HEMISPHERX BIOPHARMA INC
Form 10-Q
November 14, 2016

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, 2016

Commission File Number: 1-13441

HEMISPHERX BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

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

1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103

(Address of principal executive offices) (Zip Code)

(215) 988-0080

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

x Yes ¨ No

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

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

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

24,105,569 shares of common stock were outstanding as of November 1, 2016.

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, 2016 (Unaudited)	December 31, 2015 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,473	$ 2,115
Marketable securities	3,536	6,795
Inventory-work in process	-	1,326
Assets held for sale	764	-
Prepaid expenses and other current assets	559	335
Total current assets	9,332	10,571
Property and equipment, net	9,779	11,237
Patent and trademark rights, net	919	862
Other assets	1,546	134
Total assets	$ 21,576	$ 22,804
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,011	$ 1,213
Accrued expenses	1,420	1,219
Current portion of capital lease	-	1
Total current liabilities	2,431	2,433
Redeemable warrants	2,514	-
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 24,105,569 and 20,629,957, respectively	24	21
Additional paid-in capital	315,864	313,446
Accumulated other comprehensive income (loss)	71	(97)
Accumulated deficit	(299,328)	(292,999)
Total stockholders' equity	16,631	20,371
Total liabilities and stockholders' equity	$ 21,576	$ 22,804

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Comprehensive Loss

(in thousands, except share and per share data)

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
Clinical treatment programs	$22	$23	$76	$106
Total revenues	22	23	76	106
Costs and expenses:				
Production costs	272	353	830	1,232
Research and development	1,342	1,968	3,244	7,081
General and administrative	1,634	1,685	5,721	5,600
Total costs and expenses	3,248	4,006	9,795	13,913
Operating loss	(3,226)	(3,983)	(9,719)	(13,807)
Interest expense	-	(1)	-	(3)
Interest and other income/(expense)	40	181	156	343
Insurance proceeds from legal settlement, net	190	-	1,626	-
Gain (Loss) on sales of short term marketable securities	31	-	(56)	-
Gain from sale of income tax net operating losses	-	-	1,561	1,374
Redeemable warrants valuation adjustment	103	-	103	-
Net loss	(2,862)	(3,803)	(6,329)	(12,093)
Other comprehensive income (loss):				
Reclassification adjustments for (gain) loss on sales of short term marketable securities included in net loss	(31)	-	56	-
Unrealized gain (loss) on marketable securities	15	(215)	112	(241)
Net comprehensive loss	$(2,878)	$(4,018)	$(6,161)	$(12,334)
Basic and diluted loss per share	$(0.13)	$(0.18)	$(0.30)	$(0.62)
Weighted average shares outstanding, basic and diluted	21,832,940	20,564,538	21,046,418	19,358,962

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, 2016

(in thousands except share data)

(Unaudited)

	Common Stock Shares	Common Stock $0.001 Par Value	Additional Paid-In Capital	Accumulated Other Compre-hensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2015	20,629,957	$ 21	$ 313,446	$ (97)	$ (292,999)	$ 20,371
Equity-based compensation	17,498	-	344	-	-	344
Shares sold at the market	114,394	-	174	-	-	174
Common stock issuance	3,333,334	3	4,517	-	-	4,520
Other issuances	10,386	-	-	-	-	-
Redeemable warrants	-	-	(2,617)	-	-	(2,617)
Net comprehensive loss	-	-	-	168	(6,329)	(6,161)
Balance at September 30, 2016	24,105,569	$ 24	$ 315,864	$ 71	$ (299,328)	$ 16,631

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30, 2016 and 2015

(in thousands)

(Unaudited)

	2016	2015
Cash flows from operating activities:		
Net loss	$ (6,329)	$ (12,093)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	854	663
Amortization and abandonment of patent and trademark rights	125	166
Equity-based compensation	344	148
Realized loss on sale of marketable securities	56	-
Redeemable warrants valuation adjustment	(103)	-
Change in assets and liabilities:		
Inventories	-	(1,326)
Prepaid expenses and other current assets	(224)	121
Accounts payable	(202)	97
Accrued expenses	201	(515)
Net cash used in operating activities	(5,278)	(12,739)
Cash flows from investing activities:		

Purchase of property, equipment and construction in progress		(160)		(226)
Additions to patent, trademark and licensing rights		(282)		(188)
Deposits on capital leases refunded		14		-
Sales and maturities of short-term and long-term marketable securities		3,371		2,497
Net cash provided by investing activities		2,943		2,083
Cash flows from financing activities:				
Payments on capital leases		(1)		(19)
Proceeds from sale of stock, net of issuance costs		4,694		9,680
Net cash provided by financing activities		4,693		9,661
Net increase (decrease) in cash and cash equivalents		2,358		(995)
Cash and cash equivalents at beginning of period		2,115		2,156
Cash and cash equivalents at end of period	$	4,473	$	1,161
Supplemental disclosures of non-cash investing and financing cash flow information:				
Issuance of common stock for accounts payable	$	-	$	672
Unrealized gain (loss) on marketable securities	$	112	$	(241)
Fair Value of redeemable warrants	$	2,617	$	-

Supplemental disclosure of cash flow information:				
Cash paid for interest expense	$	-	$	(3)
Insurance proceeds from legal settlement	$	1,626	$ __- _	

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 ("Company"). 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, 2015 and 2014, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

On August 17, 2016, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split at a ratio in the range of 1-for-8 to 1-for-12. The Company's Board of Directors approved the implementation of the reverse stock split at a ratio 1-for-12. All per share numbers for prior periods have been revised to give retroactive effect to this reverse stock split.

Note 2: Net Loss Per Share

Basic and diluted net loss per share is computed using the weighted average number of shares of common stock outstanding during the period. Equivalent common shares, consisting of stock options and warrants which amounted to 4,129,215 and 1,423,190 shares for the nine months ended September 30, 2016 and 2015, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive.

Note 3: Equity-Based Compensation

The fair value of each option and equity warrant award is estimated on the date of grant using a Black-Scholes-Merton option pricing valuation model. Expected volatility is based on the historical volatility of the price of the Company's stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option and equity warrant. The Company uses historical data to estimate expected dividend yield, expected life and forfeiture rates. There were 247,917 and 66,666 options granted to employees and non-employees in the nine months ended September 30, 2016 and 2015, respectively.

Stock option for employees' activity during the nine months ended September 30, 2016 is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2016	893,771	$ 18.96	4.02	$ —
Granted	185,417	1.58	—	—
Forfeited	(227,259)	5.75	—	—
Outstanding September 30, 2016	851,929	$ 18.70	4.05	$ —
Vested and expected to vest September 30, 2016	851,929	$ 18.70	4.05	$ —
Exercisable September 30, 2016	714,950	$ 18.60	2.87	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2016	27,777	$ 3.48	7.82	$ —
Granted	185,417	1.58	—	—
Vested	(76,215)	2.10		—
Forfeited	—	—	—	—
Outstanding September 30, 2016	136,979	$ 1.67	9.35	$ —

Stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value

			(Years)		
Outstanding January 1, 2016	275,250	$ 15.48	4.31	$	—
Granted	62,500	1.63	—		—
Exercised	—	—	—		—
Forfeited	(31,667)	44.79	—		—
Outstanding September 30, 2016	306,083	$ 9.59	5.21	$	—
Vested and expected to vest September 30, 2016	306,083	$ 9.59	5.21	$	—
Exercisable September 30, 2016	257,819	$ 11.11	4.34	$	—

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

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2016	—	$ —	—	$ —
Granted	62,500	1.63	—	—
Vested	(14,236)	1.63	—	—
Forfeited	—	—	—	—
Outstanding September 30, 2016	48,264	$ 1.63	9.82	$ —

The impact on the Company’s results of operations of recording equity-based compensation for the nine months ended September 30, 2016 and 2015 was to increase costs and expenses by approximately $125,000 and $148,000, respectively, which increased loss per share by $0.01.

As of September 30, 2016 and 2015, respectively, there was $332,000 and $231,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan.

