicians about Alferon®. Hemispherx will support these efforts and will supply Alferon® at a predetermined transfer price. We have the right to buy out of the agreement at a price equal to three times Alferon® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three.

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 nine months ended September 30, 2015, the Company contributions towards the 401(k) Plan were approximately \$127,000.

#### New Accounting Pronouncements

See “Note 10: 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 II; Item 7: “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, 2014.

### RESULTS OF OPERATIONS

Three months ended September 30, 2015 versus three months ended September 30, 2014

#### Net Loss

Our net loss was approximately \$3,803,000 and \$4,202,000 for the three months ended September 30, 2015 and 2014, respectively, representing a decrease in loss of approximately \$399,000 or 10% when compared to the same period in 2014. This decrease in loss for these three months was primarily due to the following:

- 1) a decrease in general and administrative expense of \$489,000 or 22%;
- 2) an increase in interest and other income/expense of approximately \$51,000 or 39%; offset by
- 3) an increase in research and development expense of \$74,000 or 4%; and
- 4) an increase in production costs of approximately \$47,000 or 15%.

Net loss per share was \$(0.02) and \$(0.02) for the three months ended September 30, 2015 and 2014, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2015 was 246,774,460 as compared to 190,677,576 as of September 30, 2014.

#### Revenues

Revenues from our Ampligen® Cost Recovery Program were \$23,000 and \$45,000 for the three months ended September 30, 2015 and 2014, respectively. For the three months ended September 30, 2015 and 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 Costs

Production costs were approximately \$353,000 and \$306,000, respectively, for the three months ended September 30, 2015 and 2014. This increase of approximately \$47,000 or 15% was primarily due to an increase in manufacturing

facility costs being allocated to production costs not attributable to inventory.

#### Research and Development Costs

Overall Research and Development (“R&D”) costs for the three months ended September 30, 2015 were approximately \$1,968,000 as compared to \$1,894,000 for the same period a year ago, reflecting an increase of approximately \$74,000 or 4%. The primary reason for the increase in research and development costs was due to an increase in charges of \$148,000 associated with the abandonment of patents as well as an increase in costs of \$85,000 associated with stability testing and pre-production

related to the initiation of manufacturing of Alferon N Injection®. This was offset by a decrease in executive bonus and incentive compensation of \$86,000 and a decrease in polymer production costs of \$78,000 associated with Ampligen®.

#### General and Administrative Expenses

General and Administrative (“G&A”) expenses for the three months ended September 30, 2015 and 2014, were approximately \$1,685,000 and \$2,174,000, respectively, reflecting a decrease of approximately \$489,000 or 22%. The decrease in G&A expenses in 2015 was mainly due to lower legal fees of \$477,000 associated with various legal proceedings as compared to the prior period (see "Part II - Other Information; Item 1: Legal Proceedings" for details).

#### Interest and Other Income/Expense

Interest and other income/expense for the three months ended September 30, 2015 and 2014 were approximately \$181,000 and \$130,000, respectively, representing an increase of approximately \$51,000 or 39%. The primary cause for the increase in investment income during the current quarter was primarily due to realized gains resulting from the sales of marketable securities during the current period offset by a decline within the investment performance in the current period.

Nine months ended September 30, 2015 versus nine months ended September 30, 2014

#### Net Loss

Our net loss was approximately \$12,093,000 and \$12,994,000 for the nine months ended September 30, 2015 and 2014, respectively, representing a decrease in loss of approximately \$901,000 or 7% when compared to the same period in 2014. This decrease in loss for these nine months was primarily due to the following:

- 1) a decrease in general and administrative expense of \$1,610,000 or 22%;
- 2) an increase in the gain from sale of income tax net operating losses of \$248,000 or 22%; offset by
- 3) an increase in research and development expense of \$531,000 or 8%;
- 4) an increase in production costs of approximately \$309,000 or 33%; and
- 5) a decrease in interest and other income/expense of approximately \$65,000 or 16%.

