

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File No. 000-27072

**HEMISPHERX BIOPHARMA, INC.**

(Exact name of registrant as specified in its charter)

Delaware	52-0845822
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
1617 JFK Boulevard, Ste. 500, Philadelphia, Pennsylvania	19103
(Address of principal executive offices)	(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act:  
Common Stock, \$.001 par value

Securities registered pursuant to Section 12(g) of the Act:  
(Title of Each Class)  
NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter was \$29,348,045.

The number of shares of the registrant's Common Stock outstanding as of March 10, 2017 was 26,186,997.

**DOCUMENTS INCORPORATED BY REFERENCE:** None.



## TABLE OF CONTENTS

	<u>Page</u>
<b><u>PART I</u></b>	
<u>ITEM 1. Business</u>	7
<u>ITEM 1A. Risk Factors</u>	30
<u>ITEM 1B. Unresolved Staff Comments</u>	50
<u>ITEM 2. Properties</u>	50
<u>ITEM 3. Legal Proceedings</u>	50
<u>ITEM 4. Mine Safety Disclosures</u>	54
<b><u>PART II</u></b>	
<u>ITEM 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	55
<u>ITEM 6. Selected Financial Data</u>	56
<u>ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	56
<u>ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	68
<u>ITEM 8. Financial Statements and Supplementary Data</u>	69
<u>ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	69
<u>ITEM 9A. Controls and Procedures</u>	69
<u>ITEM 9B. Other Information</u>	70
<b><u>PART III</u></b>	
<u>ITEM 10. Directors, Executive Officers and Corporate Governance</u>	71
<u>ITEM 11. Executive Compensation</u>	77
<u>ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	105
<u>ITEM 13. Certain Relationships and Related Transactions and Director Independence</u>	108
<u>ITEM 14. Principal Accountant Fees and Services</u>	109
<b><u>PART IV</u></b>	
<u>ITEM 15. Exhibits and Financial Statement Schedules</u>	110

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

Certain statements in this Annual Report on Form 10-K (the “Form 10-K”), including statements under “Item 1-Business,” “Item 1A-Risk Factors” and “Item 3-Legal Proceedings” in PART I and “Item 7-Management’s Discussion and Analysis of Financial Condition and Result of Operations” in PART II, constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995. Certain, but not necessarily all, of such forward-looking statements can be identified by the use of forward-looking terminology such as “believes,” “expects,” “may,” “will,” “should,” or “anticipates” or the negative thereof or other variations thereon or comparable terminology, or by discussions of strategy that involve risks and uncertainties. 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. 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. 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. All statements other than statements of historical fact included in this Form 10-K regarding our financial position, business strategy and plans or objectives for future operations are forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects, the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance of our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to 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, we noted above that there are additional steps which the FDA has advised Hemispherx to take in our seeking approval. The final results of these and other ongoing activities, and of the FDA review, could vary materially from Hemispherx’ expectations and could adversely affect the chances for approval of the Ampligen® NDA. Any failure to satisfy the FDA’s requirements could significantly delay, or preclude outright, approval of our drugs for commercial sale in the United States.

On August 18, 2016, we received approval of our New Drug Application (“NDA”) from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”) for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe ME/CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America.

We believe that this approval provides a platform for potential commercial sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed drugs. We and GP Pharm are now working to expand the approval of rintatolimod to additional countries with a focus on Latin America. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program as discussed below and underway in Europe. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch (including possible requirements for approval of final manufacturing), and there are no assurances as to whether or when such multiple subsequent steps will be successfully performed to result in an overall successful commercialization and product launch. Approval of rintatolimod for ME/CFS in the Argentine Republic does not in any way suggest that the Ampligen® NDA in the United States will obtain commercial approval.

On May 24, 2016, we entered into an amended and restated agreement with Impatients, N.V. (“Impatients”), a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to ME/CFS. Pursuant to the agreement, Impatients, as our exclusive service provider and distributor in the Territory, is performing EAP activities 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. 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.

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

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. The validation phase was delayed because of the damage caused by the flood that occurred on January 5, 2016 at the facility. At this time, the Company believes that all repairs to the manufacturing facility have been completed. 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 most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

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

We do not undertake and specifically decline any obligation to publicly release the results of any revisions which may be made to any forward-looking statement to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events.

## PART I

### ITEM 1. Business

#### 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., all of which are incorporated in Delaware and are dormant. Our foreign subsidiary is Hemispherx Biopharma Europe N.V./S.A. which was established in Belgium in 1998.

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

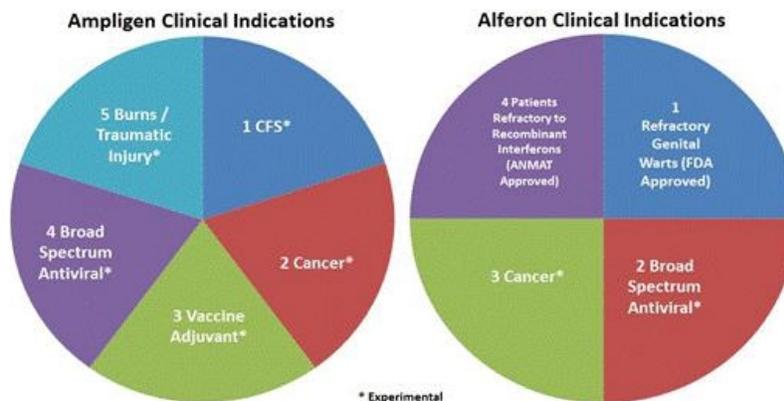
On February 19, 2016, our Board also made several changes to our executive management team in light of the termination of Dr. Carter, to provide effective and competent leadership that will properly position us to achieve our commercial goals and increase stockholder value. In this regard, Adam Pascale was named Chief Financial Officer in addition to his current responsibilities as Chief Accounting Officer. Mr. Pascale has been employed with us for 21 years, with more than two decades of public accounting experience and prior public company experience. He earned a Bachelor of Arts degree in Accounting and Finance from Rutgers University. Mr. Pascale served for several years as a CPA prior to joining the Company, and is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants. Mr. Thomas Equels, our Chief Executive Officer (“CEO”) and President, resigned as Chief Financial Officer to make way for Mr. Pascale.

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

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

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

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

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

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.

Our principal executive office is located at One Penn Center, 1617 JFK Boulevard, Philadelphia, Pennsylvania 19103, and our telephone number is 215-988-0080.

#### **AVAILABLE INFORMATION**

We file our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Exchange Act electronically with the Securities and Exchange Commission, or SEC. The public may read or copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that site is <http://www.sec.gov>.

You may obtain a free copy of our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K and amendments to those reports on the day of filing with the SEC on our website on the World Wide Web at <http://www.hemispherx.net> under the Investor Relations tab for SEC Filings or by contacting the Investor Relations Department by calling 888-557-6480 or sending an e-mail message to [ir@hemispherx.net](mailto:ir@hemispherx.net).

#### **OUR PRODUCTS**

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

#### **Ampligen®**

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

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

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

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

FDA regulations provide a formal dispute resolution process to obtain review of any FDA decision, including a decision not to approve an NDA, by raising the matter with the supervisor of the FDA office that made the decision. The formal dispute resolution process exists to encourage open, prompt discussion of scientific (including medical) disputes and procedural (including administrative) disputes that arise during the drug development, new drug review, and post-marketing oversight processes of the FDA. Depending on the outcome of a number of initiatives in the CFS community, including the FDA's Patient Focused Drug Development Initiatives, forthcoming drug guidance and other scientific initiatives by the Institute of Medicine, Center for Disease Control and National Institute of Health, we will continue to examine the opportunity for an "end-of-review" meeting. Depending on the results of these initiatives, we may request an "end-of-review" conference with the FDA as a precursor to a possible submission of a formal appeal to the Office of New Drugs within the FDA's Center for Drug Evaluation and Research regarding the FDA's decision. Please see "*Risks Associated with Our Business*" in Part I; Item 1A. Risk Factors below.

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

In May 1997, the FDA authorized an open-label treatment protocol, ("AMP-511"), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated CFS patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP-511 protocol through a consortium group of clinical sites provide safety information regarding the use of Ampligen® in patients with CFS. As of December 31, 2016, there were 27 patients participating in this open-label treatment protocol taking treatment. We are establishing an enlarged data base of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen® and/or the design of future clinical studies. In 1997, we calculated the cost per dose (400mg) of Ampligen® to be \$150 per dose consistent with the regulatory guidelines; however, we recently engaged an independent certified public accountant to recalculate the cost per dose consistent with the current guidelines, utilizing the costs to produce a vial in 2015. The independent analysis disclosed a cost per 200 mg dose of Ampligen® of \$200 per vial. In October 2016, the FDA granted our request to implement the new cost.

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

On January 11, 2017, we announced that the rintatolimod European Early Access Program ("EAP") through our agreement with Impatients designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. Impatients, doing business as 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. A competent authority in the Netherlands has recently approved 50 patients for treatment in the EAP for pancreatic cancer including a funding mechanism to remunerate us for the use of Ampligen® in the program.

#### **Alferon N Injection®**

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

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

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

Alferon N Injection® [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There are essentially no neutralizing antibodies observed against Alferon N Injection® to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year, probably due to neutralizing antibody formation.

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

### Alferon® LDO (Low Dose Oral)

Alferon® LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of natural alpha interferon and like Alferon® N Injection®, should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the body by absorption through the oral mucosa. Oral interferon could be economically feasible for patients and logistically manageable globally for development programs for prevention and, or treatment of pandemic influenza, seasonal influenza and other emerging viruses. Oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, no production of antibodies, and broad range of potential bioactivity, could be a breakthrough treatment or preventative for viral diseases.

Hemispherx currently has an FDA authorized protocol to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal influenza of more than 200 subjects. Our Phase II study has continued to be delayed.

### HISTORICAL COSTS RELATED TO OUR PRODUCTS

The following table sets forth the costs related to our major products for each of the prior three years. Our aggregate expenses from the time that we first started developing nucleic acid pharmaceutical technology in the mid 1980's through March 2003 were substantially related to the development of Ampligen®, and from that date through the current period were substantially related to Ampligen® and Alferon®.

(dollars in thousands)  
Year Ended December 31, 2016

	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Costs and Expenses					
Production costs	\$ —	\$ 1,108	\$ —	\$ —	\$ 1,108
Research and development	4,368	739	—	—	5,107
General and administrative	5,628	2,053	—	—	7,681
Total	<u>\$ 9,996</u>	<u>\$ 3,900</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 13,896</u>

(dollars in thousands)  
Year Ended December 31, 2015

	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
Costs and Expenses					
Production costs	\$ —	\$ 1,598	\$ —	\$ —	\$ 1,598
Research and development	3,452	4,586	—	—	8,038
General and administrative	2,560	4,587	—	—	7,147
Total	<u>\$ 6,012</u>	<u>\$ 10,771</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 16,783</u>

(dollars in thousands)  
Year Ended December 31, 2014

	Ampligen® NDA	Alferon N Injection®	Alferon® LDO	Other	Total
<b>Costs and Expenses</b>					
Production costs	\$ —	\$ 1,251	\$ —	\$ —	\$ 1,251
Research and development	4,561	4,427	—	—	8,988
General and administrative	4,035	5,022	—	—	9,057
<b>Total</b>	<b>\$ 8,596</b>	<b>\$ 10,700</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 19,296</b>

#### **PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS**

As of December 31, 2016, we had 50 patents worldwide with 8 additional pending patent applications comprising our intellectual property. Please see “Note 5: Patents, Trademark Rights and Other Intangibles (FASB ASC 350 General Intangibles Other than Goodwill)” under Notes to Consolidated Financial Statements for more information on these patents.

We continually review our patents’ rights to determine whether they have continuing value. Such review includes an analysis of the patent’s ultimate revenue and profitability potential. In addition, Management’s review addresses whether each patent continues to fit into our strategic business plans for Ampligen®, Alferon N Injection® and Alferon® LDO. One U.S. patent relating to our Alferon® product expired on April 2, 2013 (#5,503,828) and another on October 14, 2014 (#5,676,942) (see discussion below on patent #5,503,828 and #5,676,942).

In 2016, we received a new Ampligen® composition of matter patent in the US (9,315,528 B2) and we received twenty-eight new patents in various EU countries. In 2015, we were granted a new composition of matter patent (#2340307) by the European Patent Office. In 2014, we were granted a new composition of matter patent in the United States (#8,722,874) covering Ampligen® formulations.