On January 26, 2016, the Board, based on the recommendation of its Compensation Committee, established two programs - the 2016 Senior Executive Deferred Cash Performance Award Plan for Dr. William A. Carter and Thomas K. Equels, the Company’s two primary executive officers, and the 2016 Voluntary Incentive Stock Award Plan for Company employees and Board members other than Dr. Carter and Mr. Equels. Both Plans include a Base Pay Supplement provision.

The Company maintains a record of the number of shares of stock represented by each Incentive Right issued out of the 2016 Voluntary Incentive Stock Award Plan. During the nine months ended September 30, 2016, the Company granted rights to 140,936 split adjusted incentive shares and recorded $219,000 in equity-based compensation under this Plan.

Note 4: Inventories

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

Inventories consist of the following:	(in thousands)	
	September 30, 2016	December 31, 2015
Inventory work-in-process, January 1	$1,326	$ —
Production	—	1,443
Transfer to other assets	(1,326)	—
Spoilage	—	(117)
Inventory work-in-process, end of period	$—	$ 1,326

Commercial sales of Alferon® will not resume until new batches of commercial filled and finished product are produced and released by the FDA. The Company is 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. Due to the Company extending the timeline of Alferon® production to an excess of one year, the Company reclassified Alferon® work-process-inventory to other assets within the Company's balance sheet as of September 30, 2016.

Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the nine months ended September 30, 2016 and 2015, it was determined that none of the marketable securities had other-than-temporary impairments. At September 30, 2016 and December 31, 2015, all securities were classified as available for sale investments and were measured as Level 1 instruments of the fair value measurements standard.

Securities classified as available for sale consisted of:

September 30, 2016
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 3,465	$ 71	$ —	$ 3,536	$ 3,536	$ —
Totals	$ 3,465	$ 71	$ —	$ 3,536	$ 3,536	$ —

December 31, 2015
(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 6,892	$ —	$ (97)	$ 6,795	$ 6,795	$ —
Totals	$ 6,892	$ —	$ (97)	$ 6,795	$ 6,795	$ —

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:

September 30, 2016

As of September 30, 2016 there were no investments in a loss position.

December 31, 2015
(in thousands)

		Less Than 12 Months		12 Months or Greater		Totals	
Securities	Total number in loss position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	2	$ 2,834	$ (159)	$ 2,041	$ (21)	$4,875	$ (180)
Totals	2	$ 2,834	$ (159)	$ 2,041	$ (21)	$4,875	$ (180)

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	September 30, 2016	December 31, 2015
Compensation, including severance	$524	$ 229
Professional fees	513	619
Clinical trial expenses	109	143
Other expenses	274	228
	$1,420	$ 1,219

Note 7: Property and Equipment

	(in thousands)	
	September 30, 2016	December 31, 2015
Land, buildings and improvements	$10,530	$ 11,603
Furniture, fixtures, and equipment	5,630	5,490
Leasehold improvements	—	85
Total property and equipment	16,160	17,178
Less: accumulated depreciation and amortization	(6,381)	(5,941)
Property and equipment, net	$9,779	$ 11,237

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 three to thirty-nine years.

Assets held for sale consists of the net book value of an underutilized building located adjacent to the site of the Company’s New Jersey manufacturing facility. As part of the Company’s objectives to achieve its commercial goals and increase stockholder value, the Company has initiated the sale of underutilized assets. As a result, the Company is in the process of selling this building at its current market value and has reclassified it as held for sale at its net book value of $764,000.

Note 8: Stockholders' Equity

The Equity Incentive Plan of 2009, effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 1,250,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. 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 1,250,000 to 1,833,333; (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 Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2016 and 2015, there were 247,917 and 66,666 options granted by the Company, respectively.

On December 15, 2015, the Company entered into an Equity Distribution Agreement with Chardan Capital Markets, LLC (the "Chardan Agreement") to create an at-the-market equity program under which it may sell shares of its common stock (the "Shares") from time to time through Chardan Capital Markets, LLC, as sales agent ("Chardan"). Under the Chardan Agreement, Chardan will be entitled to a commission at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the Chardan Agreement. Effective August 26, 2016, the Company halted all future offers and sales of its common stock under the Chardan Agreement and reduced the amount of potential future offers and sales under the Chardan Agreement to $0.00. Between December 15, 2015, the date of the Chardan Agreement, and August 26, 2016, we sold an aggregate of 114,394 shares of common stock pursuant to the Chardan Agreement for aggregate net proceeds of approximately $174,000.

On September 6, 2016, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors (the "Investors") for the sale by the Company of 3,333,334 shares (the "Common Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a purchase price of $1.50 per share and sold warrants to purchase 2,500,000 shares of Common Stock (the "Warrants") for aggregate net proceeds of $4,520,000. Subject to certain ownership limitations, the Warrants will be initially exercisable six-month after issuance at an exercise price equal to $2.00 per share of Common Stock, subject to adjustments as provided under the terms of the Warrants. The Warrants are exercisable for five years from the initial exercise date.

The Company received net proceeds from the foregoing transaction (the "Offering") of approximately $4,520,000 after deducting certain fees due to the placement agent and the Company's transaction expenses. The net proceeds received by the Company from the Offering will be used for preparation for technology transfer opportunities, expenses related to Ampligen® manufacturing, working capital and general corporate purposes.

The Common Shares were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was initially filed with the Securities and Exchange Commission (the "SEC") on June 25, 2015 and subsequently declared effective on August 4, 2015 (File No. 333-205228) (the "Registration Statement"), and the base prospectus dated as of August 4, 2015 contained therein. The Company filed a prospectus supplement with the SEC on September 1, 2016 in connection with the sale of the Common Shares.

Pursuant to an engagement agreement dated July 26, 2016, the Company engaged Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC ("Wainwright"), to act as its exclusive placement agent in connection with the Offering. Pursuant to the engagement agreement, the Company paid Wainwright an aggregate fee equal to 7% of the gross proceeds received by the Company from the sale of the securities in the Offering and granted to Wainwright or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions (the "Wainwright Warrants") amounting to 166,667 warrants. The Wainwright Warrants have substantially the same terms as the Warrants, except that the Wainwright Warrants will expire on September 1, 2021 and have an exercise price equal to $1.875 per share of Common Stock. The Wainwright Warrants and the shares issuable upon exercise of the Wainwright Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable

state laws. The Company also paid Wainwright a non-accountable expense allowance of $70,000 plus a management fee equal to 1.0% of the gross proceeds raised in the Offering.

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 May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), *Revenue from Contracts with Customers*. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current U.S. GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. Upon the Company realizing operating revenues from the sale of commercialized product, the Company's adoption of this guidance may have an impact on the Company's financial statement presentation or disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. ASU 2014-15 explicitly requires management to evaluate, at each annual or interim reporting period, whether there are conditions or events that exist which raise substantial doubt about an entity's ability to continue as a going concern and to provide related disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and annual and interim periods thereafter, with early adoption permitted. The Company will continue to evaluate and monitor at each annual or interim reporting period whether there are conditions or events that exist pertaining to this guidance.

In January 2016, the ("FASB") has issued Accounting Standards Update (ASU) No. 2016-01, *Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*. The new guidance is intended to improve the recognition and measurement of financial instruments. The new guidance is effective for public companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The new guidance permits early adoption of the own credit provision. The Company believes that the adoption of the guidance may have an impact on the Company's financial statement presentation or disclosures.

In February 2016, the FASB issued ASU 2016-02 - *Leases,* which amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective for annual reporting periods beginning after December 15, 2018, and early adoption of is permitted as of the standard's issuance date. ASU 2016-02 requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company has not adopted ASU 2016-02 and believes such adoption may have an impact on the Company's financial statement presentation or disclosures.