Net loss per share was \$(0.05) and \$(0.07) for the nine months ended September 30, 2015 and 2014, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2015 was 232,307,548 as compared to 184,434,475 as of September 30, 2014.

#### Revenues

Revenues from our Ampligen® Cost Recovery Program were \$106,000 and \$157,000 for the nine months ended September 30, 2015 and 2014, respectively. Although there was a slight increase in patients utilizing Ampligen®, there was a decrease in revenue of \$51,000 or 32% primarily due to a lower dosage being prescribed to patients utilizing Ampligen® during the current period. For the nine months ended September 30, 2015 and 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 Costs

Production costs were approximately \$1,232,000 and \$923,000, respectively, for the nine months ended September 30, 2015 and 2014. This increase of approximately \$309,000 or 33% was primarily due to charges to inventory of \$117,000 resulting from vials removed from inventory for testing purposes and losses incurred during the manufacturing process. The remaining increase in production costs of \$154,000 was mainly due to an increase in stability testing and pre-production costs related to the initiation of manufacturing of Alferon N Injection®.

#### Research and Development Costs

Overall Research and Development (“R&D”) costs for the nine months ended September 30, 2015 were approximately \$7,081,000 as compared to \$6,550,000 for the same period a year ago, reflecting an increase of approximately \$531,000 or 8%. The primary reason for the increase in research and development costs was due to an increase in stability testing and pre-production

costs related to the initiation of manufacturing of Alferon N Injection® of \$648,000, an increase in polymer production costs of \$197,000 associated with Ampligen®, and an increase in other research and development costs on various projects of \$182,000. This was mainly offset by a decrease in clinical trial costs of \$122,000 associated with the conclusion of our University of Washington study in 2014 utilizing Ampligen® as an adjuvant in optimally treated breast cancer patients as data from these patients was evaluated and resources were directed to other projects, a decrease in bonus payments to an executive officer of \$247,000, and a decrease in charges of \$251,000 associated with the abandonment of patents.

#### General and Administrative Expenses

General and Administrative (“G&A”) expenses for the nine months ended September 30, 2015 and 2014, were approximately \$5,600,000 and \$7,210,000, respectively, reflecting a increase of approximately \$1,610,000 or 22%. The decrease in G&A expenses in 2015 was mainly due to lower legal fees associated with various legal proceedings as compared to the prior period (see "Part II - Other Information; Item 1: Legal Proceedings" for details).

#### Interest and Other Income/Expense

Interest and other income/expense for the nine months ended September 30, 2015 and 2014 were approximately \$340,000 and \$405,000, respectively, representing a decrease of approximately \$65,000 or 16%. The primary cause for the decrease in investment income during the current quarter was primarily due to lower fund performance and cash available for investment purposes offset by realized gains resulting from the sales of marketable securities as compared to the prior period.

#### Sale of New Jersey Tax Net Operating Loss

In January 2015, the Company effectively sold \$14,291,000 of its approximately \$28,000,000 of New Jersey state net operating loss carryforwards (for the year 2013) for approximately \$1,374,000. 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, representing an increase in cash gain of \$248,000 or 22% (see “Note 11: Funds Received From Sale of Income Tax Net Operating Losses”) for the nine months ended September 30, 2015 as compared to the same period in 2014.

#### Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2015 was approximately \$12,739,000 compared to approximately \$9,931,000 for the same period in 2014, an increase of \$2,808,000 or 28%. Excluding the proceeds from the sale of New Jersey Net Operating Loss carry-forwards, cash used in operating activities for the nine months ended September 30, 2015 increased by approximately \$3,056,000 or 28% over the comparable period in 2014. The primary reason for this increase in 2015 was due to the payout of 2014 executive incentive bonuses for approximately \$1,831,000 reflected in accrued expenses as well as an increase in inventory of \$1,326,000 during the nine months ended September 30, 2015.

