HEMISPHERX BIOPHARMA INC
Form 10-Q
November 14, 2017

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, 2017

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.)

860 N. Orange Avenue, Suite B, Orlando, FL 32801

(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
[ ] Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards pursuant to Section 13(a) of the Exchange Act. [ ]

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

31,761,221shares of common stock were outstanding as of November 1, 2017.

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, 2017 (Unaudited)	December 31, 2016 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 503	$ 2,408
Marketable securities	1,800	3,460
Accounts receivable	42	-
Assets held for sale	764	764
Prepaid expenses and other current assets	626	309
Total current assets	3,735	6,941
Property and equipment, net	8,795	9,514
Patent and trademark rights, net	860	872
Other assets	1,335	1,546
Total assets	$ 14,725	$ 18,873
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 460	$ 887
Accrued expenses	1,740	1,548
Total current liabilities	2,200	2,435
Long- term		
Note payable	1,466	-
Redeemable warrants	1,018	940
Commitments and contingencies (Note 6 and Note 13)		
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 31,077,372 and 24,202,921, respectively	31	24
Additional paid-in capital	316,748	315,980
Accumulated other comprehensive income (loss)	29	(5)
Accumulated deficit	(306,767)	(300,501)
Total stockholders' equity	10,041	15,498
Total liabilities and stockholders' equity	$ 14,725	$ 18,873

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,	
	2017	2016	2017	2016
Revenues:				
Clinical treatment programs - US	$4	$22	$101	$76
Clinical treatment programs - Europe	86	—	286	—
Total revenues	90	22	387	76
Costs and expenses:				
Production costs	399	272	887	830
Research and development	787	1,342	3,284	3,244
General and administrative	1,556	1,634	4,839	5,721
Total costs and expenses	2,742	3,248	9,010	9,795
Operating loss	(2,652)	(3,226)	(8,623)	(9,719)
Interest expense and other finance costs	(51)	—	(70)	—
Interest and other income/expense	13	40	60	156
Redeemable warrants valuation adjustment	1,438	103	2,361	103
Insurance proceeds from legal settlement, net	—	190	—	1,626
Gain (Loss) on sales of short term marketable securities	—	31	6	(56)
Gain from sale of income tax net operating losses and research credits	—	—	—	1,561
Net loss	(1,252)	(2,862)	(6,266)	(6,329)
Other comprehensive income (loss):				
Reclassification adjustments for loss on sales of short term marketable securities included in net loss	—	(31)	(6)	56
Unrealized gain on marketable securities	11	15	40	112
Net comprehensive loss	$(1,241)	$(2,878)	$(6,232)	$(6,161)
Basic and diluted loss per share	$(0.04)	$(0.13)	$(0.23)	$(0.30)
Weighted average shares outstanding, basic and diluted	30,096,500	21,832,940	27,598,715	21,046,418

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, 2017

(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, 2016	24,202,921	$ 24	$315,980	$ (5)	$ (300,501)	$ 15,498
Equity-based compensation	446,753	—	286	—	—	286
Issuance of redeemable warrants	—	—	(2,050)	—	—	(2,050)
Deemed dividends	—	—	(388)	—	—	(388)
Common stock issuance, net of costs	4,646,205	5	2,175	—	—	2,180
Common stock issued for accounts payable	1,781,493	2	745	—	—	747
Net comprehensive income (loss)	—	—	—	34	(6,266)	(6,232)
Balance at September 30, 2017	31,077,372	$ 31	$316, 748	$ 29	$ (306,767)	$ 10,041

See accompanying notes to consolidated financial statements.

HEMISPHERX BIOPHARMA, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

For the Nine Months Ended September 30, 2017 and 2016

(in thousands)

(Unaudited)

	2017	2016
Cash flows from operating activities:		
Net loss	$ (6,266)	$ (6,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property and equipment	739	854
Amortization of Debt Issuance Costs	13	-
Redeemable warrants valuation adjustment	(2,361)	(103)
Amortization and abandonment of patent and trademark rights	48	125
Equity-based compensation	286	344
Realized gain(loss) on sale of marketable securities	(6)	56
Change in assets and liabilities:		
Accounts receivable	(42)	—
Prepaid expenses and other current assets	(317)	(224)
Other assets	211	—
Accounts payable	174	(202)
Accrued expenses	340	201
	(7,181)	(5,278)

Net cash used in operating activities		
Cash flows from investing activities:		
Sale of marketable securities	1,699	3,371
Purchase of property, equipment and construction in progress	(20)	(160)
Lease deposit refund	—	14
Additions to patent and trademark rights	(36)	(282)
Net cash provided by investing activities	1,643	2,943
Cash flows from financing activities:		
Payments on capital leases	—	(1)
Debt issuance costs	(90)	—
Proceeds from note payable	1,543	—
Proceeds from sale of stock, net of issuance costs	2,180	4,694
Net cash provided by financing activities	3,633	4,693
Net increase (decrease) in cash and cash equivalents	(1,905)	2,358
Cash and cash equivalents at beginning of period	2,408	2,115
Cash and cash equivalents at end of period	$ 503	$ 4,473
Supplemental disclosures of non-cash investing and financing cash flow information:		
Unrealized gain on marketable securities	$ 40	$ 112
Insurance proceeds from legal settlement	—	$ 1,626
Stock issued for accrued expenses	$ 747	$ —

Fair value of redeemable warrants granted	$	2,050	$	2,617

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 two domestic subsidiaries: BioPro Corp. and BioAegean Corp., both 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.

The Company has incurred numerous years of substantial operating losses as it pursued its clinical and pre-clinical development activities and appropriate regulatory approval processes before any such products can be sold and marketed. As of September 30, 2017, our accumulated deficit was $306,767,000. The Company has not yet generated significant revenues from our products and may incur substantial losses in the future. The Company evaluated these conditions and events that may raise substantial doubt about the Company's ability to continue as a going concern; however, the Company believes that it has alleviated the substantial doubt by implementing certain actions. The Company reexamined its fundamental priorities in terms of direction, corporate culture and its ability to fund operations. As a result, there were significant changes at the Company including the Company restructuring its executive management team, initiating the pursuit of international sales of clinical grade materials, and implementing a cost saving program which assisted the Company in gained efficiencies and eliminated redundancies within its workforce. In addition, the Company is in the process of selling an underutilized building adjacent to its New Jersey manufacturing facility site. Also, the Company is 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 drugs and our approved drug Alferon N®. Lastly, the Company plans to access the public equity markets to raise further capital.

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, 2016 and 2015, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016.

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 5,970,948 and 2,561,299 for the three months ended September 30, 2017 and 2016 , respectively; and 9,392,453 and 4,129,215 shares for the nine months ended September 30, 2017 and 2016, respectively, are excluded from the calculation of diluted net loss per share since their effect is anti-dilutive. Due to the exchange of warrants described in Note 8(b), the number of equivalent warrants decreased in the three months ended September 30, 2017.

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 1,340,672 and 247,917 options and equity warrants granted in the nine months ended September 30, 2017 and 2016, respectively.