In August 2016, the FASB issued ASU 2016-15 - Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments (a consensus of the Emerging Issues Task Force). The new guidance is intended to address the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows under Topic 230, Statement of Cash Flows, and other Topics. The guidance addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice. The amendments apply to all entities, including both business entities and not-for-profit entities that are required to present a statement of cash flows under Topic 230. The amendments are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments in this Update should be applied using a retrospective transition method to each period presented. The Company believes that the adoption of the guidance may not have a material impact on the Company’s financial statement presentation or disclosures.

In 2016, the FASB also issued Accounting Standards Updates (“ASU”) 2016-03 through 2016-17. 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, 2015, the Company has approximately $166,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2035) available to offset future federal taxable income. The Company also has approximately $36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2033) and approximately $29,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2034 and 2035) available to offset future state taxable income.

In January 2016, the Company effectively sold $16,000,000 of its New Jersey state net operating loss carryforward for the year 2014 for approximately $1,320,000, and also sold New Jersey research and development credits for $241,000. 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 GAAP to disclose information about the fair value of all the Company’s financial instruments, whether or not these instruments are measured at fair value on the Company’s consolidated balance sheets.

The Company estimates that the fair values of cash and cash equivalents, other assets, accounts payable and accrued expenses approximate their carrying values due to the short-term maturities of these items. The Company also has certain warrants with a cash settlement feature in the unlikely occurrence of a Fundamental Transaction. The fair value of the redeemable warrants related to the Company’s August 2016 Common Stock and Warrant issuance, are calculated using a Monte Carlo Simulation. While the Monte Carlo Simulation is one of a number of possible pricing models, the Company has determined it to be industry accepted and fairly presented the fair value of the Warrants. As an additional factor to determine the fair value of the Put's liability, the occurrence probability of a Fundamental Transaction event was factored into the valuation.

The Company recomputes the fair value of the Warrants at the issuance date and 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 Company utilized the following assumptions to estimate the fair value of the August 2016 warrants:

	September 30, 2016	September 6, 2016
Underlying price per share	$1.26	$1.39
Exercise price per share	$1.88 - $2.00	$1.88 - $2.00
Risk-free interest rate	1.21%	1.21%
Expected holding period	4.90	5.00
Expected volatility	90%	90%
Expected dividend yield	-	-

The significant assumptions using the Monte Carlo Simulation approach for valuation of the Warrants are:

(i) *Risk-Free Interest Rate*. The risk-free interest rates for the Warrants are based on U.S. Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.

(ii) *Expected Holding Period*. The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.

(iii) *Expected Volatility*. Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.

(iv) *Expected Dividend Yield*. Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is $-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.

(v) *Expected Probability of a Fundamental Transaction.* The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:

a. The Company only has one product that is FDA approved but which will not be available for commercial sales for at least approximately 18 months;
b. The Company may have to perform additional clinical trials for FDA approval of its flagship product;
c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
d. Available capital for a potential buyer in a cash transaction continues to be limited;
e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;
f. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and
g. The Company's Rights Agreement and Executive Agreements make it less attractive to a potential buyer.

With the above factors utilized in analysis of the likelihood of the Put's potential Liability, the Company estimated the range of probabilities related to a Put right being triggered as:

Range of Probability	Probability
Low	0.5 %
Medium	1.0 %
High	5.0 %

The Monte Carlo Simulation has incorporated a 5.0% probability of a Fundamental Transaction to date for the life of the securities.

(vi) *Expected Timing of Announcement of a Fundamental Transaction.* As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.

(vii) *Expected 100 Day Volatility at Announcement of a Fundamental Transaction*. An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.

(viii) *Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction*. The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.

(ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction. The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants was approximately $2,514,000 at September 30, 2016 and $2,617,000 at September 6, 2016, the date of issuance.

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

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 quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of September 30, 2016, 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:

	(in thousands)			
	As of September 30, 2016			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$3,536	$3,536	$ -	$ -
Liabilities:				
Redeemable warrants	2,514	-	-	2,514

	(in thousands)			
	As of December 31, 2015			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities	$6,795	$6,795	$ -	$ -
Liabilities:				
Redeemable warrants	-	-	-	-

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

	(in thousands)
	2016
Balance at December 31, 2015	$ -
Issuance of warrants	2,617
Fair value adjustments	(103)
Balance at September 30	$ 2,514

Note 13: Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued and determined that no subsequent event, other than what is noted below, constituted a matter that required adjustment to the financial statements for the nine months ended September 30, 2016.

On November 8, 2016, the Company received a letter of intent for its underutilized building located adjacent to the site of the Company’s New Jersey manufacturing facility. The letter of intent includes a 45 day due diligence period including, but not limited to, a building inspection and environmental review. Closing is anticipated 60 days from the date of the contract execution.

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”, “inte “seek”, “plan”, “expect”, “should”, or “would,” and similar expressions intended to identify forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects, the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms, 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.

On August 18, 2016, we received approval of our New Drug Application ("NDA") from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica ("ANMAT") for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"). The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe that rintatolimod is the first drug to receive approval for this indication anywhere in the world.

We believe that this approval provides a platform for potential commercial sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. We and GP Pharm are now working to expand the approval of rintatolimod to additional countries with a focus on Latin America. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program is launched in Europe. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch (including possible requirements for approval of final manufacturing), and there are no assurances as to whether or when such multiple subsequent steps will be successfully performed to result in an overall successful commercialization and product launch.

In October 2016, we completed our technology transfer of the Ampligen® manufacturing processes to Nitto Denko Avecia Inc. ("Avecia"), formerly, Avrio Biopharmaceuticals ("Avrio"). The transfer consists of providing Avecia with all information that is relevant to the manufacturing process of Ampligen® and associated assays. This includes performing a test engineering run to identify any potential issues before moving forward with the first Good Manufacturing Practice ("cGMP") lot and confirming that the information exchange was successful. This will enable Avecia to begin manufacturing current cGMP lots of Ampligen®. The first cGMP lot is expected to be compounded, filled and finished in November and released in December, 2016, for use in the Company's Early Access Program ("EAP") in Europe and Turkey.

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) among others. 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, MERS, among others, 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.

On March 15, 2016, we received written notice from the NYSE MKT LLC that we were not in compliance with its continued listing standards because our common stock had been selling for a low price per share for a substantial period of time. The NYSE MKT determined that the continued listing of our common stock was predicated on our effecting a reverse stock split of our common stock. Our stockholders approved a reverse stock split, our Board effected a 12-to-1 reverse stock split effective August 26, 2016 and our reverse split shares started trading on August 29, 2016. On September 15, 2016, we received written notice from the NYSE MKT LLC that we were back in compliance with the continued listing standards set forth in Section 1003(f)(v) of the NYSE MKT Company Guide referenced in the Exchange's letter dated March 15, 2016. The Company will be subject to NYSE Regulation's normal continued listing monitoring. However, in accordance with Section 1009(h) of the Company Guide, if the Company is again determined to be below any of the continued listing standards within 12 months of the date of this letter, NYSE MKT will examine the relationship between the two incidents of noncompliance and re-evaluate the Company's financial recovery from the first incident. NYSE Regulation will then take appropriate action, which depending on the circumstances, may include truncating the compliance procedures described in Section 1009 of the Company Guide or immediately initiate delisting procedures.

On September 6, 2016, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors for the sale by us of 3,333,334 shares of our common stock at a purchase price of $1.50 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate gross proceeds of $5,000,000.

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.

We have been reexamining our fundamental priorities in terms of direction, corporate culture and our ability to fund operations. As a result, there have been significant changes at the Company in the past few months. As noted below, we have made several changes to the Company’s executive management team to provide effective and competent leadership that, management believes, will properly position the Company to achieve its commercial goals and increase stockholder value. Recent actions include aggressively pursuing international sales of clinical grade materials and implementing a strong financial austerity plan. We are committed to a focused business plan oriented toward

finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of our experimental drug, Ampligen®, and our approved drug Alferon®. Management's primary objectives are to create stockholder value and deliver much needed therapies to patients.

On September 16, 2015, our Board of Directors 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.