As of September 30, 2015, we had approximately \$12,375,000 in cash, cash equivalents and marketable securities inclusive of approximately \$11,214,000 in Marketable Securities, representing a decrease of approximately \$3,733,000 or 23% from December 31, 2014. The primary reason for the decrease in cash, cash equivalents and marketable securities during the nine months ended September 30, 2015 was the result of cash being utilized in operating activities of \$12,739,000 being partially offset by cash provided by financing activities of \$9,661,000 primarily from the sale of 40,993,690 shares sold pursuant to the ATM during the nine months ended September 30, 2015 (see below and "Note 8: Stockholders' Equity”) and proceeds from the sale of marketable securities of \$2,497,000 during the current quarter. In an effort to conserve cash, we conducted an analysis of our research and development

programs as well as our staffing levels within our New Jersey manufacturing facility. Our analysis disclosed an ability to gain efficiencies and eliminate redundancies within our staffing which will result in a decrease in cash flow used in operations. 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 EDA with Maxim (the "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 EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the 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 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 EDA or terminate the EDA. Up until August 4, 2015, the shares were 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. Since August 4, 2015, 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 August 4, 2015 (the "2015 Universal Shelf"). 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 EDA for an aggregate of 90,000,000 shares to be allocated for public sale under the Prospectus Supplement pursuant to the EDA. On March 6, 2015, we filed an updated Prospectus Supplement increasing the number of shares covered by the Prospectus to 117,600,000 shares.

On August 4, 2015, the Company and Maxim Group LLC amended their July 23, 2012 EDA solely for the purpose of adding the registrant's new registration statement on Form 3 (File No 333-205228) to the definition of "registration statement" as the old registration statement expired.

On August 5, 2015, the Company filed an updated Prospectus Supplement to reflect that sales under the EDA are now being conducted pursuant to the 2015 Universal Shelf. In addition, on September 16, 2015, the Company's stockholders approved up to an additional 60,000,000 of the remaining Restricted Shares for use in capital raising transactions

For the nine months ended September 30, 2015, we sold an aggregate of 40,993,690 shares that resulted in net cash proceeds of approximately \$9,680,000 after commissions paid to Maxim for approximately \$299,000 (see "Note 8: Stockholders' Equity"). The impact of the fund raising effort through the EDA is reflected in the "Consolidated Statements of Cash Flows" comparing the various financing activities for the nine months ended September 30, 2015 and 2014, respectively.

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,

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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 \$12,375,000 in cash, cash equivalents and marketable securities at September 30, 2015 as compared to \$16,108,000 at December 31, 2014.

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 September 30, 2015, 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 nine months ended September 30, 2015, 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, 2014, Note 14 - 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.  
Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William
- (b) 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.  
Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels,
- (c) 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.  
Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., William A. Carter, Charles T.
- (d) 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)

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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.

Charles T. Bernhardt III v. Hemispherx Biopharma, Inc., Dr. William A. Carter, Thomas K. Equels, Esquire, Dr. (f) 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.

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- (g) Hemispherx Biopharma, Inc. v. Johannesburg Consolidated Investments, et al., U.S. District Court for the Southern District of Florida, Case No. 4-10129-CIV.
- (h) Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 9-549-GMS.

(a) 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 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 on 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 completion of all fact discovery. On February 25, 2014, defendants filed an answer and affirmative defenses to the Amended Complaint. Also on February 25, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. After conducting significant fact discovery, the parties reached an agreement in principle to settle all claims on December 31, 2014. However, the settlement is subject to the Court's issuance of an order finally approving the terms of the parties' settlement agreement in all material respects. On March 11, 2015, the parties filed a joint motion with the Court seeking an order, inter alia, granting preliminary approval of their settlement agreement, preliminarily certifying a class for settlement purposes, and setting a date for a final settlement hearing. On April 8, 2015, the Court granted the parties' joint motion, and entered an Order preliminarily approving the parties' settlement, preliminarily certifying a class for settlement purposes, directing issuance of notice, and scheduling the final approval hearing for July 22, 2015. On July 22, 2015, the Court held the final approval hearing to determine whether the parties' settlement is fair, reasonable, adequate and should be approved, and on the same date entered an Order granting final approval of the parties' settlement. No Company funds were used to pay the settlement, which was paid from the Company's insurance coverage. The settlement did not contain any admission of fault or wrongdoing by Hemispherx or any of the individual defendants.