Stock option for employees' activity during the nine months ended September 30, 2017 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, 2017	836,256	$ 16.82	4.47	$ —
Granted	584,795	0.50	—	—
Forfeited	(208,382)	34.09	—	—
Outstanding September 30, 2017	1,212,669	$ 5.98	7.14	$ —
Vested and expected to vest September 30, 2017	1,212,669	$ 5.98	7.14	$ —
Exercisable September 30, 2017	747,788	$ 8.25	4.96	$ —

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	90,625	$ 1.72	9.33	$ —
Granted	584,795	0.50	—	—
Vested	(210,539)	1.05	—	—
Forfeited	—	—	—	—
Outstanding September 30, 2017	464,881	$ 0.49	9.86	$ —

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, 2017	271,500	$ 10.41	4.66	$	—
Granted	605,877	0.42	—		—
Exercised	—	—	—		—
Forfeited	(40,313)	19.67	—		—
Outstanding September 30, 2017	837,065	$ 2.73	6.93	$	—
Vested and expected to vest September 30, 2017	837,065	$ 2.73	6.93	$	—
Exercisable September 30, 2017	278,775	$ 7.34	5.00	$	—

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding January 1, 2017	26,389	$ 1.65	8.61	$ —
Granted	605,877	0.42	—	—
Vested	(71,198)	0.82	—	—
Forfeited	(2,778)	1.56	—	—
Outstanding September 30, 2017	558,290	$ 0.42	7.82	$ —

The impact on the Company's results of operations of recording equity-based compensation for the nine months ended September 30, 2017 and 2016 was to increase costs and expenses by approximately $286,000 and $344,000, respectively, which decreased earnings per share by $0.01 and $0.02 for September 30, 2017 and 2016, respectively.

As of September 30, 2017 and 2016, respectively, there was $537,000 and $332,000 of unrecognized equity-based compensation cost related to options granted under the Equity Incentive Plan.

In January 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 of 140,936 incentive shares associated with the Plan and recorded $219,000 in equity-based compensation. There were no incentive shares issued during the nine months ended September 30, 2017.

Effective with the semi-monthly period ended April 30, 2017, all of the members of the Company's Board of Directors agreed to accept 100% of their directors' fees in the form of options to purchase Company Common Stock. This program was terminated as of August 31, 2017. In this regard, options to purchase 355,772 shares of Company common stock were issued with exercise prices ranging from $0.36 to $0.67, a holding period of 10 years and vesting

over three years. In addition, commencing with the semi-monthly period ended June 15, 2017, certain officers of the Company and certain other employees of the Company, agreed to accept 20% of their salary in options to purchase Company Common Stock. This program was also terminated as of August 31, 2017. In this regard, options to purchase 284,795 shares of Company common stock were issued with exercise prices ranging from $0.36 to $0.49, a holding period of 10 years and vesting over three years.

As part of the cash conservation program adopted in August 2017, starting with the month of September 2017, the salaries of all the employees of the Company were paid 50% in the form of unrestricted common stock of the Company. The number of shares issued, in September 2017, to the employees under this program were 408,072 shares at stock prices ranging from $0.34 to $0.38 per share. These shares include a $3,000 bonus paid in shares to each employee to help defray any future losses. This program will continue until discontinued by the Board of Directors

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, 2017	December 31, 2016
Inventory work-in-process, January 1	$—	$ 1,326
Production	—	—
Transfer to other assets	—	(1,326)
Spoilage	—	—
Inventory work-in-process, end of period	$—	$ —

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 will continue the validation of Alferon® production and production of new Alferon® API inventory when funding becomes available. 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-In-Process inventory to other assets within the Company's balance sheet. The Alferon® Work-In-Process inventory included an initial payment for fill and finish of $211,000. The Company believes that the benefits from this initial payment will no longer be realized and decided to expense it in the current period.

Note 5: Marketable Securities

Marketable securities consist of mutual funds. For the nine months ended September 30, 2017 and 2016, it was determined that none of the marketable securities had other-than-temporary impairments. At September 30, 2017 and December 31, 2016, 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, 2017

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 1,771	$ 30	$ (1)	$1,800	$ 1,800	$ —
Totals	$ 1,771	$ 30	$ (1)	$1,800	$ 1,800	$ —

December 31, 2016

(in thousands)

Securities	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	$ 3,465	$ —	$ (5)	$3,460	$ 3,460	$ —
Totals	$ 3,465	$ —	$ (5)	$3,460	$ 3,460	$ —

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, 2017

(in thousands)

	Total	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Number In Loss Position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$402	$ (1)	$ -	$ -	$402	$ (1)
Totals	1	$402	$ (1)	$ -	$ -	$402	$ (1)

December 31, 2016

(in thousands)

	Total	Less Than 12 Months		12 Months or Greater		Totals	
Securities	Number In Loss Position	Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	1	$1,853	$ (13)	$ -	$ -	$1,853	$ (13)
Totals	1	$1,853	$ (13)	$ -	$ -	$1,853	$ (13)

Note 6: Accrued Expenses

Accrued expenses consist of the following:

	(in thousands)	
	September 30, 2017	December 31, 2016
Compensation	$330	$ 297
Professional fees	456	604
Clinical trial expenses	375	158
Other expenses	579	489
	$1,740	$ 1,548

Note 7: Property and Equipment

	(in thousands)	
	September 30, 2017	December 31, 2016
Land, buildings and improvements	$10,547	$ 10,530
Furniture, fixtures, and equipment	5,625	5,630
Total property and equipment	16,172	16,160
Less: accumulated depreciation and amortization	(7,377)	(6,646)
Property and equipment, net	$8,795	$ 9,514

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. The Company also reclassified an underutilized building as an asset held for resale totaling $764,000 adjacent to its New Jersey manufacturing facility site that it is in the process of selling.

Note 8: Stockholders' Equity

(a) Preferred Stock

The Company is authorized to issue 5,000,000 shares of $0.01 par value preferred stock with such designations, rights and preferences as may be determined by the Board of Directors. There were no Preferred Shares issued and outstanding as of September 30, 2017 and December 31, 2016.

(b) Common Stock.

The Company's stockholders approved an amendment to the Company's corporate Charter at the Annual Shareholder Meeting held in Philadelphia, PA that concluded in December 2011. This amendment increased the Company's authorized shares from 200,000,000 to 350,000,000 with specific limitations and restrictions on the usage of 75,000,000 of the 150,000,000 newly authorized shares.

In September 2015, the Company's stockholders removed the limitations and restrictions on 67,000,000 shares. The Company's stockholders approved up to an additional 60,000,000 shares for use in capital raising transactions and 7,000,000 shares for use in the Equity Plan of 2009. In August 2016, the Company effected a 12 to 1 reverse stock split of the outstanding shares, in order to become compliant with the NYSE regulations. This did not affect the number of authorized shares.

In September 2016, the Company entered into Securities Purchase Agreements with certain investors for the sale by the Company of 3,333,334 shares of its common stock at a purchase price of $1.50 per share and sold warrants to purchase 2,500,000 shares of Common Stock for aggregate net proceeds of $4,520,000 after deducting certain fees due to the placement agent and the Company's transaction expenses. Subject to certain ownership limitations, the warrants were 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.

In June 2017, pursuant to an offer to the holders of the foregoing warrants (the "Exchange Transaction"), the exercise price of the foregoing warrants was changed to $0.50. As a result the warrant holders exercised these warrant and purchased 2,370,000 shares of company common stock. As part of the Exchange Transaction, the Company issued 2,370,000 series A warrants with an exercise price of $0.60 per share, an initial exercise date of December 1, 2017 and

expiring March 6, 2022 and 7,584,000 series B warrants with an exercise price of $0.60, an initial exercise date December 1, 2017 per share and expiring March 1, 2018. The Company received net proceeds from the foregoing transaction of approximately $1,055,000, after deducting certain fees due to the placement agent and the Company's transaction expenses. In July 2017, the warrant holders exercised the remaining 130,000 warrants issued in September 2016 and purchased 130,000 shares of common stock. The Company realized additional net proceeds of $65,000 from this exercise. In conjunction with the foregoing the Company issued an additional 130,000 series A warrants and 416,000 series B warrants (with an exercise price of $0.60 and an initial exercise date January 10, 2018 on the three month anniversary of the of the initial exercise date).The net proceeds received by the Company from these offerings will be used for preparation for technology transfer opportunities, expenses related to Ampligen® manufacturing, working capital and general corporate purposes.