On February 17, 2016, our Board, by majority vote, terminated the employment of Dr. Carter, our Chairman of the Board, Chief Executive Officer and Chief Scientific Officer. As a result, Dr. Carter also is no longer a director. Dr. Mitchell, one of our independent directors, was appointed Chairman of the Board.

On February 19, 2016, our Board also made several changes to our executive management team in light of the termination of Dr. Carter, to provide effective and competent leadership that will properly position us to achieve our commercial goals and increase stockholder value. In this regard, Adam Pascale was named Chief Financial Officer in addition to his current responsibilities as Chief Accounting Officer. Mr. Pascale has been employed us for 18 years, with more than two decades of public accounting experience and prior public company experience. He earned a Bachelor of Arts degree in Accounting and Finance from Rutgers University. Mr. Pascale served for several years as a CPA prior to joining the Company, and is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants. Mr. Equels, our Chief Executive Officer ("CEO") and President, resigned as Chief Financial Officer to make way for Mr. Pascale.

On February 25, 2016, our Board appointed Thomas K. Equels, our current President, as our CEO. In that capacity, he is our principal executive officer. On June 16, 2016, Iraj Kiani resigned as a member of our Board. On September 30, 2016, Mr. Rodino resigned as a member of our Board to permit him to serve us in a new capacity. In this regard, effective October 1, 2016, we retained Mr. Rodino as our Executive Director for Governmental Relations, and as our General Counsel. In that capacity, Mr. Rodino will handle all government affairs and litigation matters on a going forward basis.

On April 20, 2016, we executed a consulting agreement with Huron Consulting Group, a global consultancy with decades of experience in the life sciences market, to advance our strategic plan to capitalize on business opportunities in the United States and in target countries around the world.

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.

The below chart provides a summary of the clinical indications for both Ampligen® and Alferon® currently under development.

We own and operate a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ to produce Alferon® and Ampligen®, and completed the construction of our $8 million facility enhancement project in 2015 which, upon FDA approval, should provide for a higher capacity, more cost effective manufacturing process for the production of Alferon N Injection®. As part of our objectives to achieve our commercial goals and increase stockholder value, we are in the process of selling an underutilized building adjacent to our New Jersey manufacturing facility site. We do not believe that the sale of this building will have an impact on the production of our products. We also are exploring the possibility of selling the primary facility if we can obtain a long term lease back of the facility on acceptable terms. Please see “Manufacturing” section below.

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

Our 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 approved for commercial sale in Argentina and is an experimental drug currently undergoing clinical development for the treatment of CFS in the United States of America. 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 protocol (e.g., “Expanded Access” 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.

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 I; Item 1A. Risk Factors below.

Until we undertake the end-of-review conference(s), or otherwise reach an agreement with the FDA regarding the design of a confirmatory study, 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 I; Item 1A, Risk Factors: "We may require additional financing which may not be available."

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, 2016, there were 27 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 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 400 mg dose of Ampligen® of $400, $200 per vial. In October 2016, the FDA granted our request to implement the new cost.

On July 12, 2012, we filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT's Orphan Drug regulations. We believe that the approval of Ampligen® as an Orphan Drug may allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for CFS. On August 18, 2016, we received approval of our New Drug Application ("NDA") from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe myalgic encephalomyelitis/chronic fatigue syndrome ("ME/CFS"). The product will be marketed by GP Pharm, our commercial partner in Latin America.

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.

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 had redirected many of our resources to complete the upgrades in the New Brunswick facility.

Other Diseases

In July 2011, we received FDA authorization to proceed with the initiation of a new clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. On April 16, 2012, a clinical trial was initiated in which Ampligen® is 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; twelve in Stage 1 and thirteen subjects in Stage 2. The study is currently on hold pending the safety data on these 25 subjects being reviewed by the Data Monitoring Committee and authorization from the FDA is received to proceed with enrollment. As of September 30, 2016, there are no active subjects in the study.

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 dose escalation in patients with resectable colorectal cancer under the clinical leadership of Dr. Amer Zureikat, an assistant professor of surgery. To date, 15 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 immune enhancer. To date, 43 patients have been treated. The University has initiated enrollment into another cancer study of recurrent ovarian cancer patients which includes Ampligen® as a component of the treatment regimen. To date, 5 patients have been treated. The University has received Institutional Review Board approval for another cancer study of subjects with chemo-refractory metastatic colorectal cancer which also includes Ampligen® as an immune enhancer. Enrollment into this study has not yet been initiated.

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 and on January 6, 2016, the EMA forwarded to us both its Public Summary of Opinion and its record designation approving the Orphan Medicinal Products Designation for Alferon® N Injection, also known as interferon alfa-n3, as a potential treatment of MERS.

On March 3, 2016, we entered into a Sales, Marketing, Distribution and Supply Agreement (the “Scien Agreement”) with Scientific Products Pharmaceutical Co. LTD, a Saudi Arabia based pharmaceutical company (“Scien”). Pursuant to the Scien Agreement, we granted Scien an exclusive license to sell, market and distribute human leukocyte derived Interferon alfa-n3 (the “Product”) for refractory/recurrent genital warts, recombinant interferon refractory patients and patients with other infectious diseases, e.g., Middle East Respiratory Syndrome (“MERS”), influenza, West Nile Virus and cancer (the “Field”) within the Gulf Cooperation Council states (the “Territory”) for Direct Access/EAP and Regulatory Agency-Approved purposes. A condition precedent to the granting of the license is the successful completion of a clinical study to be performed by the Saudi Ministry of Health on at least five persons in Saudi Arabia treating early onset patients infected with MERS. Scien will purchase the Product to be used in this study. Pursuant to the Scien Agreement, Scien will, among other things, prepare a business plan to make aware and educate physicians and patients about the Product both prior to and following approval of the Product, assist us to gain regulatory approval of Product in the Field in the Territory and, if needed, assist in recruiting clinical trial sites and principal investigators in the Field in the Territory. We have recently been informed by the Saudi Ministry of Health that they will not pursue treating patients infected with MERS with human leukocyte derived Interferon and are now looking to explore other options to conduct a clinical study to treat MERS before seeking regulatory approval.

Ebola

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 dosage schedules 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 from the COMP (Committee on Medical Products) regarding its Orphan Medicinal Product Application for Ampligen®, an experimental therapeutic, to treat Ebola Virus Disease (EVD). The European Medicines Agency (EMA) published on May 22, 2015 both its Public Opinion Summary and its record designation approving the Orphan Medicinal Product Designation for Ampligen®, also known as rintatolimod experimental therapeutic, to treat Ebola Virus Disease (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. In addition, we have formed collaborations with multiple research laboratories around the world to examine Ampligen®, an experimental therapeutic, for the treatment of Ebola Virus Disease (EVD) among others. 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, MERS, among others, 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.

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 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®. The Company is in discussion with Hollister-Stier about this purchase commitment.

On July 27, 2016, the Company reached an agreement with Avecia to serve as an additional contract manufacturer of Hemispherx's experimental drug, Ampligen®. Avecia, an FDA inspected facility, has the capabilities for the compounding and fill/finish of sterile clinical and commercial grade Ampligen® to satisfy the Company's ongoing domestic clinical studies as well as the recently initiated Early Access Program (EAP) in Europe and Turkey. We believe that Avecia will be able to meet our immediate requirements until we are able to amend our agreement with Hollister-Stier and, regardless, will be a good source of manufactured product. The Company initiated the transfer of the key raw materials and has made payments of $270,000 to Avecia for the manufacture of Ampligen®. In October 2016, the Company completed its technology transfer of the Ampligen® manufacturing processes to Avecia. The transfer consists of providing Avecia with all information that is relevant to the manufacturing process of Ampligen® and associated assays. This includes performing a test engineering run to identify any potential issues before moving forward with the first cGMP lot and confirming that the information exchange was successful. This will enable Avecia to begin manufacturing current Good Manufacturing Practice ("cGMP") lots of Ampligen®. The first cGMP lot is expected to be compounded, filled and finished in November and released in December, 2016, for use in the Company's Early Access Program ("EAP") in Europe and Turkey. 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.*