(b) 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 January 28, 2015, on request of the parties, the Court entered an Order continuing the temporary stay, subject to the requirement that the parties submit an updated joint status report within ten days of the court's entry of an order granting or denying the securities class action parties' motion for preliminary approval of their settlement agreement. The parties are currently in settlement negotiations and have provided the Court with regular reports on the status of their negotiations.

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(c) 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. The parties are currently in settlement negotiation.

(d) 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. The parties are currently in settlement negotiations.

(e) 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 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 would be in the best interests of Hemispherx and its stockholders. On January 20, 2014, the SLC moved to dismiss the Complaint. Following briefing and oral argument on the motion to dismiss, the Court denied the SLC's motion on August 18, 2015, but did dismiss the claims against former officer Robert E. Peterson. On October 13, 2015, Plaintiffs filed a Verified Amended Derivative and Class Action Complaint, asserting additional claims for breach of fiduciary duty against Board member Peter W. Rodino, declaratory judgment with respect to certain bonuses paid to officers of the Company, and a class action claim for breach of fiduciary duty against the current Board in connection with the solicitation of votes in advance of the Company's 2015 annual meeting. The Amended Complaint also removed all of the dismissed claims against Mr. Peterson.

The Company believes that the claims asserted in the shareholder derivative litigation are without merit, and is vigorously defending these actions. While the Company also believes that the claims asserted in the securities litigation are without merit, the Company has reached a settlement agreement in principle that is satisfactory to the Company. If the Court does not issue an order finally approving the terms of the parties' settlement agreement in all material respects, however, the Company intends to resume its vigorous defense of the securities litigation. 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.

(f) 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 of the Company. The claims against the Company as set forth in the Second Amended Complaint include 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 of \$275,824.09 on all counts, Bernhardt’s claim also includes a demand for attorneys’ fees and liquidated damages under the WPCL. The Company and individual defendants have filed an Answer, New Matter and

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Counterclaims. On February 11, 2015 the Company and individual defendants filed First Amended Answer, New Matter and Counterclaims which assert claims for Injurious Falsehood/Corporate Disparagement, Defamation, Replevin, Conversion, Common Law Trademark Infringement, Demand for Permanent Injunction Based on Conversion, and Demand for Permanent Injunction based on Common Law Trademark Infringement. On March 17, 2015, Bernhardt responded to the Company's claim. The Parties have agreed to a full amicable resolution of all claims. (g) 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 and is being assisted by the South African law firm of Webber Wentzel. The action to domesticate had been filed in South Africa. No gain has been recorded for this judgment as it is too early in these proceedings to predict an outcome. As required by South African law, on October 11, 2011, Hemispherx has 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 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. These bonds were forfeited and a fee award of approximately \$200,000 was issued. The final judgment still remains valid in the United States and vastly exceeds the amount of the South African fee award, thus in the United States it was fully set off. The Company has no intention to pursue this action further.

(h) Cato Capital, LLC ("Cato") brought suit against the Company on July 31, 2009, in the United States District Court for the District of Delaware (the "Court"), alleging that under a November 2008 agreement between Cato and Hemispherx, Hemispherx owes Cato a placement fee arising from subsequent Hemispherx financing and investment transactions. Hemispherx disputed these allegations, asserting that Cato failed to comply with the provisions of its own contract. The Amended Complaint sought damages in the amount of \$9,830,000.00 plus attorneys' fees and punitive damages. Pursuant to an indemnification responsibility, Hemispherx has also retained this firm to undertake the defense of the Sage Group.

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 September 29, 2014, the Court found in favor of Hemispherx and Sage on all counts, and dismissed Cato's claims in their entirety. On January 13, 2015, the Court granted the Company's motion for attorney's fees and costs and awarded the Company \$770,852.76.