Pursuant to an engagement agreement, the Company paid its placement agent an aggregate fee equal to 7% and 10.5%, respectively, of the gross proceeds received by the Company from the sale of the securities in the offerings and granted to its placement agent or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions amounting to 166,667 and 107,759, respectively, unregistered warrants. The placement agent warrants have substantially the same terms as the investor warrants, except that the 166,667 placement agent warrants will expire September 1, 2021 and have an exercise price equal to $1.875 per share of common stock and the 107,759 placement agent warrants will expire June 1, 2022 and have an exercise price of $0.625.

In August 2017, the Holders of the series A warrants and series B warrants exchanged all of their warrants for new warrants (respectively, the "Series A Exchange Warrants" and the "Series B Exchange Warrants" and, collectively, the "Exchange Warrants") identical to the series A warrants and series B warrants except as follows: the exercise price of both Exchange Warrants is $0.45 per share, subject to adjustment therein, and the number of Series B Exchange Warrants issued was proportionately reduced so that all Exchange Warrants in the Exchange Transaction do not exceed 19.9% of the number of the Company's issued and outstanding shares of Common Stock as of May 31, 2017, the date of the Exchange Transaction offer letters. The issuance of the Exchange Warrants by the Company and the shares of Common Stock issuable upon exercise of the Exchange Warrants is exempt from registration pursuant to Sections 3(a)(9) and 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act").

In February 2017, the Company entered into Securities Purchase Agreements (each, a "February Purchase Agreement") with certain investors for the sale by us of 1,818,185 shares of its common stock at a purchase price of $0.55 per share. Concurrently with the sale of the common stock, pursuant to the February Purchase Agreement, the Company also sold unregistered warrants to purchase 1,363,639 shares of common stock for aggregate net proceeds of approximately $875,000. The warrants have an exercise price of $0.75 per share, are exercisable six months after issuance, and will expire five years from the initial exercise date. Pursuant to an engagement agreement, the Company paid its placement agent 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 its placement agent or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions amounting to 90,910 unregistered warrants. The placement agent warrants have substantially the same terms as the investor warrants, except that the placement agent warrants will expire on February 1, 2022 and have an exercise price equal to $0.6875 per share of common stock.

The common stock issued in the above referenced September 6, 2016 and February 1, 2017 offerings were offered and sold by the Company pursuant to an effective shelf registration statement on Form S-3, which was initially filed with the SEC in June 2015 and subsequently declared effective on August 4, 2015 (Registration No. 333-205228) and the base prospectus dated as of August 4, 2015 contained therein. The Company filed a prospectus supplements related to these offerings with the SEC on September 1, 2016 and February 3, 2017, respectively, in connection with the sale of the common stock. The common stock issued pursuant to the above June 1, 2017 exercise of warrants were issued pursuant to an effective registration statement on Form S-1, which was initially filed with the SEC in May 2017 as subsequently amended and declared effective on May 23, 2017 (Registration No. 333-217671) and the prospectus supplement filed with the SEC on May 23, 2017.

The Equity Incentive Plan of 2009, effective June 24, 2009, as amended and giving effect to the 12 to 1 reverse stock split, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 22,000,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. Unless sooner terminated, the Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date. For the nine months ended September 30, 2017, there were 1,190,672 options granted by the Company.

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 is currently evaluating the impact of adopting this guidance on the Company's financial statements.

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 allows 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. 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 will not have a material impact on the Company's financial statement presentation or disclosures.

In 2017, the FASB also issued Accounting Standards Updates ("ASU") 2017-01 through 2017-13. 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, 2016, the Company has approximately $174,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2036) 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 $8,000,000 of New Jersey state net operating loss carryforwards (expiring in 2036) 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. In December 2016, the Company effectively sold $14,000,000 of its New Jersey state net operating loss carryforward for the year 2015 for approximately $1,120,000, and also sold New Jersey research and development credits for $189,000. The utilization of certain state net operating loss carryforwards 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 ("Warrants") related to the Company's August 2016, February 2017, June 2017 and August 2017 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, 2017	December 31, 2016
Underlying price per share	$ 0.32	$0.69-$1.26
Exercise price per share	1.88	1.88 - 2.00
Risk-free interest rate	1.76 %	1.86 %

Expected holding period	3.9		4.70	
Expected volatility	75	%	85	%
Expected dividend yield	-		-	

The Company utilized the following assumptions to estimate the fair value of the February 2017 Warrants:

	September 30, 2017		February 1, 2017	
Underlying price per share	$0.32		$0.64	
Exercise price per share	0.69-0.75		0.69-0.75	
Risk-free interest rate	1.82	%	1.86%-1.93	%
Expected holding period	4.3		5.00	
Expected volatility	70%-75	%	80%-85	%
Expected dividend yield	-		-	

The Company utilized the following assumptions to estimate the fair value of the June 2017 Warrants:

	September 30, 2017	June 1, 2017
Underlying price per share	$ 0.32	$0.53
Exercise price per share	0.63	0.60-0.63
Risk-free interest rate	1.87 %	1.11%-1.76%
Expected holding period	4.7	.7-5
Expected volatility	70 %	80 %
Expected dividend yield	-	-

The Company utilized the following assumptions to estimate the fair value of the August 2017 Warrants:

	September 30, 2017	August 23, 2017
Underlying price per share	$0.32	$0.37
Exercise price per share	0.45	0.45
Risk-free interest rate	1.15%-1.83%	1.11%-1.69%
Expected holding period	0.4-4.4	0.5-4.5
Expected volatility	70 %	70 %
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;
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 $1,018,000 at September 30, 2017 and 940,000 at December 31, 2016.

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 2017, 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, 2017			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable securities	$1,800	$1,800	$ -	$-
Liabilities:				
Redeemable warrants	$1,018	-	-	$1,018

	(in thousands) As of December 31, 2016			
	Total	Level 1	Level 2	Level 3
Assets:				
Marketable Securities	$3,460	$3,460	$ -	$-
Liabilities:				
Redeemable warrants	$940	-	-	$940

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

Balance at December 31, 2016	$940
Issuance of warrants	2,074

Modification of warrants	389
Fair value adjustments	(2,385)
Balance at September 30, 2017	$1,018

Note 13: Note Payable

In May 2017, the Company entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by the property and assets located at 783 Jersey Ave., New Brunswick, New Jersey. Subject to the lender's approval, the Company will be able to request up to $1,800,000 of the line in monthly advances during the loan term of 24 months. The Company will be able to request future advances in excess of $2,000,000 at the lender's discretion and be payable in full upon maturity. The Company will pay interest on this note at a fixed rate of 12% per annum for the first 18 months and change to a rate equal to 800 basis points above the prime rate of interest during the remainder of the term; however, the interest rate will not be less than 12% for the entire term. The note will be interest only and payable monthly through the maturity. The Company is permitted to prepay the line without penalty commencing after six months. The balance on the note at September 30, 2017 is $1,466,000 ($1,543,000 less unamortized deferred finance costs of $77,000).

Note 14: Subsequent Events

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.

The Company entered into a sale agreement on September, 11, 2017 for the sale of its property located at 5 Jules Lane, New Brunswick, New Jersey for $1,050,000. This transaction is expected to close within two weeks. The Company has recorded this property as an asset held for sale.

The Company has also completed the process for the sale of its 2016 New Jersey Net Operating Loss. The Company expects to collect $820,000 when this sale is completed.

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 as we will need additional funding to proceed with our objectives, 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 our New Brunswick, New Jersey facility. We have disclosed that in February 2013, we received a Complete Response from the U.S. Food and Drug Administration (the “FDA”) declining to approve our Ampligen® New Drug Application (“NDA”) for Chronic Fatigue Syndrome Treatment, sometimes referred to as myalgic encephalomyelitis/chronic fatigue syndrome (“ME/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 ME/CFS, as noted above, 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 in the United States.