Alferon® composition patent #5,503,828 which expired in April 2013, related to the manufacturing process for Alferon® Active Pharmaceutical Ingredient (“API”), a complex mixture of natural interferon species that is manufactured from human leukocytes obtained from human blood donors. In addition, while it is the current standard by the FDA to treat biological drug products like interferon as “Well Characterized” biologics, a process for which chemical entities can have their identity, purity, impurities, potency, and quality controlled by chemical testing, Alferon®, as a natural interferon, does not lend itself well to such testing. Moreover, FDA continues to require that each lot of Alferon® we produce be tested and released by the FDA before it can be distributed for commercial sales. Because of the complexity of the Alferon® manufacturing process and these additional regulatory requirements, we believe that potential manufacturers of generic, or so-called “bio-similar,” drug products are focused on developing recombinant interferon products, rather than natural interferon products. For these reasons, we believe the expiration of this Alferon® composition patent in April 2013 should have no or little impact on the Company. Additionally, at the receipt of the FDA certification for the revised Alferon® manufacturing process and techniques in New Brunswick, NJ, it is our intention to file for additional patent protection.

Alferon® patent #5,676,942 which expired on October 14, 2014 and Alferon® patent #5,989,441 which was set to expire on December 22, 2017, but was allowed to lapse beforehand, related to a manufacturing methodology which is no longer in use. For this reason, we believe the expiration of these Alferon® patents should have no impact on the Company.

With respect to Ampligen®, the main U.S. CFS treatment patent (#6,130,206) expires October 10, 2017 (we believe that the expiration of this patent will have minimal impact on us; see detail on U.S. 8,722,874 below). Our main patents covering HIV treatment (#4,820,696, #5,063,209, and #5,091,374) expired on April 11, 2006, November 5, 2008, and February 25, 2009, respectively. Our U.S. Ampligen® Trademark (#73/617,687) has been renewed through December 6, 2018. New therapeutic use patent applications are pending. On May 13, 2014, the United States Patent Office issued patent U.S. 8,722,874 titled “*Double-Stranded Ribonucleic Acids with Rugged Physiochemical Structure and Highly Specific Biologic Activity*” to inventors Carter, et al. and assignee Hemispherx. The patent claims a novel form of rugged dsRNA. Rugged dsRNA are nucleic acids with a unique composition and physical characteristic identified with high specificity of binding to Toll-Like Receptor 3 (TLR3), thereby conveying an important range of therapeutic opportunities. The newly discovered form of dsRNA has increased bioactivity and binding affinity to the TLR 3 receptor because of its reduced tendency to form branched dsRNA which can inhibit receptor binding. Pharmaceutical formulations containing the newly discovered nucleic acid as active ingredients, and methods of treatment with those formulations are also described in the issued patent. Hemispherx believes that the issuance of U.S. Patent 8,722,874 will help ensure that Hemispherx retains patent protection for novel formulations of Ampligen® products until at least 2029.

In September 2015, the European Patent Office granted the European version of U.S. Patent 8,722,874 with the same title as shown above to inventors Carter, et al. and assignee Hemispherx.

In addition to our patent rights relating to Ampligen®, the FDA has granted “orphan drug status” to the drug for CFS, HIV/AIDS, renal cell carcinoma and malignant melanoma. Orphan drug status grants us protection against the potential subsequent approval of other sponsors’ versions of the drug for these uses for a period of seven years following FDA approval of Ampligen® for each of these designated uses. The first NDA approval for Ampligen® as a new chemical entity will also qualify for four or five years of non-patent exclusivity during which abbreviated new drug applications seeking approval to market generic versions of the drug cannot be submitted to the FDA. (See “Government Regulation” below.)

In May 2011, a new United States Patent was granted for the use of Ampligen® as a vaccine adjuvant for use with seasonal influenza vaccine to induce an enhanced immune response against H5N1 avian influenza.

## **RESEARCH AND DEVELOPMENT (“R&D”)**

Our general focus during the past three fiscal years has been on the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based disorders.

The following table summarizes our research and development costs for the years 2016, 2015 and 2014 by project (in thousands):

	2016	2015	2014
Ampligen® New Drug Application for the treatment of CFS	\$ 4,368	\$ 3,452	\$ 4,561
Alferon® LDO	—	—	—
Alferon N Injection®	739	4,586	4,427
Other projects	—	—	—
Total research and development	<u>\$ 5,107</u>	<u>\$ 8,038</u>	<u>\$ 8,988</u>

Due to the inherent uncertainty involved in the design and conduct of clinical trials and the applicable regulatory requirements, including the factors discussed above in “OUR PRODUCTS”, we cannot predict what additional studies and/or additional testing or information may be required by the FDA. Accordingly, we are unable to estimate the nature, timing, costs and necessary efforts to complete these projects nor the anticipated completion dates. In addition, we have no basis for estimating when material net cash inflows may commence. We have yet to generate significant revenues from the sale of these developmental products. As of December 31, 2016, we had approximately \$5,868,000 in Cash, Cash Equivalents and Marketable Securities, (inclusive of approximately \$3,460,000 in Marketable Securities). Please see ITEM 1A. Risk Factors; “*We may require additional financing which may not be available*” below.

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 analysis. Until we undertake the end-of-review conference(s) with the FDA, we are unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, we estimate upon acceptance of the study’s design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. It can be reasonably anticipated that the time and cost to undertake clinical trial(s), studies and data analysis are beyond our current financial resources without gaining access to additional funding. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA’s acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations. Please see “*We most likely will require additional financing which may not be available.*” in Item 1A. Risk Factors below.

## Chronic Fatigue Syndrome (“CFS”)

Chronic Fatigue Syndrome (“CFS”), also known as Chronic Fatigue Immune Dysfunction Syndrome (“CFIDS”) and Myalgic Encephalomyelitis (“ME”), is a serious and debilitating chronic illness and a major public health problem. CFS is recognized by both the government and private sector as a significant unmet medical need, including the U.S. National Institutes of Health (“NIH”), FDA and the CDC. The CDC states on its website at <http://www.cdc.gov/cfs/index.html> that “*Chronic fatigue syndrome, or CFS, is a devastating and complex disorder characterized by overwhelming fatigue that is not improved by bed rest and that may be worsened by physical or mental activity. People with CFS most often function at a significantly lower level of activity than they were capable of before the onset of illness.*”

Many severe CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. CFS is characterized by incapacitating fatigue with profound exhaustion and extremely poor stamina, sleep difficulties and problems with concentration and short-term memory. It is also accompanied by flu-like symptoms, pain in the joints and muscles, tender lymph nodes, sore throat and new headaches. A distinctive characteristic of the illness is a worsening of symptoms following physical or mental exertion, which do not subside with rest.

For their Case Definition, the CDC states that the cause or causes of CFS have not been identified and no specific diagnostic tests are available. Therefore, in order to be diagnosed with chronic fatigue syndrome, a patient must satisfy three criteria:

1. The individual has had severe chronic fatigue for six or more consecutive months that is not due to ongoing exertion or other medical conditions associated with fatigue (these other conditions need to be ruled out by a doctor after diagnostic tests have been conducted);
2. The fatigue significantly interferes with daily activities and work; and
3. The individual concurrently has four or more of the following eight symptoms:
  - post-exertion malaise lasting more than twenty-four hour;
  - unrefreshing sleep;
  - significant impairment of short-term memory or concentration;
  - muscle pain;
  - pain in the joints without swelling or redness;
  - headaches of a new type, pattern, or severity;
  - tender lymph nodes in the neck or armpit; or
  - a sore throat that is frequent or recurring.

These symptoms should have persisted or recurred during six or more consecutive months of illness and they cannot have first appeared before the fatigue. CFS is a diagnosis of exclusion. Because no cause for CFS has been identified, current treatment programs are directed at relieving symptoms, with the goal of the patient regaining some level of function and well-being.

While CFS strikes people in all age, racial, ethnic, and socioeconomic groups, it is most prevalent amongst women. Research has shown that CFS is about three times as common in women as men, a rate similar to that of many autoimmune diseases, such as multiple sclerosis and lupus.

In June 2012, U.S. Senators Robert P. Casey, Richard Blumenthal and Kay R. Hagan sent a letter to Health and Human Services Secretary Kathleen Sebelius requesting the FDA hold a stakeholders meeting on CFS. Senators Casey and Hagan serve on the Committee on Health, Education, Labor & Pensions, which has Congressional oversight responsibility for FDA. The letter stated, “*CFS/ME represents a significant unmet medical need, one that confers on patients a lifetime of illness. A stakeholder meeting would be of great benefit, as it would offer an opportunity to examine existing treatment protocols known to FDA, address how risk/benefit determinations should be made in relation to CFS/ME treatments and identify a path forward for regulatory science in this area.*”

In April 2013, the FDA selected CFS to be the first disease in a series of meetings called Patient Focused Drug Development meetings. The two-day meeting with key stakeholders resulted in a report called *The Voice of the Patient*, published in September of 2013. In March 2014, FDA published the first ever Guidance for Industry Chronic Fatigue Syndrome/Myalgic Encephalomyelitis: Developing Drug Products for Treatment.

In February 2015, the Institute of Medicine (IOM) published a report, *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome; Redefining an Illness*. The committee was charged by HHS with evaluating the current criteria for the diagnosis of ME/CFS and recommend clinical diagnostic criteria that would address the needs of health care providers, patients, and their caregivers. The primary message of the committee is “*ME/CFS is a serious, chronic, complex, systemic disease that can profoundly affect the lives of patients.*” The IOM since published a Report Guide for Clinicians. In October 2015, NIH Director Francis S. Collins, M.D., Ph.D. announced that NIH is strengthening its efforts to advance research on ME/CFS. In an interview with ME Action, December 2015, Collins described the range of possibilities – “*everything from basic science to clinical trials for promising approaches, including Ampligen® and Rituximab*”.

#### **Other Diseases**

In July 2011, we received FDA authorization to proceed with the initiation of a new clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. On April 16, 2012, a clinical trial was initiated in which Ampligen® was nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert, Associate Professor of Medicine in the Division of Infectious Diseases and Director of the Alabama Vaccine Research Clinic. This study was the first use of Ampligen® with a seasonal vaccine in humans to assess the safety of Ampligen® when nasally delivered as a vaccine adjuvant. Another objective of this study was to determine the extent to which Ampligen® mobilizes potential protections against pandemic influenza by utilization of a seasonal flu vaccine. The study would have evaluated the potential immunologic enhancement of Ampligen® by comparing immune parameters in the group receiving Ampligen® plus FluMist® with another group receiving FluMist® plus placebo. Twenty-five subjects were enrolled; twelve in Stage 1 and thirteen subjects in Stage 2. However, the Center for Disease Control and Prevention (CDC) has indicated the nasal spray flu vaccine (live attenuated influenza vaccine or LAIV) should not be used during 2016-2017 (source: <https://www.cdc.gov/flu/professionals/vaccination/>); therefore, the study has been closed.

In December 2013, we announced that we are supporting the University of Pittsburgh's National Institutes of Health funded study (grant 1P01CA132714) currently underway as part of the University's Chemokine Modulation Research initiative which includes Ampligen® as an adjuvant. As part of this collaboration, Hemispherx has supplied clinical grade Ampligen® (rintatolimod) to the University. The study, under the leadership of Professor of Surgery Pawel Kalinski, M.D., Ph.D., involves the Chemokine Modulatory regimen developed by Dr. Kalinski's group and has successfully completed dose escalation in patients with resectable colorectal cancer under the clinical leadership of Dr. Amer Zureikat, Assistant Professor of Surgery. To date, 15 patients have been treated in this study. In addition, the University has initiated enrollment in an additional cancer study of peritoneal surface malignancies which includes Ampligen® as an immune enhancer. To date, 46 patients have been treated. The University has initiated enrollment into another cancer study of recurrent ovarian cancer patients which includes Ampligen® as a component of the treatment regimen. To date, 6 patients have been treated in the study (1 patient did not receive Ampligen). The University has received Institutional Review Board (IRB) approval for another cancer study of subjects with chemo-refractory metastatic colorectal cancer which also includes Ampligen® as an immune enhancer. Enrollment into this study has not yet been initiated.

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

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

In July 2015, we submitted an application for orphan drug designation to the European Medicines Agency (EMA) for Alferon® N to treat MERS and on January 6, 2016, the EMA forwarded to us both its Public Summary of Opinion and its record designation approving the Orphan Medicinal Products Designation for Alferon® N Injection, also known as interferon alfa-n3, as a potential treatment of MERS.

On January 11, 2017, we announced that the rintatolimod European Early Access Program (“EAP”) through our agreement with Impatients designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. Impatients, doing business as 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. A competent authority in the Netherlands has recently approved 50 patients for treatment in the EAP for pancreatic cancer including a funding mechanism to remunerate us for the use of Ampligen® in the program.