On October 24, 2014, Cato filed a notice of appeal of the Court's September 29, 2014 decision in the United States Court of Appeals for the Third Circuit (the "Third Circuit"). On March 3, 2015, Cato filed its Brief in the Third Circuit. The Company's Brief in Response was filed on April 6, 2015, with a Reply Brief by Cato filed on April 19, 2015. The Court of Appeals conducted Oral Argument on July 16, 2015. On August 21, 2015 the Court of Appeals affirmed the judgment of the District Court. On September 9, 2015 Cato sought reconsideration of the decision through re-argument or re-hearing by the en banc Court of Appeals. On September 17, 2015 the Court of Appeals denied Cato's requests. On October 1, 2015 Hemispherx filed for additional costs and fees to be added to its existing judgment. The Court has not yet ruled on that request. The mandate has been returned to the District Court for additional proceedings arising from Hemispherx' judgment.

(i) Summation.

In reference to Contingencies identified above, 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 in Contingency (b), (c), (d), (e), (f) and (h). 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 nine months ended September 30, 2015 and the year ended December 31, 2014. Also, with regards to Contingency (a), (b), (c), (d) and (e), the Company maintains a Directors and Officers Insurance Policy that provides coverage for claims and retention of legal counsel.

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:

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## 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: “Management’s Discussion and Analysis of Financial Condition and Results of Operations 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: “Management’s Discussion and Analysis of Financial Condition and Results of Operations 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 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 Part 1, Item II: “Management’s Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Ampligen®” 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 promote 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, this data has 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 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® Active Pharmaceutical Product (“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 were not submitted to the FDA to request release for commercial sale and their remaining dollar value was 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: “Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing” 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 September 30, 2015, our accumulated deficit was approximately \$289,862,000. 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 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 September 30, 2015, we had approximately \$12,375,000 in cash, cash equivalents and marketable securities (inclusive of approximately \$11,214,000 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 “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 2 - “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 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.

If we are unable to obtain additional funding, through the EDA or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

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. 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 2 - "Management's Discussion and Analysis of Financial Condition and Results of Operations; Manufacturing".

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) and another on October 14, 2014 (#5,676,942) (see discussion below on patent #5,503,828 and #5,676,942).

In 2014, we filed for three new patents that are currently pending. One patent pending is for use of Ampligen as a vaccine adjuvant for use with seasonal influenza vaccine to induce an enhanced immune response. The second is for

use of Ampligen as a method of diagnosing and stabilizing CFS symptoms in patients. The third is for use of Alferon N Injection® as a possible treatment for Oseltamivir Resistant Avian Origin Influenza A (H7N9 virus). 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.

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 of 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 which expired on October 14, 2014 and Alferon® patent #5,989,441 which was set to expire on December 22, 2017 but we let lapse, relate to a manufacturing methodology which is no longer in use. For this reason, we believe the expiration of these Alferon® patents should have no impact on the Company.

With respect to Ampligen®, the main U.S. CFS treatment patent (#6,130,206) expires October 10, 2017. Our main patents covering HIV treatment (#4,820,696, #5,063,209, and #5,091,374) expired on April 11, 2006, November 5, 2008, and February 25, 2009, respectively. Our U.S. Ampligen® Trademark (#73/617,687) has been renewed through December 6, 2018. New therapeutic use patent applications are pending including new patent applications for composition of alternative matter. 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. 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.

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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 a world-wide marketing partner 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. In addition, during the final stage of the manufacturing process for Alferon®, we encountered issues regarding a change in both the contract supplier of leukocytes and the long term supply availability related to a stockpiled (2 year) reagent used in the formulation of Alferon®. We have substantially

resolved these issues. However, due to the interruption of the required flow of leukocytes, production ceased, causing parts to malfunction in the upstream process when the system was restarted for testing. We are working diligently to make the necessary repairs within the coming months to be able to restart the validation process; however, we have yet to obtain exact time estimates for the repairs which vendors have roughly estimated at 2-3 months.

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. For more

information on Ampligen® manufacturing, please see Part 1, Item II: “Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing” above.