We completed the construction of the $8 million facility enhancement project in 2015 which, upon FDA approval, 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 soon as the necessary regulatory approvals are obtained. 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 reagent used in the formulation of Alferon®. We have substantially resolved these issues through engaging in multiple agreements with suppliers of

leukocytes as well as entering into a licensing agreement with a foreign multinational chemicals and biotechnology company that has been in business for over a century for the sourcing of the primary reagent allowing us to manufacture Alferon®. 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 were working diligently to make the necessary repairs to be able to restart the validation process; however, in the process of obtaining time estimates for the repairs we experienced a flood within portions of our manufacturing facility. As a result, we will be constrained in our ability to manufacture product in the near future due to this flood in the upstream processing cleanroom that contains the bioreactor. The flood occurred on the afternoon of January 5, 2016, caused by a malfunctioning water supply pipe for the sprinkler system covering a large amount of the cleanroom in stagnant water and silt from the sprinkler system. Our facility insurer has been proactive in addressing and covering the loss. While repairs have required preapproval by our insurer, activity moved forward quickly. The repairs noted below required special action because of the need to keep this critical manufacturing room within International Organization for Standardization (ISO) classifications and the need to certify that all the equipment that was exposed, or submerged, is in proper condition and operating effectively following the corrective actions. All HEPA filters affected by the flood were tested by an outside contractor and have passed all required tests. The flooring that was damaged has been repaired using a special epoxy that is used in cleanrooms. A large portion of the walls in the ISO classified area were damaged. We had a damage mitigation company come in to stop any moisture from seeping further into the ISO classified areas. Subsequently, all damaged walls and ceilings have been replaced with cleanroom grade materials and need no further work. Six pumps that were affected by the flood were sent back to the manufacturer for inspection and repair. Repairs that were required have been completed on the pumps and they were reinstalled in the Alferon manufacturing facility after the floor repair work was completed. All pumps will need to be qualified for use in the manufacturing process prior to the validation process for a Pre-Approval Inspection. All air ducts supplying the Alferon manufacturing area were cleaned and insulation replaced along with ceiling tiles. All smaller pieces of machinery and equipment that could not be salvaged have been replaced. We also completed the HVAC air balancing and qualification. At this time, we believe that all repairs to the manufacturing facility have been completed.

We also are exploring the possibility of selling the facility if we can obtain a long term lease back on the facility on acceptable terms.

Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. Due to the Company extending the timeline of Alferon® production to an excess of one year, we reclassified Alferon® work-process-inventory to other assets within our balance sheet as of September 30, 2016. In addition, due to the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. 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.

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, 2016 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. On May 24, 2016, we entered into a five year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with GP Pharma whereby all material provisions within the Agreement remained consistent with the original agreement.

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 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 Asembia, formerly Armada Healthcare, LLC, 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 May 24, 2016, we entered into an amended and restated 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. Pursuant to the agreement, MyTomorrows, as Hemispherx’ exclusive service provider and distributor in the Territory, would perform EAP activities. These activities would 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 would support these efforts and supply Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we would pay myTomorrows a royalty on products sold. The parties established a Joint Steering Committee comprised of representatives of both parties to oversee the EAP.

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 effective January 1, 2016. For the nine months ended September 30, 2016, the Company did not make any contributions towards the 401(k) Plan.

New Accounting Pronouncements

See Part I - Financial Information; Item 1; Financial Statements; **"**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, 2015.

RESULTS OF OPERATIONS

Three months ended September 30, 2016 versus three months ended September 30, 2015

Net Loss

Our net loss was approximately $2,862,000 and $3,803,000 for the three months ended September 30, 2016 and 2015, respectively, representing a decrease in loss of approximately $941,000 or 25% when compared to the same period in 2015. This decrease in loss for these three months was primarily due to the following:

1) a decrease in research and development expense of approximately $626,000 or 32%;

2) a decrease in production costs of approximately $81,000 or 23%;

3) a gain on the valuation adjustment on the redeemable warrants of approximately $103,000; and

4) an insurance settlement on legal expenses recorded as other income of approximately $190,000, offset by

5) a decrease in interest and other income of approximately $141,000 or 78%.

Net loss per share was $(0.13) and $(0.18) for the three months ended September 30, 2016 and 2015, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2016 was 21,832,940 as compared to 20,564,538 as of September 30, 2015.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $22,000 and $23,000 for the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2016 and 2015, 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 $272,000 and $353,000, respectively, for the three months ended September 30, 2016 and 2015. This decrease of approximately $81,000 or 23% was primarily due to a decline in ongoing stability testing on Alferon® work-in-process inventory.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2016 were approximately $1,342,000 as compared to $1,968,000 for the same period a year ago, reflecting a decrease of approximately $626,000 or 32%. The primary reason for the decrease in research and development costs was due to a decrease in general R&D expenses of approximately $708,000 including Alferon N Injection® compliance testing and clinical work and a decrease in executive salaries and wages of approximately $372,000. This was offset by a general net increase in R&D expenses of approximately $336,000 associated with Ampligen. These decreases in general R&D expenses were mainly the result of implementing a strong financial austerity plan whereby we conducted an analysis of our research and development programs and our staffing levels within our New Jersey manufacturing facility.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2016 and 2015, were approximately $1,634,000 and $1,685,000, respectively, reflecting a decrease of approximately $51,000 or 3%. The decrease in G&A expenses in 2016 was mainly due to lower professional and legal fees of approximately $50,000 during the current quarter.

Insurance settlement net of litigation expenses

The Company recorded a net insurance settlement of $190,000 during the three months ended September 30, 2016 which resulted from the legal settlements of various class action lawsuits during the current period. There were no such occurrences in the prior period.

Interest and Other Income

Interest and other income for the three months ended September 30, 2016 and 2015 were approximately $40,000 and $181,000, respectively, representing a decrease of approximately $141,000 or 78%. The primary cause for the decrease in investment income during the current period was primarily due to lower balances available to invest in the current period as compared to the prior period.

Redeemable Warrants

The quarterly fiscal revaluation of certain redeemable warrants resulted in a non-cash gain to the redeemable warrants liability for the three months ended September 30, 2016 amounting to a gain of approximately $103,000 (see Part I - Financial Information; Item 1; Financial Statements; “Note 13: Fair Value” for the various factors considered in the valuation of redeemable warrants).

Nine months ended September 30, 2016 versus nine months ended September 30, 2015

Net Loss

Our net loss was approximately $6,329,000 and $12,093,000 for the nine months ended September 30, 2016 and 2015, respectively, representing a decrease in loss of approximately $5,764,000 or 48% when compared to the same period in 2015. This decrease in loss for these nine months was primarily due to the following:

1) a decrease in research and development expense of $3,837,000 or 54%;

2) a decrease in production costs of approximately $402,000 or 33%;

3) an insurance settlement net of litigation expenses recorded as other income of $1,626,000;

4) an increase in the gain from sale of income tax net operating losses of $187,000 or 14%; and

5) a gain on the valuation adjustment on the redeemable warrants of approximately $103,000; offset by

6) a decrease in interest and other income of approximately $187,000 or 55%.

Net loss per share was $(0.30) and $(0.62) for the nine months ended September 30, 2016 and 2015, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2016 was 21,046,418 as compared to 19,358,962 as of September 30, 2015.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $76,000 and $106,000 for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2016 and 2015, 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 $830,000 and 1,232,000, respectively, for the nine months ended September 30, 2016 and 2015. This decrease of approximately $402,000 or 33% was primarily due to a decline in ongoing stability testing on Alferon® work-in-process inventory.