### **Ebola**

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

- November 2014 - We received a report from the United States Army Medical Research Institute of Infectious Diseases (“USAMRIID”) scientists stating that they had *in vitro* data indicating that Alferon®, the only multi-species, natural alpha interferon commercially approved in the U.S., successfully protected human cells against the Ebola virus (EBOV).
- November 2014 - We announced that we had received a new research report from Professor Tramontano in the Department of Life and Environmental Sciences, University of Cagliari, Italy. This biochemical study demonstrated that Ampligen® successfully binded to the lethal Ebola Virus protein designated VP35. VP35 protein normally inactivates a patient’s immune/antiviral system by binding to viral dsRNA thereby sequestering a critical antiviral/immune activator of the body, which leads to high morbidity and death rates. Ampligen® competes with viral dsRNA for VP35 binding and this finding is consistent with studies at USAMRIID demonstrating that Ampligen® inhibits Ebola virus *infectivity in vitro*.
- December 2014 - We announced that we received a new research report from researchers at Howard University, Washington DC. The report described a study in which Ampligen® strongly inhibited the Ebola mini-genome in the human embryonic kidney cell system.

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

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

Our European subsidiary, Hemispherx Biopharma Europe N.V./S.A., has been formally notified of a positive opinion from the COMP (Committee on Medical Products) regarding its Orphan Medicinal Product Application for Ampligen®, an experimental therapeutic, to treat Ebola Virus Disease (EVD). The European Medicines Agency (EMA) published on May 22, 2015 both its Public Opinion Summary and its record designation approving the Orphan Medicinal Product Designation for Ampligen®, also known as rintatolimod experimental therapeutic, to treat Ebola Virus Disease (EVD).

Our overall objectives include plans to continue seeking approval for commercialization of Ampligen® in the United States and abroad as well as to widen existing commercial therapeutic indications of Alferon® N Injection presently approved in the United States and Argentina. 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 Laboratories 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 clinical batches of Ampligen®. On January 3, 2017, we entered into a purchase order to replace the previous purchase commitment with Jubilant pursuant to which Jubilant will manufacture a commercial batch of Ampligen® for us. Pursuant to the new order, Jubilant will perform tooling and validation activities as well as final fill and finish services.

On July 27, 2016, we reached an agreement with Avrio Biopharmaceuticals, now Nitto Denko Avecia Inc. (“Avecia”) to serve as an additional contract manufacturer of Hemispherx’s experimental drug, Ampligen®. The new cGMP lot was completed in December and was released in January 2017 for use in the Early Access Program (“EAP”) in Europe. Please see “Risks Associated with Our Business” in Item 1A. Risk Factors below - *There are no long-term agreements with suppliers of required materials and services for Ampligen® and there are a limited number of raw material suppliers. If we are unable to obtain the required raw materials and/or services, we may not be able to manufacture Ampligen®.*

The construction of the \$8 million facility enhancement project was completed in 2015 which, upon FDA approval, should provide for a higher capacity and more cost effective manufacturing process for the production of Alferon N Injection®. Commercial sales of Alferon® and Alferon® API internationally are projected to begin as soon as the necessary regulatory approvals are obtained. However, commercial sales of Alferon® in the USA will not resume until new batches of commercial filled and finished product are produced and released by the FDA. We are continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application (“BLA”) for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. We will also need the FDA’s approval to release commercial product once we have submitted satisfactory stability and quality release data. We had anticipated that it would take until at least the 2nd half of 2015 before we would have Alferon® approved for commercial sales; however, during the final stage of the manufacturing process we encountered issues regarding a change in both the contract supplier of leukocytes and the long term supply availability related to a reagent used in the formulation of Alferon®. We have resolved these issues through engaging in multiple agreements with suppliers of leukocytes as well as entering into a licensing agreement with a foreign multinational chemicals and biotechnology company that has been in business for over a century for the sourcing of the primary reagent allowing us to manufacture Alferon®. However, due to the interruption of the required flow of leukocytes, production ceased, causing parts to malfunction in the upstream process when the system was restarted for testing. We were working diligently to make the necessary repairs to be able to restart the validation process; however, in the process of obtaining time estimates for the repairs we experienced a flood within portions of our manufacturing facility. As a result, we are constrained in our ability to manufacture product in the near future due to this flood in the upstream processing cleanroom that contains the bioreactor. The flood occurred on the afternoon of January 5, 2016, caused by a malfunctioning water supply pipe for the sprinkler system covering a large amount of the cleanroom in stagnant water and silt from the sprinkler system. Our facility insurer has been proactive in addressing and covering the loss. While repairs have required preapproval by our insurer, activity moved forward quickly. The repairs noted below required special action because of the need to keep this critical manufacturing room within International Organization for Standardization (ISO) classifications and the need to certify that all the equipment that was exposed, or submerged, is in proper condition and operating effectively following the corrective actions. All HEPA filters affected by the flood were tested by an outside contractor and passed all required tests. The flooring that was damaged was repaired using a special epoxy that is used in cleanrooms. A large portion of the walls in the ISO classified area were damaged. We had a damage mitigation company come in to stop any moisture from seeping further into the ISO classified areas. Subsequently, all damaged walls and ceilings were replaced with cleanroom grade materials and require no further repair. Six pumps that were affected by the flood were sent back to the manufacturer for inspection and repair. Repairs that were required were completed on the pumps and they were reinstalled in the Alferon® manufacturing facility after the floor repair work was completed. All pumps will need to be qualified for use in the manufacturing process prior to the validation process for a Pre-Approval Inspection. All air ducts supplying the Alferon® manufacturing area were cleaned and the insulation replaced along with ceiling tiles. All smaller pieces of machinery and equipment that could not be salvaged have been replaced. We also completed the HVAC air balancing and qualification. At this time, we believe that all repairs to the manufacturing facility have been completed.

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

Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. Due to the Company extending the timeline of Alferon® production to an excess of one year, we reclassified Alferon® work-process-inventory to other assets within our balance sheet as of December 31, 2016. In addition, due to the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

To formulate, fill, finish and package (“fill and finish”) Alferon N Injection® drug product, we require a FDA approved third party Contract Manufacturing Organization (“CMO”). In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with 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 \$210,000 to Althea with regard to this open purchase commitment as of December 31, 2016 and has recorded this amount within Work-In-Process inventory.

## **MARKETING/DISTRIBUTION**

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

In January 2010, we engaged an Argentinean regulatory and business design entity to explore the possibility of initiating clinical trials of Alferon N Injection®, Ampligen® and Alferon® LDO during the influenza season in Argentina. On June 14, 2010, we executed a five year exclusive Sales, Marketing, Distribution and Supply Agreement for Argentina with GP Pharm Latinoamerica ("GP Pharm"), an affiliate company of Spanish GP Pharm SA. Under this Agreement, GP Pharm 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. On November 15, 2010, we amended our June 15, 2010 agreement with GP Pharm to include Mexico in the Territory under the Sales, Marketing, Distribution and Supply Agreement. Under this Agreement, GP Pharm Mexico will be responsible for seeking regulatory approval in Mexico for Ampligen®, an experimental therapeutic, to treat CFS in Mexico and, if approval is obtained, for commercializing Ampligen® for this indication in Mexico. On May 24, 2016, we entered into a five year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the "Agreement") with GP Pharma whereby all material provisions within the Agreement remained consistent with the original agreement.

In January 2012, the ANMAT approved the sale and distribution of Alferon N Injection® (under the brand name “Naturaferon”) in Argentina. The receipt of the ANMAT approval for HPV is the first step of a regulatory process towards the commercial sales of Naturaferon®. On September 20, 2012, we filed with ANMAT an amended NDA for the use of Alferon N Injection® in patients with chronic hepatitis C who have become refractory to recombinant interferon as a result of the appearance of neutralizing antibodies against recombinant interferon. On February 6, 2013, we received the ANMAT approval for the treatment of refractory patients, that failed or were intolerant to treatment with recombinant interferon, with Naturaferon® in Argentina.

On September 6, 2011, we executed an amended agreement with Asembia, formerly Armada Healthcare, LLC, to undertake the marketing, education and sales of Alferon N Injection® throughout the United States. This agreement also provides start-up along with ongoing sales and marketing support to the Company. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. We previously extended this agreement for the previous three years also under the same terms and conditions. Due to our manufacturing process for Alferon® being on hold and there being no definitive timetable to have the facility back online, we will review our expiring agreement on August 14, 2017 with Asembia.

On September 6, 2011, we executed a new agreement with specialty distributor, BioRidge Pharma, LLC (“BioRidge”) to warehouse, ship, and distribute Alferon N Injection® on an exclusive basis in support of U.S. sales. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. We previously extended this agreement for the previous three years also under the same terms and conditions. Due to our manufacturing process for Alferon® being on hold and there being no definitive timetable to have the facility back online, we will review our expiring agreement on August 14, 2017 with Asembia.

On March 9, 2015, we executed an agreement with Emerge Health Pty Ltd. (“Emerge”) to seek approval of Ampligen® for CFS in Australia and New Zealand and to commence distribution of Ampligen® in both countries on a named-patient basis, where deemed appropriate. The parties intend to collaborate on seeking regulatory approval from Australia’s Therapeutic Goods Administration (“TGA”) and New Zealand’s Medicines and Medical Devices Safety Authority (“Medsafe”). Under this five-year exclusive license to sell, market, and distribute Ampligen in Australia and New Zealand to treat CFS, Emerge will implement regulatory-compliant programs to educate physicians about Ampligen® for CFS and seek orphan drug designation and approval of Ampligen® to treat CFS. Hemisphere will support these efforts and will supply Ampligen® at a predetermined transfer price. We have the right to buy out of the agreement at a price equal to three times Ampligen® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three. We have determined to maintain local expertise in handling the regulatory aspects of treating patients with an unapproved product and have elected not to pursue individual patient use in these territories and have subsequently terminated the agreement in 2017.

On May 24, 2016, we entered into an amended and restated five year agreement (the “Impatients Agreement”) with Impatients, N.V. (“Impatients”), a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to CFS. Pursuant to the agreement, Impatients, 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 Impatients at a predetermined transfer price. In the event that we receive Marketing Authorization in any country in the Territory, we will pay Impatients 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 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.

On January 11, 2017, we announced that the rintatolimod European Early Access Program (“EAP”) through our agreement with Impatients designed to enable access of Ampligen® to ME/CFS patients has been extended to pancreatic cancer patients beginning in the Netherlands. Impatients, doing business as 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. A competent authority in the Netherlands has recently approved 50 patients for treatment in the EAP for pancreatic cancer including a funding mechanism to remunerate us for the use of Ampligen® in the program.

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

## **COMPETITION**

RNA based products and toll-like receptors (“TLRs”) have demonstrated great promise in pre-clinical and limited clinical applications resulting in active research and development by large pharmaceutical companies and emerging biotech firms. As such, our potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have.

These companies and their competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments will offer competition to our products. Furthermore, our competitors have significantly greater experience than we do in pre-clinical testing and human clinical trials of pharmaceutical products and in obtaining FDA (in the US), European Medicines Agency (“EMA”) and Health Protection Branch (“HPB”) (in Canada), and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, EMEA and HPB product approvals before we do. If any of our products receive regulatory approvals and we commence commercial sales of our products, we will also be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have no experience. Our competitors may possess or obtain patent protection or other intellectual property rights that prevent, limit or otherwise adversely affect our ability to develop or exploit our products.

The major pharmaceutical competitors with biotech capabilities/vaccine franchises include Pfizer, GlaxoSmithKline, Merck & Co., Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. When we recommence sales of Alferon N Injection®, it will compete with Intron® A, an injectable from Merck & Co., that attempts to kill the virus and prevent reproduction along with topical treatments that are normally applied by a doctor that have a risk of damaging the skin around the wart, such as:

- Aldara®, also known as Imiquimod®, is a cream which is marketed to boost the immune systems in an attempt to rid itself of genital warts;
- Veregen® is a herbal product made from green tea leaves which is self-administered as an ointment and is used to treat external genital warts in adult patients;
- Condylox® Solution (podofilox) and Podofin® (podophyllin resin) are liquids applied externally using a cotton applicator or finger which attempts to destroy genital warts by halting cell growth; and
- Trichloroacetic acid (TCA) or Bichloroacetic acid (BCA) are chemical treatments which attempt to externally “burn off” genital warts.

## **GOVERNMENT REGULATION**

Regulation by governmental authorities in the U.S. and foreign countries is and will be a significant factor in the manufacture and marketing of Alferon® products and our ongoing research and product development activities. Ampligen® and other products developed from the ongoing research and product development activities will require regulatory clearances prior to commercialization. In particular, new drug products for humans are subject to rigorous pre-clinical and clinical testing as a condition for clearance by the FDA and by similar authorities in foreign countries. The lengthy process of seeking these approvals, and the ongoing process of compliance with applicable statutes and regulations, has and will continue to require the expenditure of substantial resources. Any failure by us or our collaborators or licensees to obtain, or any delay in obtaining, regulatory approvals could materially adversely affect the marketing of any products developed by us and our ability to receive product or royalty revenue. We have received Orphan Drug designation for certain therapeutic indications, which we believe might under certain conditions, help to accelerate the process of drug development and commercialization. Alferon N Injection® is only approved for use in intraslesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other applications requires regulatory approval.