We also have disclosed that, in August 2016, we received approval of our 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 ME/CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. 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 as discussed below and underway in Europe in pancreatic cancer. 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 we most likely will need additional funds to manufacture product at a sufficient level for a commercial launch. 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. Approval of rintatolimod for ME/CFS in the Argentine Republic does not in any way suggest that the Ampligen® NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

We also have disclosed that, in January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program. No assurance can be given that Ampligen® will prove effective in the treatment of pancreatic cancer.

In June 2017, we signed an amendment to the EAP with myTomorrows. This amendment is for MyTomorrows to provide support services to Hemispherx with respect to the execution of the 511-Program ("511-Services"). The 511-Services shall be rendered for a period of 6 months to be renewed with additional 6 month periods with written mutual consent, or until termination of the 511-Program. The 511-Services shall be rendered free of charge.

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen® in the United States and abroad as well as seeking to broaden commercial therapeutic indications for Alferon N Injection® presently approved in the United States and Argentina. We continue to pursue 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 commercialize our products, widen commercial therapeutic indications of Alferon N Injection® and/or capitalize on our collaborations with research laboratories to examine our products are subject to a number of significant risks and uncertainties including, but not limited to our ability to enter into more definitive agreements with some of the research laboratories and others that we are collaborating with, to fund and conduct additional testing and studies, whether or not such testing is successful or requires additional testing and meets the requirements of the FDA and comparable foreign regulatory agencies. We do not know when, if ever, our products will be generally available for commercial sale for any indication.

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

The production of new Alferon® API inventory will not commence until the validation phase is complete. While the facility is approved by FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed by a successful Pre-Approval Inspection by the FDA prior to commercial sale of newly produced inventory product. If and when the Company obtains a reaffirmation of FDA BLA status and has begun production of new Alferon® API, it will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. We 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.

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 first formed in 1966 and in the early 1970s were 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 two domestic subsidiaries BioPro Corp., and BioAegean Corp., both 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.

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.

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

We own and operate a 30,000 sq. ft. facility in New Brunswick, NJ with the objective of producing Alferon® and Ampligen® upon FDA approval. 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.

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

We have taken significant actions to focus on our business and management and reserve capital so the Company can better achieve its commercial goals, including, but not limited to, a strict anti-nepotism policy, listing for sale underutilized assets, 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 drugs and our approved drug Alferon N Injection®.

We have relocated our principal executive office to 860 N. Orange Avenue, Suite B, Orlando, FL 32801, and we are in process of moving our Finance and Administration office within the Philadelphia area. The telephone number for our executive office is (407) 839-0095 and for our Finance & Administration office is 215-988-0080

OUR PRODUCTS

Our primary pharmaceutical product platform consists of our experimental compound, Ampligen®, and our FDA approved natural interferon product, Alferon N Injection®.

Ampligen®

Ampligen® is approved for 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 in the United States, that is administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I):poly(C_{12}U).

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

In February 2013, we received a CRL from the FDA declining to approve our 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 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 II; Item 1A, Risk Factors: "*We will 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. 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 2015, we 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 October 2016, the FDA granted our request to implement the new cost which was initiated during the quarter ended March 31, 2017. As of September 30, 2017, there are 18 patients participating in this open-label treatment protocol.

In July 2012, we filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT's Orphan Drug regulations. We believe that the approval of Ampligen® as an Orphan Drug may allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for CFS. In August 2016, we received approval of our NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of ME/CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. 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 we most likely will need additional funds to manufacture product at a sufficient level for a commercial launch.

In January 2017, we announced that the EAP through our agreement with myTomorrows designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program.

In June 2017, we signed an amendment to the EAP with myTomorrows. This amendment is for myTomorrows to provide support services to Hemispherx with respect to the execution of the 511-Program ("511-Services"). The 511-Services shall be rendered for a period of 6 months to be renewed with additional 6 month periods with written mutual consent, or until termination of the 511-Program. The 511-Services shall be rendered free of charge.

In August, 2017 we announced that we have commenced full data analysis of an intranasal human safety study of Ampligen® plus FluMist® known as AMP-600. The study was previously closed, but the initiation of full data analysis awaited the FDA's evaluation of preliminary reports of blinded study findings. That evaluation was completed

per formal notification from the FDA in August, 2017. Intranasal Ampligen was generally well-tolerated in the study

In April 2017 we entered into a material transfer agreement with Sanofi Vaccine Technologies, France.

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®.

Other Diseases

In December 2013, we announced that we were supporting the University of Pittsburgh'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., involved the Chemokine Modulatory regimen developed by Dr. Kalinski's group and successfully completed the Phase 1 dose escalation in patients with resectable colorectal cancer. In the 1st quarter of this year, Dr. Kalinski relocated to Roswell Park Cancer Institute (RPCI) in Buffalo, NY. Dr. Kalinski is currently working to establish a cancer program at RPCI which will continue to require a supply of Ampligen®. The cancer protocols utilizing Ampligen® at the University of Pittsburgh have been closed except for the ovarian study for which Dr. Edwards is the investigator. This study of recurrent ovarian cancer patients which includes Ampligen® as a component of the treatment regimen has enrolled 9 patients to date.

In July 2015, we submitted an application for orphan drug designation to the European Medicines Agency (EMA) for Alferon® N to treat MERS and in January 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. In addition, we concluded our 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. Although we believe that the threat of both MERS and Ebola globally may reemerge in the future, it appears that the spread of these disorders has somewhat diminished. As a result, we have elected to focus our research and development efforts on other areas at this time.

In January 2017, we announced that the EAP through our agreement with myTomorrows designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program.

As of September 30, 2017, 29 pancreatic patients have received treatment with single-agent Ampligen® immuno-oncology therapy in an EAP managed by Amsterdam-based myTomorrows, an international leader in providing physician access to experimental medicines.

In July 2017, we entered into a Material Transfer Agreement with Roswell Park Cancer Institute (RPCI) in Buffalo, NY to continue the cancer studies with Dr. Pawel Kalinski and his associates.

Laboratory experiments do not necessarily indicate clinical benefit. Some of the research both past and present has been, and may in the future be, sponsored in part by contracts or grants from us to various independent research entities.

Manufacturing

We had a Supply Agreement with Jubilant Hollister-Stier LLC of Spokane, Washington ("Jubilant"), pursuant to which Jubilant would formulate and package Ampligen® from the key raw materials that Hemispherx would supply to them. This Supply Agreement expired March 11, 2014. In October 2014, we entered into a purchase commitment with Jubilant for approximately $700,000 for the manufacture of batches of Ampligen®. In January 2017, we entered into a purchase order to replace the previous purchase commitment with Jubilant pursuant to which Jubilant will manufacture batches of Ampligen® for us. Pursuant to the new order, Jubilant will perform tooling and validation activities as well as final fill and finish services. The first lot is expected to be manufactured in the first quarter of 2018, once all validation activities are complete.

In July 2016, we reached an agreement with Avrio Biopharmaceuticals, now Nitto Denko Avecia Inc. ("Avecia") to serve as an additional contract manufacturer of our experimental drug, Ampligen®. In May 2017, we filed a complaint against Nitto Avecia Pharma Services, Inc. ("NAPS"), the successor to Avrio Biopharmaceuticals, LLC ("Avrio"), primarily for breach of contract. Please see "Item 1: Legal Proceedings" in Part II and "Risks Associated with Our Business" in Part I, Item 1A. Risk Factors within our 2016 Form 10-K filed with the Securities and Exchange Commission on March 31, 2017.

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. While the facility is approved by the FDA under the 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. Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. We estimate we will need approximately $10,000,000 to commence the manufacturing process. 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, 2017. In addition, due to the high cost estimates to bring the facility back online, we 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.

In May 2017, we entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by our assets and property located at 783 Jersey Ave., New Brunswick, New Jersey. See Note 13- Note payable above for a more complete description of the terms of the note payable.