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®. 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 on 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. In October 2014, we entered into a purchase commitment with a contract manufacturer (Hollister Stier) for approximately \$700,000 for the manufacture of clinical batches of Ampligen®.

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® manufacturing, please see Part 1, Item II: “Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing” above.

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 recently completed our \$8 million facility enhancement project which should provide for a higher capacity, more cost effective manufacturing process for the production of Alferon N Injection®. The production of new Alferon® API inventory commenced in February 2015. 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, we will need FDA approval to release the final product confirming the quality and stability to allow commercial sales to resume. For more information, please see Part 1, Item II: “Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing” above for more information. 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 Alferon® API at our enhanced manufacturing facility and Althea gains FDA's approval to formulate, fill and finish Alferon, can batches of Alferon® be released by the FDA for commercial sales. We are unable to provide any assurances that the FDA will approve our enhanced manufacturing process and/or newly created finish product lots formulated, filled and finished at Althea. 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.

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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. 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, we will need FDA approval to release the final product confirming the quality and stability to allow commercial sales to resume. For more information, please see Part 1, Item II: "Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing" above. 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.

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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 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 and clinical trial insurance.

We maintain a limited amount of Products Liability and Clinical Trial insurance coverage world-wide for Ampligen® and Alferon® due to the minimal amount of historical loss claims regarding these products in the marketplace. Any claims against our products, Ampligen®, Alferon N Injection® and Alferon® LDO, 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.

With our recent development on the collaborative agreement with myTomorrows to provide access to our natural alpha interferon for patients that have become intolerant to treatment with recombinant interferon or where such treatment fails in South America and Europe, we have initiated the process of enhancing our insurance coverage for any potential sales that may arise from this arrangement.

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. 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. Mr. Equels is also

a key employee with reference to operational and financial management.

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

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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.

Four Shareholder Derivative Actions Have Been Filed Against Us and We May Be Subject to Civil Liabilities.

As described in Part II; Item 1. Legal Proceedings, four shareholder derivative actions have been filed 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 nine month period ended September 30, 2015, the trading price of our common stock has ranged from \$0.33 to \$0.16 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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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.

We 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 EDA with Maxim. Through September 30, 2015, we had sold an aggregate of approximately 40,993,690 shares under the EDA. Pursuant to the 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 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 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, 2012. 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 September 30, 2015, for Dr. Carter, our Chief Executive Officer and President, who already beneficially owns approximately 3.96% 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 nine months ended September 30, 2015.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

On September 28, 2015, the Company and William A. Carter, M.D., agreed to extend the period for notice of non-renewal to December 1, 2015 as provided within the June 11, 2010 Amended and Restated Engagement Agreement entered into between the Company and Dr. Carter related to patent development. The agreement terminates on December 31, 2015; however, the Agreement automatically renews for a successive one year period after the termination date unless written notice of refusal to renew is given by either party at least 90 days prior to the termination date or the expiration of any renewal period.

On November 11, 2015, the Company's Board of Directors amended and restated the Company's by-laws to delete section 5.7, related to fee shifting due to changes in the Delaware General Corporation Law.

ITEM 6: Exhibits

(a) Exhibits

- 3.1 Amended and Restated By-Laws.
- 10.1 Early Access Agreement with Impatiens N.V. dated August 3, 2015(1)(2).
- 10.2 Addendum to Early Access Agreement with Impatiens N.V. dated October 16, 2015(1).
- 10.3 Letter agreement between Dr. Carter and the Company dated September 28, 2015 extending the period for notice of non-renewal to December 1, 2015 within the June 11, 2010 Amended and Restated Engagement Agreement entered into between the Company and Dr. Carter.
- 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 September 30, 2015 formatted in eXtensible Business Reporting Language ("XBRL"): (i) Condensed Balance Sheets ; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Changes in Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements.
- (1) Confidential portions of this exhibit have been redacted and filed separately with the Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
- (2) Previously filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2015. It is refiled herewith solely to correct section numbering errors.

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

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

Date: November 16, 2015