Research and Development Costs

Overall Research and Development ("R&D") costs for the nine months ended September 30, 2016 were approximately $3,244,000 as compared to $7,081,000 for the same period a year ago, reflecting a decrease of approximately $3,837,000 or 54%. The primary reason for the decrease in research and development costs was due to a decrease in general R&D expenses of approximately $2,400,000 including Alferon N Injection® compliance testing and clinical work and a decrease in executive salaries and wages of approximately $1,362,000. This was offset by a general net increase in R&D expenses of approximately $231,000 associated with Ampligen®. These decreases in general R&D expenses were mainly the result of implementing a strong financial austerity plan whereby we conducted an analysis of our research and development programs and our staffing levels within our New Jersey manufacturing facility.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2016 and 2015, were approximately $5,721,000 and $5,600,000, respectively, reflecting an increase of approximately $121,000 or 2%. The increase in G&A expenses in 2016 was mainly due to higher salaries and wages and severance related costs of approximately $107,000.

Interest and Other Income

Interest and other income for the nine months ended September 30, 2016 and 2015 were approximately $156,000 and $343,000, respectively, representing a decrease of approximately $187,000 or 55%. The primary cause for the decrease in investment income during the current period was primarily due to lower balances available to invest in the current period as compared to the prior period.

Insurance settlement net of litigation expenses

The Company recorded a net insurance settlement of $1,626,000 during the nine months ended September 30, 2016 which resulted from the legal settlements of various class action lawsuits during the current period. Insurance proceeds received of $3,726,000 were offset by litigation settlement expenses of $2,100,000. There were no such expenses in the prior period (see "Part II - Other Information; Item 1: Legal Proceedings" for details).

Loss on Sale of Marketable Securities

Loss on sale of marketable securities was $56,000 and $0, respectively, for the nine months ended September 30, 2016 and 2015. Our securities sold during the current period resulted in net realized losses. There were no such sales that incurred losses in 2015 for the same period.

Sale of New Jersey Tax Net Operating Loss

In January 2016, the Company effectively sold $16,000,000 of its approximately $29,000,000 of New Jersey state net operating loss carryforwards (for the year 2014) for approximately $1,320,000 and sold research credits for $241,000. 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, representing an increase in cash gain of $187,000 or 14% (see Part I - Financial Information; Item 1; Financial Statements; “Note 11**:** Funds Received from Sale of Income Tax Net Operating Losses”) for the nine months ended September 30, 2016 as compared to the same period in 2015.

Redeemable Warrants

The quarterly fiscal revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the nine months ended September 30, 2016 amounting to a gain of approximately $103,000 (see Part I - Financial Information; Item 1; Financial Statements; “Note 13: Fair Value” for the various factors considered in the valuation of redeemable warrants).

Liquidity and Capital Resources

Cash used in operating activities for the nine months ended September 30, 2016 was approximately $5,278,000 compared to approximately $12,739,000 for the same period in 2015, a decrease of $7,461,000 or 59%. The primary reason for this decrease in cash used in operations in 2016 was due to lower operating expenses whereby we conducted an analysis of our research and development programs as well as our staffing levels within our New Jersey manufacturing facility which resulted in a decrease in cash flow used in operations in 2016. In addition, the Company received net proceeds from an insurance settlement of $1,626,000 which resulted from the legal settlements of various class action lawsuits during the current period. Also, the Company paid the 2014 executive incentive bonuses in January 2015 for approximately $1,232,000 reflected in accrued expenses and also paid for work in process inventory of $1,326,000 in 2015.

Cash provided by investing activities for the nine months ended September 30, 2016 was approximately $2,943,000 compared to approximately $2,083,000 in cash provided by investing activities for the same period in 2015, an increase of $860,000. The primary reason for the increase can be attributable to additional sales and maturities of marketable securities during the current period of $3,371,000 as compared to $2,497,000 in the prior period.

Cash provided by financing activities for the nine months ended September 30, 2016 was approximately $4,693,000 compared to approximately $9,661,000 for the same period in 2015, a decrease of $4,968,000. Cash provided by financing activities for the nine months ended September 30, 2016 primarily represented net proceeds received from the sale of common stock pursuant to a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors for the sale by us of 3,333,334 shares of our common stock at a purchase price of $1.50 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate net proceeds of $4,520,000. Cash provided by financing activities for the nine months ended September 30, 2015 primarily represented the Company receiving net proceeds of $9,680,000 from the sale of 3,416,141 shares sold pursuant to the ATM during the nine months ended September 30, 2015 (see Part I - Financial Information; Item 1; Financial Statements; "Note 8: Stockholders' Equity”).

As of September 30, 2016, we had approximately $8,009,000 in cash, cash equivalents and marketable securities, inclusive of approximately $3,536,000 in Marketable Securities, representing a decrease of approximately $901,000 from December 31, 2015. 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 in 2016 and beyond. 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. In this regard, due to the repair issues mentioned above within our NJ facility and the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. However, there is no assurance that such financing will be available.

On May 24, 2016, we entered into an amended and restated 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. Pursuant to the agreement, MyTomorrows, as Hemispherx’ exclusive service provider and distributor in the Territory, would perform EAP activities. These activities would 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 would support these efforts and supply Ampligen to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we would pay myTomorrows a royalty on products sold. The parties would establish a Joint Steering Committee composes of representative of both parties to oversee the EAP.

We have been reexamining our fundamental priorities in terms of direction, corporate culture and our ability to fund operations. As a result, there have been significant changes at the Company in the past few months. The CEO of the Company was terminated and the Board of Directors has made several changes to the Company’s executive management team to provide effective and competent leadership that, management believes, will properly position the Company to achieve its commercial goals and increase stockholder value. Recent actions include aggressively pursuing international sales of clinical grade materials and implementing a strong financial austerity plan. We are committed to a focused business plan oriented toward finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of its experimental drug and its approved drug Alferon®. A co-development partner may help in the acceleration of the commercialization of many of our potential experimental drugs as they have access to additional resources and capital; however, there can be no assurance that such co-development partnerships will be on acceptable terms, or that such partnerships, will be acceptable from a profitability standpoint. Management’s primary objectives are to create stockholder value and deliver much needed therapies to patients.

In 2015, Mr. Equels waived his right under his employment agreement to any future payment of any incentive bonus related to the sale of the Company’s stock or other securities by, or on behalf of, the Company pursuant to the Maxim Equity Distribution Agreement or any similar or successor ATM equity distribution agreement. Mr. Equels voluntarily provided this waiver in an effort to preserve cash and to help the Company to ensure its short term commercialization goals.

On January 26, 2016, the Board, based on the recommendation of its Compensation Committee, established two programs - the 2016 Senior Executive Deferred Cash Performance Award Plan for Dr. William A. Carter and Thomas K. Equels, the Company’s two primary executive officers, and the 2016 Voluntary Incentive Stock Award Plan for Company employees and Board members other than Dr. Carter and Mr. Equels. Both Plans include a Base Pay Supplement provision.

The Company maintains a record of the number of shares of stock represented by each Incentive Right issued out of the 2016 Voluntary Incentive Stock Award Plan. During the nine months ended September 30, 2016, the Company issued 140,936 incentive shares associated with the Plan and recorded $219,000 in equity-based compensation. For a more detailed subscription of these plans, please see *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations, Liquidity and Capital Resources* section within the Company's 2015 Form 10-K filed with the SEC on March 29, 2016.

On December 15, 2015, we entered into an Equity Distribution Agreement with Chardan Capital Markets, LLC (the "Chardan Agreement") to create an at-the-market equity program under which we may sell shares of our common stock from time to time through Chardan Capital Markets, LLC, as sales agent ("Chardan"). Under the Chardan Agreement, Chardan will be entitled to a commission at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the Chardan Agreement. Sales of the Shares, if any, under the Chardan Agreement 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 Chardan. The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Chardan Agreement or terminate the Chardan Agreement. Effective August 26, 2016, the Company halted all future offers and sales of its common stock under the Chardan Agreement and reduced the amount of potential future offers and sales under the Chardan Agreement to $0.00. Between December 15, 2015, the date of the Chardan Agreement, and August 26, 2016, we sold an aggregate of 114,394 shares of common stock pursuant to the Chardan Agreement for aggregate net proceeds of approximately $174,000.