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 Ajinomoto Althea, Inc., formerly 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. We have paid approximately $211,000 to Althea with regard to this open purchase commitment as of September 30, 2017 and had recorded this amount within Work-In-Process inventory. We believe that the benefits from this initial $211,000 payment will no longer be realized and have expensed it in the current period.

Licensing/Collaborations/Joint Ventures

To maximize the availability of Ampligen® to patients on a worldwide basis, we have embarked on a strategy to license the product and/or to collaborate and/or create a joint venture with companies that have the demonstrated capabilities and commitment to successfully gain approval and commercialize Ampligen® in their respective territories of the world. Ideal partners would have the following characteristics: well established global and regional experience and coverage, robust commercial infrastructure, strong track record of successful development and registration of in-licensed products, as well as a therapeutic area fit (ME/CFS, immuno-oncology. etc.).

Marketing/Distribution

If we are unable to achieve licensing, collaboration and/or joint ventures, our marketing strategy for Ampligen® will be to be part of 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® and Ampligen® during the influenza season in Argentina. In June 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 is 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. In November 2010, we amended our June 14, 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. In May 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 for five years. This was extended in January 2017 for an additional five years until 2022. The receipt of the ANMAT approval for HPV is the first step of a regulatory process towards the commercial sales of Naturaferon®. In September 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. In February 2013, we received the ANMAT approval for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon, with Naturaferon® in Argentina.

In September 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. In July 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. In August 2017 we extended this agreement through August 14, 2019 subject to the same terms and conditions.

In September 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. In July 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. In August 2017, we extended this agreement through August 14, 2019 subject to the same terms and conditions.

In May 2016, we entered into an amended and restated five year agreement (the “Impatients Agreement”) with Impatients, N.V. ("myTomorrows"), a Netherlands based company, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in the Territory, is performing EAP activities. These activities will be directed to (a) the education of physicians and patients regarding the possibility of early access to innovative medical treatments not yet the subject of a Marketing Authorization (regulatory approval) through named-patient use, compassionate use, expanded access and hospital exemption, (b) patient and physician outreach related to a patient-physician platform, (c) the securing of Early Access Approvals (exemptions and/or waivers required by regulatory authorities for medical treatments prior to Marketing Authorization) for the use of such treatments, (d) the distribution and sale of such treatments pursuant to such Early Access Approvals, (e) pharmacovigilance (drug safety) activities and/or (f) the collection of data such as patient-reported outcomes, doctor-reported experiences and registry data. We are supporting these efforts and supplying Ampligen® to myTomorrows at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay myTomorrows a royalty on products sold. Pursuant to the Impatients Agreement, the royalty would be a percentage of Net Sales (as defined in the Impatients Agreement) of Ampligen® sold in the Territory where Marketing Authorization was obtained, and the maximum royalty would be a percentage of Net Sales. The formula to determine the percentage of Net Sales will be based on the number of patients that are entered into the EAP. The Company believes that disclosure of the exact maximum royalty rate and royalty termination date could cause competitive harm. However, to assist the public in gauging these terms, the actual maximum royalty rate is somewhere between 2% and 10% and the royalty termination date is somewhere between 8 and 15 years from the First Commercial Sale of a product within a specific country. The parties established a Joint Steering Committee comprised of representatives of both parties to oversee the EAP. No assurance can be given that activities under the EAP will result in Marketing Authorization or the sale of substantial amounts of Ampligen® in the Territory. In 2017, the Company commenced sales of recently manufactured Ampligen® in international programs.

In January 2017, we announced that the EAP through our agreement with myTomorrows designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program.

In June 2017, we signed an amendment to the EAP with myTomorrows. This amendment is for myTomorrows to provide support services to Hemispherx with respect to the execution of the 511-Program ("511-Services"). The 511-Services shall be rendered for a period of 6 months to be renewed with additional 6 month periods with written mutual consent, or until termination of the 511-Program. The 511-Services shall be rendered free of charge.

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, 2017, the Company did not make any contributions towards the 401(k) Plan.

New Accounting Pronouncements

See **"**Note 10: Recent Accounting Pronouncements".

Disclosure About Off-Balance Sheet Arrangements

None.

Critical Accounting Policies

There have been no material changes in our critical accounting policies and estimates from those disclosed in Part II; Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations; Critical Accounting Policies" contained in our Annual Report on Form 10-K for the year ended December 31, 2016.

RESULTS OF OPERATIONS

Three months ended September 30, 2017 versus three months ended September 30, 2016

Net Loss

Our net loss was approximately $1,252,000 and $2,862,000 for the three months ended September 30, 2017 and 2016, respectively, representing a decrease in loss of approximately $1,610,000 or 56% when compared to the same period in 2016. This decrease in loss for these three months was primarily due to the following:

1) an increase from the redeemable warrant valuation adjustment of $1,335,000;
2) an increase in Ampligen® sales of approximately $68,000; and
3) a decrease in research and development expense of $555,000 or 41%; offset by
4) an increase in production costs of $127,000 or 47% and
5) a decrease in net insurance proceeds of $190,000 received in 2016 but none in 2017,

Net loss per share was $(0.04) and $(0.13) for the three months ended September 30, 2017 and 2016, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2017 was 30,096,500 as compared to 21,832,940 as of September 30, 2016.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $90,000 and $22,000 for the three months ended September 30, 2017 and 2016, respectively. The reason for the increase in revenues of $68,000, an increase of 309%, between periods was primarily due to our EAP through our agreement with myTomorrows designed to enable access of Ampligen® to pancreatic cancer patients in the Netherlands. For the three months ended September 30, 2017 and 2016, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the EAP and our 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 $399,000 and $272,000, respectively, for the three months ended September 30, 2017 and 2016, representing an increase of $127,000 in production costs in the current period. These costs primarily represent stability testing and pre-production expenses related to Alferon®.

In addition, we recorded a charge in the current period of $211,000 related to amounts paid to Althea for costs to fill and finish Alferon® and had recorded these amounts within Work-In-Process inventory. We no longer believe that the benefits from these payments will be realized and have written off the amount in the current period.

Research and Development Costs

Overall Research and Development ("R&D") costs for the three months ended September 30, 2017 were approximately $787,000 as compared to $1,342,000 for the same period a year ago, reflecting a decrease of approximately $555,000 or 41%. The primary reasons for the decrease in research and development costs were due to a decrease in Ampligen® stability and compliance testing of approximately $162,000 for use in the EAP to treat pancreatic cancer patients in the Netherlands, a decrease in AMP 511 costs of approximately $294,000 associated with Ampligen® clinical study work and a decrease in Alferon® related activity of approximately $99,000.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the three months ended September 30, 2017 and 2016, were approximately $1,556,000 and $1,634,000, respectively, reflecting a decrease of approximately $78,000 or 5%. The G&A expenses were essentially flat during the three months ended September 30, 2017 compared to September 30, 2016, reflecting normal operational fluctuations.

Redeemable Warrants

The quarterly fiscal revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the three months ended September 30, 2017 amounting to a higher gain of approximately $1,335,000 (see Part I; Item 1; Financial Statements; "Note 12: Fair Value" for the various factors considered in the valuation of redeemable warrants).

Insurance Proceeds from Legal Settlement

In the three months ended September 30, 2016 insurance proceeds, net of costs, of approximately $190,000 were received from the settlement of litigations. There were no insurance proceeds received in the three months ended September 30, 2017.

Gain (Loss) on Sale of Marketable Securities

There was no gain or (loss) on sale of marketable securities for the three months ended September 30, 2017 as compared to a gain of approximately $31,000 for the three months ended September 30, 2016.