We are subject to various federal, state and local laws, regulations and recommendations relating to such matters as safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use of and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research work. Prior to our construction phase, our laboratory and production facility in New Brunswick, New Jersey was approved for the manufacture of Alferon N Injection®. While our facility had been granted approval of its BLA by the FDA for the manufacture of Alferon®, this status will need to be reaffirmed as we have completed the facility's enhancements and believe it will again be able to obtain FDA approval. However, there can be no assurance that this facility, or facilities owned and operated by third parties that are utilized in the manufacture of our products, will obtain and/or continue to maintain FDA approval. For information about the current status of our Ampligen® NDA please see "Our Products; Ampligen®" above.

#### **HUMAN RESOURCES**

As of March 1, 2017, we had personnel consisting of 32 full-time employees and 2 part-time employees. Twenty-three (23) of the combined personnel are engaged in our research, development, clinical, and manufacturing effort with 11 performing regulatory, general administration, data processing, including bio-statistics, financial and investor relations functions. We have no union employees.

While we have been successful in attracting skilled and experienced scientific personnel, there can be no assurance that we will be able to attract or retain the necessary qualified employees and/or consultants in the future.

#### **DATA MONITORING COMMITTEE**

We meet with experts from time to time in areas of clinical and scientific interest.

In May 2010, we formed a Data Monitoring Committee ("DMC") that consists of two independent regulatory and medical experts along with a biostatistics expert. The function of the DMC is to perform independent safety and efficacy analyses on our clinical trials. During 2014, 2015 and 2016, the DMC focused its attention on the clinical trial (AMP-600) in which Ampligen® is being nasally administered in conjunction with FluMist® to healthy human volunteers at the University of Alabama at Birmingham under the auspices of Dr. Paul Goepfert. As required by the study's protocol, the DMC has held three meetings and has reviewed the safety data on the first 12 subjects enrolled in Stage 1 and approved the study to proceed to Stage 2 which began in March 2014. As of December 31, 2016, the study is closed after enrolling 25 subjects in Stage 2. Closure of the study was due to the recommendation of CDC of not using a live attenuated influenza vaccine during 2016-2017.

## 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-K. Among the key factors that have a direct bearing on our results of operations are:

### Risks Associated with Our Business

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

Ampligen® and related products. The development of Ampligen® and our other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary right of third parties. Our investigational products are in various stages of clinical and pre-clinical development and require further clinical studies and appropriate regulatory approval processes before any such products can be marketed. We do not know when, if ever, Ampligen® or our other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale (Please see the next Risk Factor and Part 1, Item I: “Business; Our Products; Ampligen®” for more information).

Alferon N Injection®. Although Alferon N Injection® is approved for marketing in the United States for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, to date it has not been approved for other indications. We face many of the risks discussed above, with regard to developing this product for use to treat other ailments (Please see the next Risk Factor and Part 1, Item I: “Business; Our Products; Alferon N Injection®” above for more information).

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

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

All of our drugs and associated technologies, other than Alferon N Injection®, are investigational in the U.S. and must receive prior regulatory approval by appropriate regulatory authorities for commercial distribution and sale and are currently legally available only through clinical trials in the U.S. with specified disorders. At present, Alferon N Injection® is approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval in the U.S. and abroad.

Our products, including Ampligen®, are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries, including, but not limited to, the FDA in the U.S., the Health Protection Branch (“HPB”) of Canada, the Agency for the European Medicines Agency (“EMA”) in Europe and the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (“ANMAT”) in Argentina. Obtaining regulatory approvals is a rigorous and lengthy process and requires the expenditure of substantial resources. In order to obtain final regulatory approval of a new drug, we must demonstrate to the satisfaction of the regulatory agency that the product is safe and effective for its intended uses and that we are capable of manufacturing the product to the applicable regulatory standards. We require regulatory approval in order to market Ampligen® or any other proposed product and receive product revenues or royalties. We cannot assure you that Ampligen® will ultimately be demonstrated to be safe and efficacious. While Ampligen® is authorized for use in clinical trials in the U.S., we cannot assure you that additional clinical trial approvals will be authorized in the United States or in other countries, in a timely fashion or at all, or that we will complete these clinical trials. In addition, although Ampligen® has been authorized by the FDA for treatment use under certain conditions, including provision for cost recovery, there can be no assurance that such authorization will continue in effect.

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

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

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

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

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

- not be able to demonstrate to the satisfaction of the FDA that our product candidate is safe and effective for any indication;
- the FDA may disagree with the design or implementation of our clinical trials or other studies;
- the results of the clinical trials or other studies may not demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from clinical trials or other studies;
- the data collected from clinical trials and other studies of a product candidate may not be sufficient to support the submission of a NDA;
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval; and
- the FDA may not approve the proposed manufacturing processes and facilities for a product candidate.

In 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® Active Pharmaceutical Product ("API"), which would need to be released by the FDA before those materials could be used in commercial product. After conducting all of the appropriate tests on samples of the inventory during 2013, we concluded that we could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection®. Accordingly, these lots were not submitted to the FDA to request release for commercial sale and their remaining dollar value was written-off. In the absence of FDA approvals for product manufactured from existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale. (Please see Part 1, Item I: "Business; Our Products; Manufacturing" above for more information).

Alferon® LDO has been approved for pre-clinical testing for possible use as prophylaxis and treatment against influenza. While the studies to date have been encouraging, preliminary testing in the laboratory and in animal models is not necessarily predictive of successful results in clinical testing or human treatment. No assurance can be given that similar results will be observed in clinical trials. Use of Alferon® as a possible treatment of influenza requires prior regulatory approval. In October 2009, we originally submitted a protocol to the FDA proposing to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. In December 2010, the FDA authorized this Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects. Our Phase II study has been delayed. The outcome of this confirmatory study, if and when resumed, will allow us to better evaluate the potential effectiveness of this product and to proceed with this study of seasonal and pandemic influenza. We are unable to provide any assurances that the Phase II Alferon® LDO study for the prophylaxis and treatment of seasonal and pandemic influenza will be undertaken.

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

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

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

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

We last reported net profit from 1985 through 1987. Since 1987, with a major emphasis on new drug diagnostic and development, we have incurred substantial operating losses, as we pursued our clinical trial effort to get our experimental drug, Ampligen®, approved. As of December 31, 2016, our accumulated deficit was approximately \$300,501,000. We have not yet generated significant revenues from our products and may incur substantial and increased losses in the future. We cannot assure that we will ever achieve significant revenues from product sales or become profitable. We require, and will continue to require, the commitment of substantial resources to develop our products. We cannot assure that our product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

*We most likely will require additional financing which may not be available.*

The development of our products requires the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2016, we had approximately \$5,868,000 in cash, cash equivalents and marketable securities (inclusive of approximately \$3,460,000 in Marketable Securities). However, if we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted.

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

Given the challenging economic conditions, we continue to review every aspect of our operations for cost and spending reductions to assure our long-term financial stability while maintaining the resources necessary to achieve our primary objectives of obtaining NDA approval of Ampligen® along with the manufacturing, marketing and distribution of our products, including Alferon N Injection®. Due to the repair issues mentioned above within our NJ facility and the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. We may also need additional capital to eventually commercialize and sell Ampligen® or Alferon® LDO and/or recommence and increase sales of Alferon N Injection® or our other products. We anticipate considering multiple options in an attempt to secure funding, including but not limited to such methods as the sales of additional equity, licensing agreements, partnering with other organizations, debt financing or other sources of capital.

We did raise approximately \$850,000 in February 2017 from the sale of our securities. However, if we are unable to obtain additional funding, through an Equity Distribution Agreement ("EDA"), other sales of securities, the sale or mortgaging of our New Jersey properties and/or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

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

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

In April 2012, FDA reviewers raised certain questions about the status of our existing lots of older Work-In-Process Alferon® materials and Alferon® API, which would need to be released by the FDA before those materials could be used in commercial product. After conducting all of the appropriate tests on samples of the inventory during 2013, we concluded that we could not alleviate certain questions the FDA had about the older Work-In-Process Alferon N Injection® and their remaining dollar value has been written-off. Commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale.

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

If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. For more information on Alferon N Injection® regarding potential commercial sales, please see Part II, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations Business; Manufacturing".

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

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

We need to preserve and acquire enforceable patents covering the use of Ampligen® for a particular disease in order to obtain exclusive rights for the commercial sale of Ampligen® for such disease. We obtained all rights to Alferon N Injection®, and we plan to preserve and acquire enforceable patents covering its use for existing and potentially new diseases. Our success depends, in large part, on our ability to preserve and obtain patent protection for our products and to obtain and preserve our trade secrets and expertise. Certain of our know-how and technology is not patentable, particularly the procedures for the manufacture of our experimental drug, Ampligen®. We also have been issued a patent which affords protection on the use of Ampligen® in patients with Chronic Fatigue Syndrome. We have not yet been issued any patents in the United States for the use of Ampligen® as a sole treatment for any of the cancers which we have sought to target. For more information on Patents, please see PART I, Item I – “Business; Patents”.

We cannot assure that our competitors will not seek and obtain patents regarding the use of similar products in combination with various other agents, for a particular target indication prior to our doing so. If we cannot protect our patents covering the use of our products for a particular disease, or obtain additional patents, we may not be able to successfully market our products.

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

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

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

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

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

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

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

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

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

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

We cannot assure that our U.S. or foreign marketing strategy will be successful or that we will be able to establish future marketing or third party distribution agreements on terms acceptable to us, or that the cost of establishing these arrangements will not exceed any product revenues. Our inability to establish viable marketing and sales capabilities would most likely have a materially adverse effect on us. There can be no assurances that the approved Alferon N Injection® product will be returned to prior sales levels.

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

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

There are a limited number of suppliers in the United States and abroad available to provide the raw and packaging materials/reagents for use in manufacturing Ampligen® and Alferon®. At present, we do not have any agreements with third parties for the supply of any of these materials or we are relying on a limited source of reagent suppliers necessary for the manufacture of Alferon®. We have established relevant manufacturing operations within our New Brunswick, New Jersey facility for the production of Ampligen® polymers from raw materials in order to obtain a more consistent manufacturing basis in the quantities necessary for clinical testing. 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 we would supply. This Supply Agreement expired March 11, 2014. On January 3, 2017, we entered into a purchase order with Jubilant pursuant to which Jubilant will manufacture a commercial batch of Ampligen® for us. Pursuant to the new order, Jubilant will perform tooling and validation activities as well as final fill and finish services. In July 2016, we reached an agreement with Avecia to serve as an additional contract manufacturer of Ampligen® for use with clinical studies as well as the recently initiated Early Access Program (EAP) in Europe and Turkey. Should there be an unanticipated delay in receiving new product from Hollister-Stier and/or Avecia at that time, or should we experience an unexpected demand for Ampligen® in our clinical studies or pursuant to the EAP, our ability to supply Ampligen® most likely will be adversely affected.

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

Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels.

If we are unable to obtain or manufacture the required materials/reagents, and/or procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Ampligen®. The costs and availability of products and materials we need for the production of Ampligen® are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, ownership of intellectual property, FDA and other governmental regulations. There can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all. For more information on Ampligen® manufacturing, please see Part 1, Item I: "Business; Our Products; Manufacturing" above.

***There are a limited number of organizations in the United States available to provide the final manufacturing steps of formulation, fill, finish and packing sets for Alferon N Injection® and Ampligen®.***

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

In January 2012, we agreed to a Technology, Transfer, Validation and Commercial Supply Agreement with Althea regarding the fill and finish process for Alferon N Injection®. As we no longer have any existing inventory, commercial sales of Alferon® will not resume until new batches of Alferon® inventory and API can be produced, filled and finished, and released by the FDA for commercial sale.

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 we 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 clinical batches of Ampligen®. On January 3, 2017, we entered into a purchase order to replace the previous purchase commitment with Jubilant pursuant to which Jubilant will manufacture a commercial batch of Ampligen® for us. Pursuant to the new order, Jubilant will perform tooling and validation activities as well as final fill and finish services. We are unable to provide any assurances that the FDA will approve the inventory manufactured by us or produced by Jubilant. If this finish goods inventory is not granted approval by the FDA, our operations may be materially adversely affected. This Supply Agreement expired on March 11, 2014. We are working towards an amendment to the existing Supply Agreement which may contain additional fees as part of entering into the extension. In July 2016, we reached an agreement with Avecia to serve as an additional contract manufacturer of Ampligen® for use with clinical studies as well as the recently initiated Early Access Program (EAP) in Europe and Turkey. Should there be an unanticipated delay in receiving new product or should we experience an unexpected demand for Ampligen® in our clinical studies or pursuant to the EAP, our ability to supply Ampligen® most likely will be adversely affected.