On September 6, 2016, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain investors for the sale by us of 3,333,334 shares of our Common Stock at a purchase price of $1.50 per share. Concurrently with the sale of the Common Stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate gross proceeds of $5,000,000. The net proceeds from the transactions were approximately $4,520,000 after deducting certain fees due to the transaction expenses of the placement agent and the Company. The net proceeds received by the Company from the transactions will be used for preparation for technology transfer opportunities, expenses related to Ampligen® manufacturing, working capital and general corporate purposes. See Part I - Financial Information; Item 1; Financial Statements; "Note 8: Stockholders' Equity".

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.*"

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $8,009,000 in cash, cash equivalents and marketable securities, inclusive of approximately $3,536,000 in Marketable Securities as of September 30, 2016, representing a decrease of approximately $901,000 from December 31, 2015.

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 Chief Executive Officer and our 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 our Chief Financial Officer concluded that the controls and procedures were effective as of September 30, 2016, 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, 2016, 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

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

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

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

(d) 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.

(e) Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 9-549-GMS.

(a) 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. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties

engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' Settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court entered an Order granting final approval of the parties' settlement and awarding the plaintiffs' counsel $660,000 in attorneys' fees. The Settlement resolves all claims asserted in this action ("Zicherman") and the two related consolidated state-court actions referenced below, Michael Desclos v. Hemispherx Biopharma, Inc. et al., and Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al. The Settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies.

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

(b) Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement (“Settlement”). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties’ Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties’ settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court entered an Order granting final approval of the parties’ settlement and awarding the plaintiffs’ counsel $660,000 in attorneys’ fees. The Settlement, which resolves all claims asserted in this action (“Desclos”) and the two related actions, Zicherman, referenced above, and the state court action referenced below, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys’ fees award, which was funded by Hemispherx’s insurance companies.

(c) On April 23, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On May 10, 2013, the Court entered an order staying this case pending the outcome of the ruling on the Federal Securities Class Action Defendants' motion to dismiss. On January 24, 2014, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the Court entered an order consolidating this action with the shareholder derivative action, Michael Desclos v. Hemispherx Biopharma, Inc., et al., described above. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement (“Settlement”). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties’ Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties’ settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court entered an Order granting final approval of the parties’ settlement and awarding the plaintiffs’ counsel $660,000 in attorneys’ fees. The Settlement, which resolves all claims asserted in this action and the two related actions, Zicherman and Desclos, referenced above, does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company

funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies.

(d) 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 (the "Amended 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 and all individual defendants except former Board member Richard C. Piani answered the Amended Compliant on November 19, 2015. The Court entered a scheduling order on December 2, 2015, but on January 5, 2016, the parties agreed to suspend all litigation for 60 days and to attempt to resolve the action through mediation. The parties engaged in a mediation on February 10, 2016, and reached an agreement in principle to settle all claims on April 27, 2016. That agreement was memorialized in a Stipulation and Agreement of Settlement (the "Settlement Stipulation") which was filed with the Court on June 8, 2016. The settlement was subject to the Court's finally approving the terms of the parties' settlement agreement in all material respects. On June 8, 2016, concurrent with the filing of the Settlement Stipulation, the parties filed a joint proposed scheduling order, which the Court entered the same day (the "Scheduling Order"). The Scheduling Order preliminarily certified the class for settlement purposes, directed the Company to issue notice (in the form approved by the Court) to Company stockholders and members of the putative class, and scheduled a settlement approval hearing (the "Settlement Approval Hearing") to occur on September 9, 2016. At a final settlement hearing on September 19, 2016, the Court of Chancery of the State of Delaware approved a settlement of the derivative and class action case captioned Kastis, et al. v. Carter, et al and awarded the plaintiffs' counsel $1.25 million in attorneys' fees. No Company funds were used to pay the settlement or attorneys' fees award; the settlement was funded by Hemispherx's insurance companies which paid to Hemispherx $3.5 million in settlement of several policy disputes, in part related to this claim, that were in policy mediation. The final settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants.

(e) 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 owed 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. On February 10, 2016 the Court increased Hemispherx' judgment by an additional $48,725.75 to reflect the costs of defending the Cato appeal. On February 11, 2016 the Court of Appeals returned the mandate to the District Court. The Company is pursuing collection of its judgment in the amount of $829,578.51.

ITEM 1A: Risk Factors

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

Risks Associated with Our Business

No assurance of successful product development and finding co-development partners.

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).

We are committed to a focused business plan oriented toward finding co-development partners with the necessary capital and expertise required to commercialize the many therapeutic aspects of our experimental drugs and our FDA approved drug Alferon N®. If we are unable to find a suitable co-development partner to assist in the product development and commercialization of our experimental drugs and our FDA approved drug Alferon N®, we may be unable to continue or complete our development and commercialization of our products. In addition, there can be no assurance that such co-development partnerships would be on acceptable terms, or that such partnerships, will be acceptable from a profitability standpoint.

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 1, 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, 2016, our accumulated deficit was approximately $299,328,000. 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, 2016, we had approximately $8,009,000 in cash, cash equivalents and marketable securities (inclusive of approximately $3,536,000 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 or otherwise reach an agreement with the FDA regarding the design of a confirmatory study, 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®. Due to the repair issues mentioned above within our NJ facility and the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. 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. We may also review the possibility of selling the remaining work-in-process inventory through the EAP; however, this inventory has yet to go through the fill and finish process.

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 the Risk Factor "*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 1, Item II: "Management's Discussion and Analysis of Financial Condition and Results of Operations Business; 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 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. For more information on Patents, please see 2015 Form 10-K, PART I, Item I – “Business; Patents”.

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.

-44-

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

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

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

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

We have limited marketing and sales capability. If we are unable to obtain additional distributors and our current and future distributors do not market our products successfully, we may not generate significant revenues or become profitable.

We have limited marketing and sales capability. We are dependent upon existing and, possibly future, marketing agreements and third party distribution agreements for our products in order to generate significant revenues and become profitable. As a result, any revenues received by us will be dependent in large part on the efforts of third parties, and there is no assurance that these efforts will be successful.

Our commercialization strategy for Ampligen® for CFS, if and when it is approved for marketing and sale by the FDA, may include licensing/co-marketing agreements utilizing the resources and capacities of a strategic partner(s). We continue to seek 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/reagent suppliers for Ampligen® and Alferon®. If we are unable to obtain the required raw materials/Reagents and/or services, we may not be able to manufacture Ampligen® and Alferon®.

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 and abroad available to provide the raw and packaging materials/reagents for use in manufacturing Ampligen® and Alferon®. At present, we do not have any agreements with third parties for the supply of any of these materials or we are relying on a limited source of reagent suppliers necessary for the manufacture of Alferon®. 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 July 2016, we reached an agreement with Avecia to serve as an additional contract manufacturer of Ampligen® for use with clinical studies as well as the recently initiated Early Access Program (EAP) in Europe and Turkey. We believe that we have sufficient quantities of Ampligen® to meet our limited near term projected needs until we start receiving product from Avecia. Should there be an unanticipated delay in receiving new product from Avecia or should we experience an unexpected demand for Ampligen® in our clinical studies or pursuant to the EAP, our ability to supply Ampligen® most likely will be adversely affected. Although the Company has engaged Avecia, we will continue to work towards an amended agreement with Hollister-Stier.