Nine months ended September 30, 2017 versus nine months ended September 30, 2016

Net Loss

Our net loss was approximately $6,266,000 and $6,329,000 for the nine months ended September 30, 2017 and 2016, respectively, representing a decrease in loss of approximately $63,000 or 1.0% when compared to the same period in 2016. This increase in loss for these nine months was primarily due to the following:

1) a decrease in the gain from sale of income tax net operating losses of $1,561,000;
2) a decrease in net insurance proceeds of $1,626,00 received in 2016 but none in 2017;
3) an increase in research and development expense of $40,000 or 1%; offset by,
4) a decrease in general and administrative expense of $882,000 or 15%;
5) an increase in Ampligen® sales of approximately $311,000; and
6) an increase from the redeemable warrant valuation of $2,258,000.

Net loss per share was $(0.23) and $(0.30) for the nine months ended September 30, 2017 and 2016, respectively. The weighted average number of shares of our common stock outstanding as of September 30, 2017 was 27,598,715 as compared to 21,046,418 as of September 30, 2016.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $387,000 and $76,000 for the nine months ended September 30, 2017 and 2016, respectively. The increase in revenues of $311,000, an increase of 409%, between periods was primarily due to our EAP through our agreement with MyTomorrows designed to enable access of Ampligen® to pancreatic cancer patients in the Netherlands. For the nine months ended September 30, 2017 and 2016, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the EAP and our 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 $887,000 and $830,000, respectively, for the nine months ended September 30, 2017 and 2016, representing an increase of $57,000 in production costs in the current period. These costs primarily represent stability testing and pre-production expenses related to Alferon®.

In addition, we recorded a charge in the current period of $211,000 related to amounts paid to Althea for costs to fill and finish Alferon® and had recorded these amounts within Work-In-Process inventory. We no longer believe that the benefits from these payments will be realized and have written off the amount in the current period.

Research and Development Costs

Overall Research and Development ("R&D") costs for the nine months ended September 30, 2017 were approximately $3,284,000 as compared to $3,244,000 for the same period a year ago, reflecting an increase of approximately $40,000 or 1%. The primary reason for the increase in research and development costs was an increase in AMP 511 costs of approximately $245,000 associated with Ampligen® clinical study work. This was offset by a decrease in Alferon® related activity of approximately $192,000.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the nine months ended September 30, 2017 and 2016, were approximately $4,839,000 and $5,721,000, respectively, reflecting a decrease of approximately $882,000 or 15%. The decrease in G&A expenses during the current period was mainly due to a one-time charge of $850,000 in 2016 resulting from a severance payment to a former executive upon termination.

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, 2017 amounting to a higher gain of approximately $2,258,000 (see Part I; Item 1; Financial Statements; “Note 12: Fair Value” for the various factors considered in the valuation of redeemable warrants).

Insurance Proceeds from Legal Settlement

In the nine months ended September 30, 2016 insurance proceeds, net of costs, of approximately $1,626,000 were received from the settlement of litigations. There were no insurance proceeds received in the nine months ended September 30, 2017.

Gain (Loss) on Sale of Marketable Securities

There was a gain (loss) on sale of market securities disclosed a gain of $6,000 for the nine months ended September 30, 2017 as compared to a loss of approximately ($56,000) for the nine months ended September 30, 2016.

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. There was no sale of New Jersey state net operating loss in the nine months ended September 30, 2017.

Liquidity and Capital Resources

As of September 30, 2017, we had approximately $2,303,000 in cash, cash equivalents and marketable securities inclusive of approximately $1,800,000 in Marketable Securities, representing a decrease of approximately $3,565,000 from December 31, 2016. Cash used in operating activities for the nine months ended September 30, 2017 was

approximately $7,181,000 compared to approximately $5,278,000 for the same period in 2016, an increase of $1,903,000 or 36%. The primary reasons for this increase in cash used in operations in 2017 was the receipt of $1,561,000 in funds in 2016 from the sale of our New Jersey state net operating loss carryforwards and $1,626,000 of insurance proceeds for litigation settlements. There were no such receipt of funds in 2017. In addition, prepaid expenses and other current assets increased by approximately $317,000 as compared to the prior period as a result of a deposit paid to our contract manufacturer of approximately $320,000 in 2017.

Cash provided by investing activities for the nine months ended September 30, 2017 was approximately $1,643,000 compared to cash used in investing activities of approximately $2,943,000 for the same period in 2016, representing a decrease of $1,300,000. The primary reason for the decrease was the sale of marketable securities of approximately $1,699,000 during the current period compared to $3,371,000 the nine months ended September 30, 2016.

Cash provided by financing activities for the nine months ended September 30, 2017 was approximately $3,633,000 compared to approximately $4,693,000 for the same period in 2016, a decrease of $1,060,000. The primary reason for this decrease was that we received net proceeds of $2,180,000 from the sale of shares of our common stock and $1,543,000 from a note payable, net of $77,000 debt issuance costs in the current period compared to $4,694,000 from the sale of shares in the corresponding period in 2016.

If we are unable to commercialize and sell Ampligen® 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 high cost estimates to bring the facility back online, we most likely will need additional funds to reach our goals to finance the revalidation process in our facility and to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection and to commercialize our products. However, there is no assurance that such financing will be available.

In an effort to conserve cash, effective with the semi-monthly period ended April 30, 2017, all of the members of the Company's Board of Directors agreed to accept 100% of their directors' fees in the form of options to purchase Company Common Stock. This program was terminated as of August 31, 2017. As of September 1, 2017, the directors agreed to defer 100% of their fees until cash is available.

In addition, commencing with the semi-monthly period ended June 15, 2017, certain officers of the Company, and certain other employees of the Company, agreed to accept 20% of their salary in options to purchase Company Common Stock. This program was also terminated as of August 31, 2017. As of September 1, 2017, certain officers agreed to defer 40% of their salaries until cash is available and all employees agreed to be paid 50% of their salaries in the form of unrestricted common stock of the Company.

We have reexamined our fundamental priorities in terms of direction, corporate culture and our ability to fund operations and have made significant changes at the Company. In February 2016, the former CEO of the Company was terminated and the Board of Directors 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 February 2017, we entered into Securities Purchase Agreements (each, a "Purchase Agreement") with certain investors for the sale by us of 1,818,185 shares of our common stock at a purchase price of $0.55 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 1,363,639 shares of common stock for aggregate net proceeds of approximately $875,000. We also issued placement agent warrants for the purchase of an aggregate of 90,909 shares of our common stock.

In May 2017, we entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by our assets and property located at 783 Jersey Ave., New Brunswick, New Jersey. Subject to the lender's approval, we will be able to request up to $1,800,000 of the line in monthly advances during the loan term of 24 months. We will be able to request future advances in excess of $2,000,000 at the lender's discretion and be payable in full upon maturity. We will pay interest on this note at a fixed rate of 12% per annum for the first 18 months and change to a rate equal to 800 basis points above the prime rate of interest during the remainder of the term; however, the interest rate will not be less than 12% for the entire term. The note will be interest only and payable monthly through the maturity. We are permitted to prepay the line without penalty commencing after six months. The balance on this note is $1,543,000 as of September 30, 2017.

In June 2017, pursuant to an offer (the "Exchange Transaction") to the holders of warrants issued to investors in September 2016 (the "2016 Warrants"), the exercise price of the 2016 warrants was changed to $0.50. As a result the warrant holders exercised 2016 Warrants and purchased 2,370,000 shares of Company common stock. The Company realized net proceeds of $1,055,000 from this exercise. As part of the Exchange Transaction, the Company issued 2,370,000 series A warrants with an exercise price of $0.60 per share, an initial exercise date of December 1, 2017 and expiring March 6, 2022, and 7,584,000 series B warrants with an exercise price of $0.60, an initial exercise date December 1, 2017 per share and expiring March 1, 2018.