If we are unable to procure services needed in the final steps in the manufacturing process, we may be unable to manufacture Alferon N Injection® and/or Ampligen®. The costs and availability of products and materials we need for the production of Ampligen® and the commercial production of Alferon N Injection® and other products which we may commercially produce are subject to fluctuation depending on a variety of factors beyond our control, including competitive factors, changes in technology, and FDA and other governmental regulations and there can be no assurance that we will be able to obtain such products and materials on terms acceptable to us or at all. For more information on Ampligen® and Alferon N Injection® manufacturing, please see Part I, Item I: “Business; Our Products; Manufacturing” above.

***There is no assurance that our manufacturing facility will again be granted a BLA certification by the FDA or return to commercial, large-scale production. In addition, our inability to timely fix the issues caused by the 2016 flood in our manufacturing facility could hinder our ability sustain sales of our products, if and when such sales commence.***

We completed the construction of our \$8 million facility enhancement project in 2015 which, upon FDA approval, should provide for a higher capacity, more cost effective manufacturing process for the production of Alferon N Injection®. The production of new Alferon® API inventory commenced in February 2015. While the facility is approved by FDA under the BLA for Alferon®, this status will need to be reaffirmed upon the completion of the facility’s enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status, we will need FDA approval to release the final product confirming the quality and stability to allow commercial sales to resume. For more information, please see Part II, Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations Business; Our Products; Manufacturing” above for more information. There can be no assurance the BLA status will be recertified by the FDA upon the completion of the enhancement process or that the manufacturing facility will return to commercial, large-scale production for Alferon®. Additionally, there can be no assurance that any given product will be determined to be safe and effective, or capable of being manufactured under applicable quality standards.

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

Our ability to manufacture at our manufacturing facility was also hampered and delayed by the flood. See Part I, Item 1. Business: “Marketing”.

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

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

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

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

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

Ampligen® has been produced to date in limited quantities for use in our clinical trials, and we are dependent upon a qualified third party supplier for the manufacturing, filling, finish and packaging process. The failure to continue these arrangements or to achieve other such arrangements on satisfactory terms could have a material adverse effect on us. In furtherance of the capital improvement program at our New Brunswick, NJ facility to upgrade our manufacturing capability to produce bulk quantities of Alferon N Injection® API, the validation phase of the Alferon® manufacturing project is currently underway. While the facility is approved by FDA under the BLA for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status, we will need FDA approval to release the final product confirming the quality and stability to allow commercial sales to resume. For more information, please see Part 1, Item I: "Business; Our Products; Manufacturing" above. In light of these contingencies, there can be no assurances that the approved Alferon N Injection® product will be returned to production on a timely basis, if at all. The failure to obtain FDA approval of any of our manufacturing process would most likely have a materially adverse impact upon us.

Also to be successful, our products must be manufactured in commercial quantities in compliance with regulatory requirements and at acceptable costs. We believe, but cannot assure, that our enhancements to our manufacturing facilities will be adequate for our future needs for the production of our proposed products for large-scale commercialization. We intend to ramp up our existing facility and/or utilize third party facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. We will need to comply with regulatory requirements for such facilities, including those of the FDA pertaining to cGMP requirements or maintaining our BLA status. There can be no assurance that such facilities can be used, built, or acquired on commercially acceptable terms, or that such facilities, if used, built, or acquired, will be adequate for the production of our proposed products for large-scale commercialization or our long-term needs.

We have never produced Ampligen®, Alferon® or any other products in large commercial quantities. We must manufacture our products in compliance with regulatory requirements in large commercial quantities and at acceptable costs in order for us to be profitable. We intend to utilize third party manufacturers and/or facilities if and when the need arises or, if we are unable to do so, to build or acquire commercial-scale manufacturing facilities. If we cannot manufacture commercial quantities of Ampligen® and/or Alferon®, or continue to maintain third party agreements for its manufacture at costs acceptable to us, our operations will be significantly affected. If and when the Ampligen® NDA is approved, we may need to find an additional vendor to manufacture the product for commercial sales. Also, each production lot of Alferon N Injection® is subject to FDA review and approval prior to releasing the lots to be sold. This review and approval process could take considerable time, which would delay our having product in inventory to sell, nor can we provide any assurance as to the receipt of FDA approval of our finished inventory product. There can be no assurances that the Ampligen® and/or Alferon® can be commercially produced at costs acceptable to us.

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

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

***Our products may be subject to substantial competition.***

Ampligen®. Competitors may be developing technologies that are, or in the future may be, the basis for competitive products. Some of these potential products may have an entirely different approach or means of accomplishing similar therapeutic effects to products being developed by us. These competing products may be more effective and less costly than our products. In addition, conventional drug therapy, surgery and other more familiar treatments may offer competition to our products. Furthermore, many of our competitors have significantly greater experience than we do in preclinical testing and human clinical trials of pharmaceutical products and in obtaining FDA, HPB and other regulatory approvals of products. Accordingly, our competitors may succeed in obtaining FDA, HPB or other regulatory product approvals more rapidly than us. There are no drugs approved for commercial sale with respect to treating CFS in the United States. The dominant competitors with drugs to treat disease indications in which we plan to address include Pfizer, GlaxoSmithKline, Merck & Co., Novartis and AstraZeneca. Biotech competitors include Baxter International, Fletcher/CSI, AVANT Immunotherapeutics, AVI BioPharma and Genta. These potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Although we believe our principal advantage is the unique mechanism of action of Ampligen® on the immune system, we cannot assure that we will be able to compete.

Alferon N Injection®. Our competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than we have. Alferon N Injection® currently competes with Merck's injectable recombinant alpha interferon product (Intron® A) for the treatment of genital warts. In addition, other pharmaceutical firms offer self-administered topical cream, for the treatment of external genital and perianal warts such as Graceway Pharmaceuticals (Aldara®), Watson Pharma (Condylox®) and MediGene (Veregen®). Alferon N Injection® also competes with surgical, chemical, and other methods of treating genital warts. We cannot assess the impact products developed by our competitors, or advances in other methods of the treatment of genital warts, will have on the commercial viability of Alferon N Injection®. If and when we obtain additional approvals of uses of this product, we expect to compete primarily on the basis of product performance. Our competitors have developed or may develop products (containing either alpha or beta interferon or other therapeutic compounds) or other treatment modalities for those uses. There can be no assurance that, if we are able to obtain regulatory approval of Alferon N Injection® for the treatment of new indications, we will be able to achieve any significant penetration into those markets. In addition, because certain competitive products are not dependent on a source of human blood cells, such products may be able to be produced in greater volume and at a lower cost than Alferon N Injection®. Currently, our wholesale price on a per unit basis of Alferon N Injection® is higher than that of the competitive recombinant alpha and beta interferon products. Please see risk factor "We may not be profitable unless we can protect our patents and/or receive approval for additional pending patents" above for additional information.

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

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

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

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

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

Alferon N Injection®. At present, Alferon N Injection® is approved for the intralesional (within the lesion) treatment of refractory or recurring external genital warts in adults. In clinical trials conducted for the treatment of genital warts with Alferon N Injection®, patients did not experience serious side effects; however, there can be no assurance that unexpected or unacceptable side effects will not be found in the future for this use or other potential uses of Alferon N Injection® which could threaten or limit such product's usefulness.

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

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

We face an inherent business risk of exposure to product liability claims in the event that the use of Ampligen®, Alferon N Injection® or other of our products results in adverse effects. This liability might result from claims made directly by patients, hospitals, clinics or other consumers, or by pharmaceutical companies or others manufacturing these products on our behalf. Our future operations may be negatively affected from the litigation costs, settlement expenses and lost product sales inherent to these claims. While we will continue to attempt to take appropriate precautions, we cannot assure that we will avoid significant product liability exposure.

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

***The loss of services of key personnel could hurt our chances for success.***

Our success is dependent on the continued efforts of our staff, especially certain doctors and researchers. The loss of the services of personnel key to our operations could have a material adverse effect on our operations and chances for success. The loss of key personnel or the failure to recruit additional personnel as needed could have a materially adverse effect on our ability to achieve our objectives.

***Uncertainty of health care reimbursement for our products.***

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

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

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

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

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

**Risks Associated with an Investment in Our Common Stock:**

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

The market price of our common stock has been and is likely to be volatile. This is especially true given the current significant instability in the financial markets. In addition to general economic, political and market conditions, the price and trading volume of our stock could fluctuate widely in response to many factors, including:

- announcements of the results of clinical trials by us or our competitors;
- announcements of availability or projections of our products for commercial sale;
- announcements of legal actions against us and/or settlements or verdicts adverse to us;
- adverse reactions to products;
- governmental approvals, delays in expected governmental approvals or withdrawals of any prior governmental approvals or public or regulatory agency comments regarding the safety or effectiveness of our products, or the adequacy of the procedures, facilities or controls employed in the manufacture of our products;
- changes in U.S. or foreign regulatory policy during the period of product development;
- developments in patent or other proprietary rights, including any third party challenges of our intellectual property rights;
- announcements of technological innovations by us or our competitors;
- announcements of new products or new contracts by us or our competitors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by securities analysts and whether our earnings meet or exceed the estimates;
- conditions and trends in the pharmaceutical and other industries;
- new accounting standards;
- overall investment market fluctuation;
- restatement of prior financial results;
- notice of NYSE MKT non-compliance with requirements; and
- occurrence of any of the risks described in these “Risk Factors”.

Our common stock is listed for quotation on the NYSE MKT. For the year ended December 31, 2016, the trading price of our common stock has ranged from \$0.65 to \$2.64 per share. We expect the price of our common stock to remain volatile. The average daily trading volume of our common stock varies significantly.

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

We may issue shares to be used to meet our capital requirements or use shares to compensate employees, consultants and/or Directors. In this regard, we have registered securities for public sale pursuant to a universal shelf registration statement and we had been selling shares under this shelf registration statement and the EDA with Maxim. Effective December 15, 2015, we halted all future offers and sales of our Common Stock under the EDA with Maxim and reduced the amount of potential future offers and sales under the EDA to \$0.00. Between July 23, 2012, the date of the EDA, and December 15, 2015, we sold an aggregate of 8,881,788 shares of Common Stock pursuant to the EDA for aggregate gross proceeds of \$47,453,220. On December 15, 2015, we filed a prospectus supplement related to the issuance and sale of up to \$7,941,000 of our common stock from time to time through our sales agent, Chardan Capital Markets, LLC. Effective August 26, 2016, we halted all future offers and sales of its common stock under the Chardan Agreement and reduced the amount of potential future offers and sales under the Chardan Agreement to \$0.00. Between December 15, 2015, the date of the Chardan Agreement, and August 26, 2016, we sold an aggregate of 114,394 shares of common stock pursuant to the Chardan Agreement for aggregate net proceeds of approximately \$74,000. On September 6, 2016, we entered into Securities Purchase Agreements with certain investors for the sale by us of 3,333,334 shares of our common stock at a purchase price of \$1.50 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate net proceeds of \$4,520,000. We also issued placement agent warrants for the purchase of an aggregate of 166,667 shares of our common stock. On February 1, 2017, we entered into Securities Purchase Agreements 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 \$850,000. We also issued placement agent warrants for the purchase of an aggregate of 90,909 shares of our common stock. Please see Item 7-Management's Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources" in PART II.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of substantial amounts of our common stock in the public market, including additional sale of securities pursuant to the EDA with Chardan or otherwise under the universal shelf registration statement or upon exercise of outstanding options and warrants, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities.

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

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

***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 1B. Unresolved Staff Comments.**

None.

**ITEM 2. Properties.**

We currently lease through June 2018, our headquarters located in Philadelphia, Pennsylvania consisting of a suite of offices of approximately 6,760 square feet.

We also own, occupy and use our New Brunswick, New Jersey laboratory and production facility. These facilities consist of two buildings located on 2.8 acres. One building is a two story facility consisting of a total of approximately 30,000 square feet. This facility contains offices, laboratories and production space. It also contains space designated for research and development, packaging, quality assurance and quality control laboratories. Building Two has 11,670 square feet consisting of offices, laboratories, warehouse space, shipping, receiving and packaging areas. The property has parking space for approximately 100 vehicles.

As part of our objectives to achieve our commercial goals and increase stockholder value, we have initiated the sale of underutilized assets. As a result, we are in the process of selling Building Two at its current market value. We also are exploring the possibility of mortgaging our facility or selling it if we can obtain a long term lease back on the facility on acceptable terms.