In addition, 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 reagent used in the formulation of Alferon®. We have substantially resolved these issues through engaging in multiple agreements with suppliers of leukocytes as well as entering into a licensing agreement with a foreign multinational chemicals and biotechnology company that has been in business for over a century for the sourcing of the primary reagent allowing us to manufacture Alferon®. 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 were working diligently to make the necessary repairs to be able to restart the validation process; however, in the process of obtaining time estimates for the repairs we experienced a flood within portions of our manufacturing facility. As a result, we will be constrained in our ability to manufacture product in the near future due to this flood in the upstream processing cleanroom that contains the bioreactor. The flood occurred on the afternoon of January 5, 2016, caused by a malfunctioning water supply pipe for the sprinkler system covering a large amount of the cleanroom in stagnant water and silt from the sprinkler system. Our facility insurer has been proactive in addressing and covering the loss. While repairs have required preapproval by our insurer, activity moved forward quickly. The repairs noted below required special action because of the need to keep this critical manufacturing room within International Organization for Standardization (ISO) classifications and the need to certify that all the equipment that was exposed, or submerged, is in proper condition and operating effectively following the corrective actions. All HEPA filters affected by the flood were tested by an outside contractor and have passed all required tests. The flooring that was damaged has been repaired using a special epoxy that is used in cleanrooms. A large portion of the walls in the ISO classified area were damaged. We had a damage mitigation company come in to stop any moisture from seeping further into the ISO classified areas. Subsequently, all damaged walls and ceilings have been replaced with cleanroom grade materials and need no further work. Six pumps that were affected by the flood were sent back to the manufacturer for inspection and repair. Repairs that were required have been completed on the pumps and they were reinstalled in the Alferon manufacturing facility after the floor repair work was completed. All pumps will need to be qualified for use in the manufacturing process prior to the validation process for a Pre-Approval Inspection. All air ducts supplying the Alferon manufacturing area were cleaned and insulation replaced along with ceiling tiles. All smaller pieces of machinery and equipment that could not be salvaged have been replaced. We also completed the HVAC air balancing and qualification. At this time, we believe that all repairs to the manufacturing facility have been completed.

Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. 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.

If we are unable to obtain or manufacture the required materials/reagents, 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®. We are in discussion with Hollister-Stier about this purchase commitment. In July 2016, we reached an agreement with Avecia to serve as an additional contract manufacturer of Ampligen® for use with clinical studies as well as the recently initiated Early Access Program (EAP) in Europe and Turkey. Avecia should be able to meet our immediate requirements. We believe that we have sufficient quantities of Ampligen® to meet our limited near term projected needs until we start receiving product from Avecia. Should there be an unanticipated delay in receiving new product from Avecia or should we experience an unexpected demand for Ampligen® in our clinical studies or pursuant to the EAP, our ability to supply Ampligen® most likely will be adversely affected.

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 or return to commercial, large-scale production.

We completed the construction of our $8 million facility enhancement project in 2015 which, upon FDA approval, 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.

Our ability to manufacture at our manufacturing facility was also hampered and delayed by the damage resulting from the flood in January 2016. See Part 1, Item II: “Management's Discussion and Analysis of Financial Condition and Results of Operations Business; “Marketing”.

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

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

Changes in methods of manufacturing, including commercial scale-up, may affect the chemical structure of Ampligen® and other RNA drugs, as well as their safety and efficacy. The transition from limited production of pre-clinical and clinical research quantities to production of commercial quantities of our products will involve distinct management and technical challenges and may require additional management, technical personnel and capital to the extent such manufacturing is not handled by third parties. While we believe that the Company could successfully upgrade our production capability at our New Brunswick, NJ facility in a commercial scale-up of Ampligen®, there can be no assurance that our manufacturing will be successful or that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards, economically, and in commercial quantities, or successfully marketed.

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

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

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

In furtherance of the capital improvement program at our New Brunswick, NJ facility to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API, the validation phase of the Alferon® manufacturing project is currently underway. 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 risk factor “We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents" above for additional information.

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

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

Ampligen®. We believe that Ampligen® has been generally well tolerated with a low incidence of clinical toxicity, particularly given the severely debilitating or life threatening diseases that have been treated. A mild flushing reaction has been observed in approximately 15-20% of patients treated in our various studies. This reaction is occasionally accompanied by a rapid heartbeat, a tightness of the chest, urticaria (swelling of the skin), anxiety, shortness of breath, subjective reports of “feeling hot”, sweating and nausea. The reaction is usually infusion-rate related and can generally be controlled by reducing the rate of infusion. Other adverse side effects include liver enzyme level elevations, diarrhea, itching, asthma, low blood pressure, photophobia, rash, visual disturbances, slow or irregular heart rate, decreases in platelets and white blood cell counts, anemia, dizziness, confusion, elevation of kidney function tests, occasional temporary hair loss and various flu-like symptoms, including fever, chills, fatigue, muscular aches, joint pains, headaches, nausea and vomiting. These flu-like side effects typically subside within several months.

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

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

Alferon N Injection®. At present, Alferon N Injection® is 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 could hurt our chances for success.

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers. The loss of the services of personnel key to our operations could have a material adverse effect on our operations and chances for success. The loss of 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 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 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.

We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate public disclosure of confidential or proprietary information, we could incur liability and our product development and commercialization efforts could be delayed.

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 months ended September 30, 2016, the trading price of our common stock has ranged from $2.64 to $0.84 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

Our stock price may be adversely affected if a significant amount of shares is 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 securities for public sale pursuant to a universal shelf registration statement and we had been selling shares under this shelf registration statement and the EDA with Maxim. Effective December 15, 2015, we halted all future offers and sales of our Common Stock under the EDA with Maxim and reduced the amount of potential future offers and sales under the EDA to $0.00. Between July 23, 2012, the date of the EDA, and December 15, 2015, we sold an aggregate of 8,881,788 shares of Common Stock pursuant to the EDA for aggregate gross proceeds of $47,453,220. On December 15, 2015, we filed a prospectus supplement related to the issuance and sale of up to $7,941,000 of our common stock from time to time through our sales agent, Chardan Capital Markets, LLC. Effective August 26, 2016, the Company halted all future offers and sales of its common stock under the Chardan Agreement and reduced the amount of potential future offers and sales under the Chardan Agreement to $0.00. Between December 15, 2015, the date of the Chardan Agreement, and August 26, 2016, we sold an aggregate of 114,394 shares of common stock pursuant to the Chardan Agreement for aggregate gross proceeds of approximately $180,000. On September 6, 2016, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain investors for the sale by us of 3,333,334 shares of our common stock at a purchase price of $1.50 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate net proceeds of $4,520,000. We also issued placement agent warrants for the purchase of an aggregate of 166,667 shares of our common stock. Please see Part I, Item II - Management’s Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources” above for more information.

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 Chardan or otherwise under the universal shelf registration statement or upon exercise of outstanding options and warrants, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

Provisions of our Certificate of Incorporation and Delaware law may make it more difficult for someone to acquire control of us or for our stockholders to remove existing management, and might discourage a third party from offering to acquire us, even if a change in control or in Management would be beneficial to our stockholders. For example, our Certificate of Incorporation allows us to issue shares of preferred stock without any vote or further action by our stockholders. Our Board of Directors has the authority to fix and determine the relative rights and preferences of preferred stock. Our Board of Directors also has the authority to issue preferred stock without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In this regard, on November 2, 2012, we amended and restated our Stockholder Rights Plan (“Rights Plan”) and, under the Rights Plan, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right initially entitles holders to buy one-hundredth unit of preferred stock for $30.00 and may be redeemed prior to November 19, 2017, the expiration date, at $0.001 per Right under certain circumstances. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock.

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

Aside from the sale of the Warrants to purchase 2,500,000 shares of our Common Stock and the Placement Agent Warrants to purchase an aggregate of 166,667 shares of our Common Stock in the transactions pursuant to the September 6, 2016, Securities Purchase Agreement with certain investors, we did not have any unregistered sales nor repurchase any of our securities during the nine months ended September 30, 2016. Please see Part I, Item II - Management's Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources" above for more information.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

None.

ITEM 6: Exhibits

(a) Exhibits

1.1	Engagement Letter, dated as of August 26, 2016 by and between Hemispherx Biopharma, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC. (1)
4.1	Form of Investor Common Stock Purchase Warrant issued on September 6, 2016. (1)
10.1	Form of Securities Purchase Agreement dated August 30, 2016 with the Company and certain investors. (1)
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, 2016 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)	Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 1-13441) filed September 1, 2016 and is hereby incorporated by reference.

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/ Thomas K. Equels
Thomas K. Equels, Esq.
Chief Executive Officer & President

/s/ Adam Pascale
Adam Pascale
Chief Financial Officer

Date: November 14, 2016