In addition, in July 2017, the warrant holders exercised the remaining 130,000 2016 Warrants and purchased 130,000 shares of common stock. The Company realized net proceeds of $65,000 from this exercise. In conjunction with the foregoing the Company issued 130,000 series A warrants with an exercise price of $0.60 per share and an initial exercise date of January 10, 2018 an expiring March 6, 2022, and 416,000 series B warrants with an exercise price of $0.60 and an initial exercise date January 10, 2018 on the three month anniversary of the of the initial exercise date.

In August 2017, the Holders of the series A warrants and series B warrants exchanged all of their series A warrants and series B warrants for new warrants (respectively, the "Series A Exchange Warrants" and the "Series B Exchange Warrants" and, collectively, the "Exchange Warrants") identical to the series A warrants and series B warrants except as follows: the exercise price of both Exchange Warrants is $0.45 per share, subject to adjustment therein, and the number of Series B Exchange Warrants issued was proportionately reduced so that all Exchange Warrants in the Exchange Transaction do not exceed 19.9% of the number of the Company's issued and outstanding shares of Common Stock as of May 31, 2017, the date of the Exchange Transaction offer letters. The issuance of the Exchange Warrants by the Company and the shares of Common Stock issuable upon exercise of the Exchange Warrants is exempt from registration pursuant to Sections 3(a)(9) and 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act").

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 will require additional financing which may not be available*".

The proceeds from our financing have been used to fund infrastructure growth including manufacturing, regulatory compliance and market development along with our efforts regarding the Ampligen® NDA and preparedness for the FDA pre-approval inspections of the New Brunswick manufacturing facility. There can be no assurances that, if needed, we will raise adequate funds from these or other sources, which may have a material adverse effect on our ability to develop our products. Also, we have the ability to curtail discretionary spending, including some research and development activities, if required to conserve cash.

ITEM 3: Quantitative and Qualitative Disclosures About Market Risk

We had approximately $2,303,000 in cash, cash equivalents and marketable securities at September 30, 2017 as compared to $5,868,000 at December 31, 2016.

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

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In designing and evaluating our disclosure controls and procedures, our management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act. Based on that evaluation and the material weaknesses described below our Chief Executive Officer and Chief Financial Officer had concluded that our disclosure controls and procedures were not effective for the September 30, 2017 period. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weakness related to the completeness and accuracy of the recording of the exercise of certain redeemable warrants. Specifically, controls over the recording of the exercise of those warrants were insufficient to ensure that the exercised warrants were properly evaluated. The control deficiency could have result in a misstatement of the Company's retained earnings, additional paid in capital and net income that would not have been prevented or detected.

Changes in Internal Controls

Management has taken the following actions in the current period that materially affect, or are reasonably likely to materially affect, our internal control over financial reporting and to remediate the material weaknesses described above. We will not deem the material weakness remediated until we have two quarters without any errors and have concluded the additional control is effective to mitigate the material weakness.

The Company engaged a third-party subject matter expert to aid in identifying and applying GAAP rules related to complex accounting transactions.

Other than discussed above, there have not been any changes in our internal control over financial reporting during the quarter ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II – OTHER INFORMATION

ITEM 1: Legal Proceedings

In May 2017 Hemispherx filed a complaint in the Philadelphia County Court of Common Pleas Civil Trial Division against Nitto Avecia Pharma Services, Inc. ("NAPS"), the successor to Avrio Biopharmaceuticals, LLC ("Avrio"), primarily for breach of contract. Pursuant to the agreement, Avrio was to provide fill and finish services of Ampligen®. Hemispherx is seeking damages in excess of $650,000 due to Avrio's gross negligence and omissions during the fill and finish process which led to a significant loss of product. In June 2017, NAPS filed an answer denying liability and counter claiming breach of contract by Hemispherx. The litigation is in the early stages and there can be no guarantee that Hemispherx will be successful.

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:

We 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, 2017, we had approximately $2,303,000 in cash, cash equivalents and marketable securities (inclusive of approximately $1,800,000 in Marketable Securities). However, if we are unable to commercialize and sell Ampligen® 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 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 also will need additional capital to eventually commercialize and sell Ampligen® 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 did raise approximately $875,000 in February 2017 from the sale of our securities.

In June 2017, the exercise price of the 2016 Warrants was changed to $0.50. As a result the warrant holders exercised these warrants and purchased 2,500,000 shares of company common stock. The Company realized net proceeds of $1,120,000 from these exercises.

However, if we are unable to obtain additional funding, through an Equity Distribution Agreement (“EDA”) or other sales of securities and/or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

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. In September 2016, we sold 3,333,334 shares of our common stock and issued warrants to purchase 2,500,000 shares of common stock. The warrants were exercised in June and July 2017. In February we sold 1,818,185 shares of our common stock and issued warrants. In August 2017, these warrants were exchanged for warrants to purchase an aggregate of 5,300,000 shares of common stock at an exercise price of $0.45 per share, most exercisable commencing December 1, 2017. We have registered the shares issuable upon exercise of these warrants for public sale and, should the market price of our common stock exceed the exercise price of these warrants, some or all of these warrants may be exercised.

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 our equity distribution agreements with Chardan Capital Markets, LLC and Maxim Group LLC 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.

Please also see Part I, Item IA – "Risk Factors" for more information concerning risks associated with our business and risks associated with an investment in our common stock contained within our 2016 Form 10-K filed with the SEC on March 31, 2017.

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. Please see "Cautionary Statement Regarding Forward-Looking Statements" set forth before Part I of this report.

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

In August 2017, in an exchange transaction, the Holders of Series A Warrants and Series B Warrants issued in June and July 2017 exchanged all of their warrants for new warrants (respectively, the "Series A Exchange Warrants" and the "Series B Exchange Warrants" and, collectively, the "Exchange Warrants") identical to the warrants except as follows: The exercise price of both Exchange Warrants is $0.45 per share, subject to adjustment therein, and the number of Series B Exchange Warrants issued was proportionately reduced so that all Exchange Warrants in the Exchange Transaction do not exceed 19.9% of the number of the Company's issued and outstanding shares of Common Stock as of May 31, 2017, the date of the Exchange Transaction offer letters. Series A Exchange Warrants for an aggregate of 2,500,000 shares and Series B Exchange Warrants for an aggregate of 2,800,000 shares were issued in this exchange transaction. The issuance of the Exchange Warrants by the Company and the shares of Common Stock issuable upon exercise of the Exchange Warrants is exempt from registration pursuant to Sections 3(a)(9) and 4(a)(2) of the Securities Act.

Effective with the semi-monthly period ended April 30, 2017, all of the members of the Company's Board of Directors agreed to accept 100% of their directors' fees in the form of options to purchase Company Common Stock until it was no longer necessary. In this regard, options to purchase 355,772 shares of Company common stock were issued. This program was terminated as of August 31, 2017. In addition, commencing with the semi-monthly period ended June 15, 2017, certain officers of the Company, and certain other employees of the Company, agreed to accept 20% of their salary in options to purchase Company Common Stock until it was no longer necessary. In this regard, options to purchase 284,795 shares of Company common stock were issued. This program was also terminated as of August 31, 2017.

ITEM 3: Defaults upon Senior Securities

None.

ITEM 4: Mine Safety Disclosures

Not Applicable.

ITEM 5: Other Information

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.

The Company entered into a sale agreement on September, 11, 2017 for the sale of its property located at 5 Jules Lane, New Brunswick, New Jersey for $1,050,000. This transaction is expected to close within two weeks.

The Company has also completed the process for the sale of its 2016 New Jersey Net Operating Loss. The Company expects to collect $820,000 when this sale is completed.

The Board determined that it was in the best interests of the Company to extend the term and amend certain other provisions of its Rights Agreement. As a result, on November 14, 2017, the Company executed a Second Amended and Restated Rights Agreement with American Stock Transfer & Trust Company, LLC, its Rights Agent (the "Rights Agreement").