**ITEM 3. Legal Proceedings.**

- (a) *Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William M. Mitchell, Richard C. Piani, David Strayer and Charles T. Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:13-cv-00243-WY.*
- (b) *Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, March 2013 Term, No. 110.*
- (c) *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, April 2013 Term, No. 3458.*
- (d) *Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Richard C. Piani, William M. Mitchell, Iraj E. Kiani and Robert E Peterson, Chancery Court of the State of Delaware, June 18, 2013, Case No. 8657.*
- (e) *Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 9-549-GMS.*

- (a) On January 15, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the United States District Court for the Eastern District of Pennsylvania. Purporting to assert claims on behalf of the Company, the Complaint in this action, *Mark Zicherman v. Hemispherx Biopharma, Inc., et al.*, alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On February 22, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On July 3, 2013, Plaintiff filed an Amended Complaint, adding David R. Strayer, M.D., as a Defendant. On July 18, 2013, the Court entered an order staying the case as against Dr. Strayer pending the outcome of the motion to dismiss the securities class action. On January 24, 2014, the Court denied the defendants' motion to dismiss the securities class action. On March 26, 2014, the Court entered an order to continue the temporary stay, and on March 27, 2014, the Court entered an order placing the action in the Civil Suspense File. On April 11, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On January 28, 2015, on request of the parties, the Court entered an Order continuing the temporary stay, subject to the requirement that the parties submit an updated joint status report within ten days of the court's entry of an order granting or denying the securities class action parties' motion for preliminary approval of their settlement agreement. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' Settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court entered an Order granting final approval of the parties' settlement, awarding the plaintiffs' counsel \$660,000 in attorneys' fees, and dismissing the action and all claims alleged therein against all defendants with prejudice. The Settlement resolves all claims asserted in this action ("Zicherman") and the two related consolidated state-court actions referenced below, *Michael Desclos v. Hemispherx Biopharma, Inc. et al.*, and *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al.* The Settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies.
- (b) On March 4, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, *Michael Desclos v. Hemispherx Biopharma, Inc., et al.*, alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On April 10, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On January 24, 2013, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the court entered an order consolidating this action with the shareholder derivative action, *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al.*, described below. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court in Zicherman entered an Order granting final approval of the parties' settlement and awarding the plaintiffs' counsel \$660,000 in attorneys' fees. The Settlement, which resolves all claims asserted in this action ("Desclos") and the two related actions, Zicherman, referenced above, and the state court action referenced below, *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al.*, does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies. On December 2, 2016, the Court in this action removed the case from deferred status, and on December 5, 2016, the prothonotary entered the plaintiffs' praecipe to mark the case settled, discontinued, and ended in its entirety, and with prejudice.

- (c) On April 23, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al.*, alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On May 10, 2013, the Court entered an order staying this case pending the outcome of the ruling on the Federal Securities Class Action Defendants' motion to dismiss. On January 24, 2014, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the Court entered an order consolidating this action with the shareholder derivative action, *Michael Desclos v. Hemispherx Biopharma, Inc., et al.*, described above. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court in Zicherman entered an Order granting final approval of the parties' settlement and awarding the plaintiffs' counsel \$660,000 in attorneys' fees. The Settlement, which resolves all claims asserted in this action and the two related actions, Zicherman and Desclos, referenced above, does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies. On December 2, 2016, the Court in this action removed the case from deferred status, and on December 8, 2016, the prothonotary entered the plaintiffs' praecipe to mark the case settled, discontinued, and ended in its entirety, and with prejudice.

- (d) On June 18, 2013, a Stockholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the Court of Chancery of the State of Delaware. The Complaint in this action, Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., et al., alleges breaches of fiduciary duties, waste of corporate assets and unjust enrichment. The Company's Board of Directors appointed a Special Litigation Committee ("SLC") to review the allegations set forth in the Complaint. On September 10, 2013, the Court entered a Stipulation and Order staying all proceedings in this action pending the SLC's review and recommendation concerning the allegations contained in the Complaint. On December 20, 2013, the SLC issued its Report, in which it concluded that dismissing the Complaint would be in the best interests of Hemispherx and its stockholders. On January 20, 2014, the SLC moved to dismiss the Complaint. Following briefing and oral argument on the motion to dismiss, the Court denied the SLC's motion on August 18, 2015, but did dismiss the claims against former officer Robert E. Peterson. On October 13, 2015, Plaintiffs filed a Verified Amended Derivative and Class Action Complaint (the "Amended Complaint"), asserting additional claims for breach of fiduciary duty against Board member Peter W. Rodino, declaratory judgment with respect to certain bonuses paid to officers of the Company, and a class action claim for breach of fiduciary duty against the current Board in connection with the solicitation of votes in advance of the Company's 2015 annual meeting. The Amended Complaint also removed all of the dismissed claims against Mr. Peterson. The Company and all individual defendants except former Board member Richard C. Piani answered the Amended Complaint on November 19, 2015. The Court entered a scheduling order on December 2, 2015, but on January 5, 2016, the parties agreed to suspend all litigation for 60 days and to attempt to resolve the action through mediation. The parties engaged in a mediation on February 10, 2016, and reached an agreement in principle to settle all claims on April 27, 2016. That agreement was memorialized in a Stipulation and Agreement of Settlement (the "Settlement Stipulation") which was filed with the Court on June 8, 2016. The settlement was subject to the Court's finally approving the terms of the parties' settlement agreement in all material respects. On June 8, 2016, concurrent with the filing of the Settlement Stipulation, the parties filed a joint proposed scheduling order, which the Court entered the same day (the "Scheduling Order"). The Scheduling Order preliminarily certified the class for settlement purposes, directed the Company to issue notice (in the form approved by the Court) to Company stockholders and members of the putative class, and scheduled a settlement approval hearing (the "Settlement Approval Hearing") to occur on September 9, 2016. At the Settlement Approval Hearing on September 9 and September 19, 2016, the Court approved the settlement, awarded plaintiffs' counsel \$1.25 million in attorneys' fees and expenses, and dismissed the action with prejudice. No stockholders or members of the putative class objected to the settlement. No Company funds were used to pay the settlement or attorneys' fees award; the settlement and fee award were funded by Hemispherx's insurance policies. The final settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants.
- (e) Cato Capital, LLC ("Cato") brought suit against the Company on July 31, 2009, in the United States District Court for the District of Delaware (the "Court"), alleging that under a November 2008 agreement between Cato and Hemispherx, Hemispherx owed Cato a placement fee arising from subsequent Hemispherx financing and investment transactions. Hemispherx disputed these allegations, asserting that Cato failed to comply with the provisions of its own contract. The Amended Complaint sought damages in the amount of \$9,830,000.00 plus attorneys' fees and punitive damages. Pursuant to an indemnification responsibility, Hemispherx has also retained this firm to undertake the defense of the Sage Group.

The Parties had a Non-Jury trial on March 4, 5 and 6, 2013 before the United States District Court for the District of Delaware. On September 29, 2014, the Court found in favor of Hemispherx and Sage on all counts, and dismissed Cato's claims in their entirety. On January 13, 2015, the Court granted the Company's motion for attorney's fees and costs and awarded the Company \$770,852.76.

On October 24, 2014, Cato filed a notice of appeal of the Court's September 29, 2014 decision in the United States Court of Appeals for the Third Circuit (the "Third Circuit"). On March 3, 2015, Cato filed its Brief in the Third Circuit. The Company's Brief in Response was filed on April 6, 2015, with a Reply Brief by Cato filed on April 19, 2015. The Court of Appeals conducted Oral Argument on July 16, 2015. On August 21, 2015 the Court of Appeals affirmed the judgment of the District Court. On September 9, 2015 Cato sought reconsideration of the decision through re-argument or re-hearing by the en banc Court of Appeals. On September 17, 2015 the Court of Appeals denied Cato's requests. On October 1, 2015 Hemispherx filed for additional costs and fees to be added to its existing judgment. On February 10, 2016 the Court increased Hemispherx' judgment by an additional \$48,725.75 to reflect the costs of defending the Cato appeal. On February 11, 2016 the Court of Appeals returned the mandate to the District Court. The Company is pursuing collection of its judgment in the amount of \$829,578.51.

**ITEM 4. Mine Safety Disclosures.**

Not Applicable.

**PART II**

**ITEM 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Since October 1997 our common stock has been listed and traded on the NYSE MKT (formerly AMEX) under the symbol HEB. The following table sets forth the high and low list prices for our Common Stock for the last two fiscal years as reported by the NYSE MKT. Such prices reflect inter-dealer prices, without retail mark-up, mark-downs or commissions and may not necessarily represent actual transactions. The following prices give retroactive effect to the 12-to-1 reverse stock split effected on August 26, 2016.

<b>COMMON STOCK</b>	<u>High</u>	<u>Low</u>
<u>Time Period:</u>		
January 1, 2016 through March 31, 2016	\$ 2.40	\$ 0.78
April 1, 2016 through June 30, 2016	\$ 1.92	\$ 1.24
July 1, 2016 through September 30, 2016	\$ 2.64	\$ 1.24
October 1, 2016 through December 31, 2016	\$ 1.26	\$ 0.65
January 1, 2015 through March 31, 2015	\$ 3.96	\$ 2.52
April 1, 2015 through June 30, 2015	\$ 3.48	\$ 2.40
July 1, 2015 through September 30, 2015	\$ 2.52	\$ 1.68
October 1, 2015 through December 31, 2015	\$ 2.16	\$ 0.72

As of March 10, 2017, there were approximately 201 holders of record of our Common Stock. This number was determined from records maintained by our transfer agent and does not include beneficial owners of our securities whose securities are held in the names of various dealers and/or clearing agencies.

On March 10, 2017, the last sale price for our common stock on the NYSE MKT was \$0.52 per share.

We have not paid any cash dividends on our Common Stock in recent years. It is management’s intention not to declare or pay dividends on our Common Stock, but to retain earnings, if any, for the operation and expansion of our business.

The following table gives information about our Common Stock that may be issued upon the exercise of options, warrants and rights under all of our equity compensation plans as of December 31, 2016:

<u>Plan Category</u>	<u>Number of Securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average Exercise price of Outstanding options, warrants and rights</u>	<u>Number of securities Remaining available for future issuance under equity compensation plans (excluding securities reflected in column) (a)</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders:	1,107,755	\$ 14.48	533,170
Equity compensation plans not approved by security holders:	2,830,517	\$ 2.16	-
<b>Total</b>	<b>3,938,272</b>	<b>\$ 5.63</b>	<b>533,170</b>

**ITEM 6. Selected Financial Data (in thousands except for share and per share data).**

The selected consolidated financial data set forth below should be read in conjunction with our consolidated financial statements, and the related notes thereto, and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, included in this Annual Report. The statement of operations and balance sheet data presented below for, and as of the end of, each of the years in the five-year period ended December 31, 2016 are derived from our audited consolidated financial statements. Historical results are not necessarily indicative of the results to be expected in the future.

Year Ended December 31	2012	2013	2014	2015	2016
<b>Statement of Operations Data:</b>					
Revenues and license fee income	\$ 213	\$ 150	\$ 197	\$ 133	\$ 92
Total costs and expense <sup>(1)</sup>	20,553	17,317	19,296	16,783	13,896
Interest expense and financing costs	24	16	11	3	-
Redeemable warrants valuation adjustment	(85)	(281)	(14)	-	(1,677)
Net loss	(17,354)	(16,225)	(17,450)	(15,230)	(7,502)
Net loss applicable to common stockholders	(17,354)	(16,225)	(17,450)	(15,230)	(7,502)
Basic and diluted net loss per share	\$ (1.44)	\$ (1.20)	\$ (1.08)	\$ (0.72)	\$ (0.34)
Shares used in computing basic and diluted net loss per share	11,751,411	13,943,799	15,690,998	19,679,315	21,818,206
<b>Balance Sheet Data:</b>					
Working capital	\$ 32,079	\$ 16,020	\$ 12,071	\$ 8,138	\$ 4,506
Total assets	57,699	31,867	29,440	22,804	18,873
Debt, net of discount	7,051	—	—	—	—
Stockholders’ equity	44,700	29,298	25,004	20,371	15,498
<b>Cash Flow Data:</b>					
Cash used in operating activities	(13,136)	(16,901)	(13,964)	(16,053)	(7,380)
Capital expenditures	\$ (5,755)	\$ (898)	\$ (504)	\$ (240)	\$ (160)

(1) General and Administrative expenses include stock compensation expense of \$356, \$376, \$326, \$181 and \$410 for the years ended December 31, 2012, 2013, 2014, 2015 and 2016, respectively.

**ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

The following discussion and analysis is related to our financial condition and results of operations for the three years ended December 31, 2016. This information should be read in conjunction with ITEM 6 – “Selected Financial Data” and our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K.

**Statement of Forward-Looking Information**

Certain statements in the section are “forward-looking statements”. You should read the information in “Cautionary Statement Regarding Forward-Looking Statements” set forth before Part I of this report above for more information about our presentation of information.

## **Background**

We are a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based disorders. We were founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, we have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases.

We have reported net income only from 1985 through 1987. Since 1987, we have incurred, as expected, substantial operating losses due to our conducting research and development programs.

We have been reexamining our fundamental priorities in terms of direction, corporate culture and our ability to fund operations. As a result, there have been significant changes at the Company in the past year. As noted below, we have made several changes to the Company's executive management team to provide effective and competent leadership that, management believes, will properly position the Company to achieve its commercial goals and increase stockholder value. Recent actions include aggressively pursuing international sales of clinical grade materials and implementing a strong financial austerity plan. We are committed to a focused business plan oriented toward finding senior co-development partners with the capital and expertise needed to commercialize the many potential therapeutic aspects of our experimental drug, Ampligen®, and our approved drug Alferon®. Management's primary objectives are to create stockholder value and deliver much needed therapies to patients.

## **Fair Value**

In connection with the equity financing in August 2016, we issued warrants (the "Warrants") that are single compound derivatives containing both an embedded right to obtain stock upon exercise (a "Call") and a series of embedded rights to settle the Warrants for cash upon the occurrence of certain events (each, a "Put"). Generally, the Put provisions allow the Warrant Holders liquidity protection; the right to receive cash in certain situations where the Holders would not have a means of readily selling the shares issuable upon exercise of the Warrants (e.g., where there would no longer be a significant public market for our common stock). However, because the contractual formula used to determine the cash settlement value of the embedded Put requires use of certain assumptions, the cash settlement value of the embedded Put can differ from the fair value of the unexercised embedded Call option at the time the embedded Put option is exercised.

We recompute the fair value of the Warrants at the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If we were to alter our assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

## RESULTS OF OPERATIONS

### Year ended December 31, 2016 versus year ended December 31, 2015

#### Net Loss

Our net loss was approximately \$7,502,000 and \$15,230,000 for the year ended December 31, 2016 and 2015, respectively, representing a decrease in loss of approximately \$7,728,000 or 51% when compared to the same period in 2015. This decrease in loss for this year was primarily due to the following:

- 1) a decrease in research and development expense of \$2,931,000 or 36%;
- 2) a decrease in production costs of approximately \$490,000 or 31%;
- 3) an insurance settlement net of litigation expenses recorded as other income of \$1,626,000;
- 4) an increase in the gain from sale of income tax net operating losses of \$1,496,000 or 109%; and
- 5) a gain on the valuation adjustment on the redeemable warrants of approximately \$1,677,000; offset by
- 6) an increase in general and administrative expense of approximately \$534,000 or 7%.

Net loss per share was \$(0.34) and \$(0.77) for the year ended December 31, 2016 and 2015, respectively. The weighted average number of shares of our common stock outstanding as of December 31, 2016 was 21,818,206 as compared to 19,679,315 as of December 31, 2015.

#### Revenues

Revenues from our Ampligen® Cost Recovery Program were \$92,000 and \$133,000 for the year ended December 31, 2016 and 2015, respectively. For the years ended December 31, 2016 and 2015, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the FDA approved open-label treatment protocol, (“AMP-511”), that allows patient access to Ampligen® for treatment in an open-label safety study.

#### Production Costs

Production costs were approximately \$1,108,000 and 1,598,000, respectively, for the year ended December 31, 2016 and 2015. This decrease of approximately \$490,000 or 31% was primarily due to a decline in ongoing stability testing on Alferon® Work-In-Process inventory.

#### Research and Development Costs

Overall Research and Development (“R&D”) costs for the year ended December 31, 2016 were approximately \$5,107,000 as compared to \$8,038,000 for the same period a year ago, reflecting a decrease of approximately \$2,931,000 or 36%. The primary reason for the decrease in research and development costs was due to a decrease in general R&D expenses of approximately \$2,489,000 including Alferon N Injection® compliance testing and clinical work and a decrease in executive salaries and wages of approximately \$1,478,000. This was offset by a general net increase in R&D expenses of approximately \$916,000 associated with Ampligen®. These decreases in general R&D expenses were mainly the result of implementing a strong financial austerity plan whereby we conducted an analysis of our research and development programs and our staffing levels within our New Jersey manufacturing facility.

### **General and Administrative Expenses**

General and Administrative (“G&A”) expenses for the years ended December 31, 2016 and 2015, were approximately \$7,681,000 and \$7,147,000, respectively, reflecting an increase of approximately \$534,000 or 7%. The increase in G&A expenses in 2016 was mainly due to higher salaries and wages and severance related costs in the current period.

### **Interest and Other Income**

Interest and other income for the years ended December 31, 2016 and 2015 were approximately \$129,000 and \$364,000, respectively, representing a decrease of approximately \$235,000 or 65%. The primary cause for the decrease in investment income during the current period was primarily due to lower balances available to invest in the current period as compared to the prior period.

### **Insurance settlement net of litigation expenses**

We recorded a net insurance settlement of \$1,626,000 during the year ended December 31, 2016 which resulted from the legal settlements of various class action lawsuits during the current period. Insurance proceeds received of \$3,726,000 were offset by litigation settlement expenses of \$2,100,000. There were no such expenses in the prior period (see “Part I; Item 3: Legal Proceedings” for details).

### **Loss on Sale of Marketable Securities**

Loss on sale of marketable securities was \$0 and \$315,000, respectively, for the years ended December 31, 2016 and 2015. Our securities sold during the current period resulted in net realized losses. Our analysis in 2015 of the trading value for marketable securities for the year ended December 31, 2015 resulted in an observation that some of our investments had experienced a decrease in market value for a period of longer than the last twelve consecutive months. Accordingly, an estimated impairment loss of \$315,000 was recognized in 2015.

### **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. Also, in December 2016, the Company effectively sold \$14,000,000 of its New Jersey state net operating loss carryforwards (for the year 2015) for approximately \$1,120,000 and sold research credits for \$189,000. In January 2015, the Company effectively sold \$14,291,000 of its approximately \$28,000,000 of New Jersey state net operating loss carryforwards (for the year 2013) for approximately \$1,374,000, representing an increase in cash gain of \$1,496,000 or 109% (see Part II; Item 8; Financial Statements and Supplementary Data; “Note 13: Income Tax”) for the year ended December 31, 2016 as compared to the same period in 2015.

### **Redeemable Warrants**

The quarterly fiscal revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the year ended December 31, 2016 amounting to a gain of approximately \$1,677,000 (see Part II; Item 8; Financial Statements and Supplementary Data; “Note 17: Fair Value” for the various factors considered in the valuation of redeemable warrants).

### **Year ended December 31, 2015 versus year ended December 31, 2014**

#### **Net Loss**

Our net loss was approximately \$15,230,000 and \$17,450,000 for the year ended December 31, 2015 and 2014, respectively, representing a decrease in loss of approximately \$2,220,000 or 13% when compared to the same period in 2014. This decrease in loss for period was primarily due to the following:

- 1) a decrease in research and development expense of \$2,931,000 or 36%;
- 2) a decrease in production costs of approximately \$490,000 or 31%;
- 3) an insurance settlement net of litigation expenses recorded as other income of \$1,626,000;
- 4) an increase in the gain from sale of income tax net operating losses of \$1,496,000 or 109%; and
- 5) a gain on the valuation adjustment on the redeemable warrants of approximately \$1,677,000; offset by
- 6) an increase in general and administrative expense of approximately \$534,000 or 7%.

Net loss per share was \$(0.77) and \$(1.11) for the year ended December 31, 2015 and 2014, respectively. The weighted average number of shares of our common stock outstanding as of December 31, 2015 was 19,679,315 as compared to 15,690,998 as of December 31, 2014.

#### **Revenues**

Revenues from our Ampligen® Cost Recovery Program were \$133,000 and \$197,000 for the year ended December 31, 2015 and 2014, respectively. Although there was a slight increase in the patients utilizing Ampligen® in 2015, there was a decrease in revenue of \$64,000 or 33% primarily due to a lower dosage being prescribed to patients utilizing Ampligen® during the current period. For the years ended December 31, 2015 and 2014, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the FDA approved open-label treatment protocol, (“AMP-511”), that allows patient access to Ampligen® for treatment in an open-label safety study.

### Production Costs

Production costs were approximately \$1,598,000 and \$1,251,000, respectively, for the year ended December 31, 2015 and 2014. This increase of approximately \$347,000 or 28% was primarily due to charges to inventory of \$117,000 resulting from vials removed from inventory for testing purposes and losses incurred during the manufacturing process. The remaining increase in production costs of \$230,000 was mainly due to an increase in facility costs related to the manufacturing of Alferon N Injection®.

### Research and Development Costs

Overall Research and Development (“R&D”) costs for the year ended December 31, 2015 were approximately \$8,038,000 as compared to \$8,988,000 for the same period a year ago, reflecting a decrease of approximately \$950,000 or 11%. The primary reason for the decrease in research and development costs was due to a decrease in clinical trial costs of \$122,000 associated with the conclusion of our University of Washington study in 2014 utilizing Ampligen® as an adjuvant in optimally treated breast cancer patients as data from these patients was evaluated and resources were directed to other projects, a decrease in bonus charges to executive officers of \$628,000, a decrease in charges of \$228,000 associated with the abandonment of patents and a decrease in research and development costs of \$131,000 associated with Ampligen®. This was offset by an increase in stability testing and pre-production costs related to the initiation of manufacturing of Alferon N Injection® of \$232,000 during the period.

### General and Administrative Expenses

General and Administrative (“G&A”) expenses for the year ended December 31, 2015 and 2014, were approximately \$7,147,000 and \$9,057,000, respectively, reflecting a decrease of approximately \$1,910,000 or 21%. The decrease in G&A expenses in 2015 was mainly due to lower legal fees of \$1,495,000 associated with various legal proceedings as compared to the prior period (see “Part I; Item 3: Legal Proceedings” for details) as well as a decrease in bonus charges to executives of \$513,000 as compared to the prior period.

### Interest and Other Income

Interest and other income for the year ended December 31, 2015 and 2014 were approximately \$364,000 and \$665,000, respectively, representing a decrease of approximately \$301,000 or 45%. The primary cause for the decrease in investment income during the current year was primarily due to lower cash available for investment purposes as compared to the prior period.

### Impairment Loss from Marketable Securities

Impairment loss from marketable securities was \$315,000 and \$145,000, respectively, for the years ended December 2015 and 2014. Our analysis in 2015 of the trading value for marketable securities for the year ended December 31, 2015 resulted in an observation that some of our investments had experienced a decrease in market value for a period of longer than the last twelve consecutive months. Accordingly, an estimated impairment loss of \$315,000 was recognized in 2015 for the sustained decrease in the respective market value as compared to \$145,000 in the prior period.

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

In January 2015, the Company effectively sold \$14,291,000 of our approximately \$28,000,000 of New Jersey state net operating loss carryforwards (for the year 2013) for approximately \$1,374,000. In February 2014, we effectively sold \$13,900,000 of our approximately \$25,000,000 of New Jersey state net operating loss carryforwards (for the year 2012) for approximately \$1,126,000, representing an increase in cash gain of \$248,000 or 22% (see "Note 13: Funds Received from Sale of Income Tax Net Operating Losses") for the year ended December 31, 2015 as compared to the same period in 2014.

#### Liquidity and Capital Resources

Cash used in operating activities for the year ended December 31, 2016 was approximately \$7,380,000 compared to approximately \$16,053,000 for the same period in 2015, a decrease of \$8,673,000 or 54%. The primary reason for this decrease in cash used in operations in 2016 was due to lower operating expenses whereby we conducted an analysis of our research and development programs as well as our staffing levels within our New Jersey manufacturing facility which resulted in a decrease in cash flow used in operations in 2016. Also, the Company received \$1,309,000 in net proceeds from the sale of its New Jersey state net operating loss carryforwards for 2015 earlier than anticipated in December 2016. In addition, the Company received net proceeds from an insurance settlement of \$1,626,000 which resulted from the legal settlements of various class action lawsuits during the current period. Also, the Company paid the 2014 executive incentive bonuses in January 2015 for approximately \$1,232,000 reflected in accrued expenses and also paid for Work-In-Process inventory of \$1,326,000 in 2015.

Cash provided by investing activities for the year ended December 31, 2016 was approximately \$2,930,000 compared to approximately \$6,352,000 in cash provided by investing activities for the same period in 2015, a decrease of \$3,422,000. The primary reason for the decrease can be attributable to sales and maturities of marketable securities during the current period of \$3,370,000 as compared to \$6,842,000 in the prior period.