On November 19, 2002, the Board 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 (the "Record Date"). Pursuant to the Rights Agreement, each Right entitles the registered holder to purchase from the Company a unit consisting of one one-hundredth of a share (a "Unit") of Series A Junior Participating Preferred Stock, par value $0.01 per share (the "Series A Preferred Stock") at a Purchase Price of $21.00 per Unit, subject to adjustment. The description and terms of the Rights are set forth in the Rights Agreement.

Initially, the Rights attached to all Common Stock certificates representing shares outstanding at the Record Date. The Rights attach to all certificates (or book entry notation) of shares of Common Stock issued after the Record Date. No separate Rights Certificates will be distributed. Subject to certain exceptions specified in the Rights Agreement, the Rights will separate from the Common Stock and a Distribution Date will occur upon the earlier of (i) 10 days following a public announcement that a person or group of affiliated or associated persons (an "Acquiring Person") has acquired beneficial ownership of 15% or more of the outstanding shares of Common Stock (the "Stock Acquisition Date"), other than as a result of repurchases of stock by the Company or certain inadvertent actions by institutional or certain other stockholders or (ii) 10 business days (or such later date as the Board shall determine) following the commencement of a tender offer or exchange offer that would result in a person or group becoming an Acquiring Person. Until the Distribution Date, (i) the Rights will be evidenced by certificates and Book Entry Notations for the Common Stock (collectively, "Common Stock Certificates") and will be transferred with and only with such Common Stock Certificates, (ii) new Common Stock Certificates issued after the Record Date will contain a notation incorporating the Rights Agreement by reference and (iii) the surrender for transfer of any Common Stock Certificates outstanding will also constitute the transfer of the Rights associated with the Common Stock represented by such Common Stock Certificate. Pursuant to the Rights Agreement, the Company reserves the right to require prior to the occurrence of a Triggering Event (as defined below) that, upon any exercise of Rights, a number of Rights be exercised so that only whole shares of Preferred Stock will be issued.

The Rights are not exercisable until the Distribution Date and will expire at 5:00 P.M. (New York City time) on November 14, 2022, unless such date is extended or the Rights are earlier redeemed or exchanged by the Company as described below.

As soon as practicable after the Distribution Date, Rights Certificates will be mailed to holders of record of the Common Stock as of the close of business on the Distribution Date and, thereafter, the separate Rights Certificates alone will represent the Rights. Except as otherwise determined by the Board of Directors, only shares of Common Stock issued prior to the Distribution Date will be issued with Rights.

In the event that a Person becomes an Acquiring Person, except pursuant to an offer for all outstanding shares of Common Stock which the Board determines to be fair and not inadequate and to otherwise be in the best interests of the Company and its stockholders, after receiving advice from one or more investment banking firms (a "Qualified Offer"), each holder of a Right will thereafter have the right to receive, upon exercise, Common Stock (or, in certain circumstances, cash, property or other securities of the Company) having a value equal to two times the exercise price

of the Right. Notwithstanding any of the foregoing, following the occurrence of the event set forth in this paragraph, all Rights that are, or (under certain circumstances specified in the Rights Agreement) were, beneficially owned by any Acquiring Person will be null and void. However, Rights are not exercisable following the occurrence of the event set forth above until such time as the Rights are no longer redeemable by the Company as set forth below.

In the event that, at any time following the Stock Acquisition Date, (i) the Company engages in a merger or other business combination transaction in which the Company is not the surviving corporation (other than a merger or business combination with an entity which acquired the shares pursuant to a Qualified Offer in which holders of the Company common stock receive the same consideration per share as in the Qualified Offer), (ii) the Company engages in a merger or other business combination transaction in which the Company is the surviving corporation and the Common Stock of the Company is changed or exchanged, or (iii) 50% or more of the Company's assets, cash flow or earning power is sold or transferred, each holder of a Right (except Rights which have previously been voided as set forth above) shall thereafter have the right to receive, upon exercise, common stock of the acquiring company having a value equal to two times the exercise price of the Right. The events set forth in this paragraph and in the second preceding paragraph are referred to as the “Triggering Events”.

At any time after a person becomes an Acquiring Person and prior to the acquisition by such person or group of fifty percent (50%) or more of the outstanding Common Stock, the Board may exchange the Rights (other than Rights owned by such person or group which have become void), in whole or in part, at an exchange ratio of one share of Common Stock, or one one-hundredth of a share of Preferred Stock (or of a share of a class or series of the Company's preferred stock having equivalent rights, preferences and privileges), per Right (subject to adjustment).

The Purchase Price payable, and the number of Units of Preferred Stock or other securities or property issuable, upon exercise of the Rights subsequent to the reverse split of the Company’s outstanding shares of Common Stock effected in August 2016 are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Stock, (ii) if holders of the Preferred Stock are granted certain rights or warrants to subscribe for Preferred Stock or convertible securities at less than the current market price of the Preferred Stock, or (iii) upon the distribution to holders of the Preferred Stock of evidences of indebtedness or assets (excluding regular quarterly cash dividends) or of subscription rights or warrants (other than those referred to above).

No fractional Units will be issued and, in lieu thereof, an adjustment in cash will be made based on the market price of the Preferred Stock on the last trading date prior to the date of exercise.

At any time prior to such time as any Person becomes an Acquiring Person, the Company may redeem the Rights in whole, but not in part, at a price of $0.01 per Right (payable in cash, Common Stock or other consideration deemed appropriate by the Board of Directors). Immediately upon the action of the Board of Directors ordering redemption of the Rights, the Rights will terminate and the only right of the holders of Rights will be to receive the $0.01 redemption price.

Until a Right is exercised, the holder thereof, as such, will have no rights as a stockholder of the Company, including, without limitation, the right to vote or to receive dividends. While the distribution of the Rights will not be taxable to stockholders or to the Company, stockholders may, depending upon the circumstances, recognize taxable income in the event that the Rights become exercisable for Common Stock (or other consideration) of the Company or for common stock of the acquiring company or in the event of the redemption of the Rights as set forth above.

Any of the provisions of the Rights Agreement may be amended by the Board of Directors of the Company prior to the Distribution Date. After the Distribution Date, the provisions of the Rights Agreement may be amended by the Board in order to cure any ambiguity, to make changes which do not adversely affect the interests of holders of Rights, or to shorten or lengthen any time period under the Rights Agreement. The foregoing notwithstanding, no amendment may be made at such time as the Rights are not redeemable.

This summary description of the Rights Agreement and the Rights does not purport to be complete and is qualified in its entirety by reference to the Rights Agreement, which is incorporated herein by reference.

ITEM 6: Exhibits

	Amendment to the Amended and Restated Certificate of Designations, Preferences and Rights of the Series A Junior Participating Preferred Stock. (included in Exhibit 4.3)
4.1	Form of New Series A Warrant issued in August 2017. (1)
4.2	Form of New Series B Warrant issued in August 2017. (1)
4.3	Second Amended and Restated Rights Agreement, dated as of November xx, 2017, between the Company and American Stock Transfer & Trust Company, LLC. The Second Amended and Restated Right Agreement includes the Form of Amendment to the Amended and Restated Certificate of Designations, Preferences and Rights of the Series A Junior Participating Preferred Stock, the Form of Rights Certificate and the Summary of the Right to Purchase Preferred Stock.(2)
10.1	Form of August 2017 Agreement between the Company and the Warrantholders. (1)
10.2	Form of Employee Pay Reduction Plan. (3)
10.3	Form of Executive Compensation Deferral Plan. (3)
10.4	Form of Directors' Compensation Deferral Plan. (3)
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, 2017 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 filed August 23, 2017 and is hereby incorporated by reference.

(2) Filed with the Securities and Exchange Commission as an exhibit to the Company's Registration Statement on Form 8-A filed November 14, 2017 and is hereby incorporated by reference.

(3) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed August 29, 2017 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, 2017

-37-