Cash provided by financing activities for the year ended December 31, 2016 was approximately \$4,743,000 compared to approximately \$9,660,000 for the same period in 2015, a decrease of \$4,917,000. Cash provided by financing activities for the year ended December 31, 2016 primarily represented net proceeds received from the sale of common stock pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with certain investors for the sale by us of 3,333,334 shares of our common stock at a purchase price of \$1.50 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 2,500,000 shares of common stock for aggregate net proceeds of \$4,520,000. Cash provided by financing activities for the year ended December 31, 2015 primarily represented the Company receiving net proceeds of \$9,680,000 from the sale of 3,416,141 shares sold pursuant to the ATM (see Part II; Item 8; Financial Statements and Supplementary Data; "Note 7: Stockholders' Equity").

As of December 31, 2016, we had approximately \$5,868,000 in cash, cash equivalents and marketable securities, inclusive of approximately \$3,460,000 in Marketable Securities, representing a decrease of approximately \$3,042,000 from December 31, 2015. In an effort to conserve cash, we conducted an analysis of our research and development programs as well as our staffing levels within our New Jersey manufacturing facility. Our analysis disclosed an ability to gain efficiencies and eliminate redundancies within our staffing which will result in a decrease in cash flow used in operations in 2016 and beyond. If we are unable to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. In this regard, due to the repair issues mentioned above within our NJ facility and the high cost estimates to bring the facility back online, we most likely will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. However, there is no assurance that such financing will be available.

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

In 2015, Mr. Equels waived his right under his employment agreement to any future payment of any incentive bonus related to the sale of the Company's stock or other securities by, or on behalf of, the Company pursuant to the Maxim Equity Distribution Agreement or any similar or successor ATM equity distribution agreement. Mr. Equels provided this waiver as part of the litigation settlements in 2016 as well as in an effort to preserve cash and to help the Company to ensure its short term commercialization goals.

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

On December 15, 2015, we entered into an Equity Distribution Agreement with Chardan Capital Markets, LLC (the "Chardan Agreement") to create an at-the-market equity program under which we may sell shares of our common stock from time to time through Chardan Capital Markets, LLC, as sales agent ("Chardan"). Under the Chardan Agreement, Chardan will be entitled to a commission at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the Chardan Agreement. Sales of the Shares, if any, under the Chardan Agreement may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Chardan. The Company has no obligation to sell any of the Shares, and may at any time suspend offers under the Chardan Agreement or terminate the Chardan Agreement. Effective August 26, 2016, the Company halted all future offers and sales of its common stock under the Chardan Agreement and reduced the amount of potential future offers and sales under the Chardan Agreement to \$0.00. Between December 15, 2015, the date of the Chardan Agreement, and August 26, 2016, we sold an aggregate of 114,394 shares of common stock pursuant to the Chardan Agreement for aggregate net proceeds of approximately \$174,000.

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

On February 1, 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 \$850,000. We also issued placement agent warrants for the purchase of an aggregate of 90,909 shares of our common stock. See also Part II; Item 8; Financial Statements and Supplementary Data; "Note 7: Stockholders' Equity" and "Note 18: Subsequent Events" for both of the above transactions.

On March 29, 2017, we entered into a term sheet with a bridge funding company to obtain a two year funding line of up to \$4,000,000 secured by our New Brunswick, New Jersey facility. Subject to the lender's approval, we will be able to request up to \$3,000,000 of the line in monthly advances during the loan term of 24 months. To obtain advances, we are required to provide the lender with an operating budget and with monthly financial statements reflecting an increase in production and sales of our products in accordance with that budget. We will be able to request future advances in excess of the \$3,000,000 if and when we verify to the lender's satisfaction that our net sales revenue will be adequate to service the then outstanding loan amount plus contemplated additional future advances. We are permitted to prepay the line without penalty commencing after six months. No assurance can be given that we will enter into a definitive loan agreement with the lender. In addition, we cannot assure the actual amount of funding that will be provided under the line.

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 I, Item 1A. Risk Factors; "*We may require additional financing which may not be available.*"

Contractual Cash Obligations	Total	(dollars in thousands)				
		Obligations Expiring by Period				
		2017	2018	2019	2020	2021
Manufacture clinical batches - Ampligen®	\$ 700	\$ 700	\$ —	\$ —	\$ —	\$ —
Manufacture validation batches - Alferon®	622	622	—	—	—	—
Operating Leases	229	161	68	—	—	—
<b>Total</b>	<b>\$ 1,551</b>	<b>\$ 1,483</b>	<b>\$ 68</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>

#### Certain Relationships and Related Transactions

Refer to PART III, ITEM 13 - "Certain Relationships and Related Transactions, and Director Independence."

#### New Accounting Pronouncements

Refer to "Note 2(i) – Recent Accounting Standards and Pronouncements" under Notes to Consolidated Financial Statements.

#### Disclosure about Off-Balance Sheet Arrangements

None.

#### Critical Accounting Policies

Financial Reporting Release No. 60 requires all companies to include a discussion of critical accounting policies or methods used in the preparation of financial statements. Our significant accounting policies are described in the Notes to Consolidated Financial Statements. The significant accounting policies that we believe are most critical to aid in fully understanding our reported financial results are the following:

##### Revenue

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

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

##### Inventories

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

##### Patents and Trademarks

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

### Long-Lived Assets

We assess long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that we considers in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in its use of the assets. We measure the recoverability of assets that it will continue to use in its operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired.

We measure the impairment by comparing the difference between the asset grouping's carrying value and its fair value. Long-lived assets are considered a non-financial asset and are recorded at fair value only if an impairment charge is recognized. Impairments are determined for groups of assets related to the lowest level of identifiable independent cash flows. We make subjective judgments in determining the independent cash flows that can be related to specific asset groupings. In addition, as we review our manufacturing process and other manufacturing planning decisions, we must make subjective judgments regarding the remaining useful lives of assets. When we determine that the useful lives of assets are shorter than originally estimated, we accelerate the rate of depreciation over the assets' new, shorter useful lives.

### Stock-Based Compensation

Under FASB ASC 718-Compensation-Stock Compensation ("ASC 718") share-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the requisite service period. We adopted the provisions of ASC-718, using a modified prospective application. Under this method, compensation cost is recognized for all share-based payments granted, modified or settled after the date of adoption, as well as for any unvested awards that were granted prior to the date of adoption.

The fair value of each option award is estimated on the date of grant using a Black-Scholes-Merton pricing option valuation model. Expected volatility is based on the historical volatility of the price of our common stock. The risk-free interest rate is based on U.S. Treasury issues with a term equal to the expected life of the option. We use historical data to estimate expected dividend yield, expected life, which represents the period of time the options are expected to be outstanding until they are exercised, and forfeiture rates.

### Redeemable Warrants

We utilize the guidance contained in ASC 480 (formerly SFAS 150) in the determination of whether to record warrants and options as Equity and/or Liability. If the guidance of ASC 480 is deemed inconclusive, we continue our analysis utilizing ASC 815 (formerly EITF 00-19).

Our method of recording the related value attempts to be consistent with the standards as defined by the Financial Accounting Standards Board utilizing the concept of "Fair Value" from ASC 820-10-55-1 that states that any fair value measurement requires that the reporting entity to determine the valuation technique(s) appropriate for the measurement, considering the availability of data with which to develop inputs that represent the assumptions that market participants would use in pricing the asset or liability and the level in the fair value hierarchy within which the inputs fall.

We recomputed the value of the redeemable warrants at the end of each quarterly period. We use the Monte Carlo Simulation approach which includes subjective input assumptions that are consistently applied each quarter. If we were to alter our assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different. As discussed in greater detail in "Fair Value" at the beginning of this ITEM 7, the significant assumptions using this model are: (i) Risk-Free Interest Rate; (ii) Expected Holding Period; (iii) Expected Volatility; (iv) Expected Dividend Yield; (v) Expected Probability of a Fundamental Transaction; (vi) Expected Timing of Announcement of a Fundamental Transaction; (vii) Expected 100 Day Volatility at Announcement of a Fundamental Transaction; (viii) Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction; and (ix) Expected Time Between Announcement and Consummation of a Fundamental Transaction.

### Concentration of Credit Risk

Our policy is to limit the amount of credit exposure to any one financial institution and place investments with financial institutions evaluated as being credit worthy, or in short-term money markets, which are exposed to minimal interest rate and credit risks. At and since January 1, 2015, we have had bank deposits and overnight repurchase agreements that exceed federally insured limits.

Concentration of credit risk, with respect to receivables, is limited through our credit evaluation process. We do not require collateral on our receivables. Our receivables historically consisted principally of amounts due from wholesale drug companies. At both December 31, 2016 and 2015 there were no receivables.

All sales for years ended December 31, 2016 and 2015 were prepaid by the customer related to the Ampligen® cost recovery treatment program.

### **ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.**

We had approximately \$5,868,000 in cash, cash equivalents and Marketable Securities 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 or three to twelve month financial instruments. We employ established conservative policies and procedures to manage any risks with respect to investment exposure.

**ITEM 8. Financial Statements and Supplementary Data.**

The consolidated balance sheets as of December 31, 2016 and 2015, and our consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2016, together with the report of RSM US LLP, our independent registered public accountants, is included at the end of this report. Reference is made to the "Index to Financial Statements and Financial Statement Schedule" on page F-1.

**ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures.**

None.

**ITEM 9A. Controls and Procedures.**

Effectiveness of Control Procedures

As of December 31, 2016, the end of the period covered by this report, 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 the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Exchange Act. Our disclosure controls and procedures are intended to ensure that the information we are required to disclose in the reports that we file or submit under the Securities Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission's rules and forms and (ii) accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as the principal executive and financial officers, respectively, to allow final decisions regarding required disclosures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the controls and procedures were effective as of December 31, 2016 to ensure that material information was accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Our management has concluded that the financial statements included in this Form 10-K present fairly, in all material respects our financial position, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

Changes in Internal Control over Financial Reporting

We made no changes in our internal control over financial reporting during the last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act).

### Management's Report on Internal Control over Financial Reporting

Our Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rules 13a-15(f) or 15d-15(f), under the Exchange Act. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers and affected by our Board of Directors, Management and other personnel, and to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on its financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, Management used the criteria set forth in the framework in 2013 established by the Committee of Sponsoring Organizations of the Treadway Commission Internal Control --Integrated Framework, (COSO). Based on this assessment, Management has not identified any material weaknesses as of December 31, 2016. A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management has concluded that we did maintain effective internal control over financial reporting as of December 31, 2016, based on the criteria set forth in "Internal Control --Integrated Framework" issued by the COSO.

#### **ITEM 9B. Other Information.**

None.

### PART III

#### ITEM 10. Directors and Executive Officers and Corporate Governance.

The following sets forth biographical information about each of our Directors and Executive Officers as of the date of this report:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Thomas K. Equels, Esq.	64	Executive Vice Chairman of the Board, Chief Executive Officer and President
Peter W. Rodino III	65	Executive Director Gov't Relations, General Counsel & Secretary
William M. Mitchell, M.D., Ph.D.	82	Chairman of the Board and Director
Stewart L. Appelrouth	63	Director
Adam Pascale	69	Chief Financial Officer
David R. Strayer, M.D.	71	Chief Scientific Officer and Medical Director
Wayne S. Springate	45	Senior Vice President of Operations

Each Director has been elected to serve until the next annual meeting of stockholders, or until his earlier resignation, removal from office, death or incapacity. Each Executive Officer serves at the discretion of the Board of Directors, subject to rights, if any, under contracts of employment.

In February 2016, our Board of Directors terminated the employment of Dr. Carter, our Chairman of the Board, Chief Executive Officer and Chief Scientific Officer. As a result, Dr. Carter also was no longer a director. Dr. Mitchell was named Chairman of the Board. It also made several changes to our executive management team. In this regard, Thomas K. Equels was named our Chief Executive Officer and Adam Pascale was named Chief Financial Officer. Mr. Equels resigned as Chief Financial Officer to make way for Mr. Pascale.

In June 2016, Iraj Kiani resigned as a member of our Board. On September 30, 2016, Mr. Rodino resigned as a member of our Board to permit him to serve us in a new capacity. In this regard, effective October 1, 2016, we retained Mr. Rodino as our Executive Director for Governmental Relations, and as our General Counsel. In that capacity, Mr. Rodino handles all government affairs and litigation matters on a going forward basis. Mr. Rodino was also appointed Secretary of the Company in November 2016.

We believe our Board Members represent a desirable diversity of backgrounds, skills, education and experiences, and they all share the personal attributes of dedication to be effective directors. In recommending Board candidates, Corporate Governance and Nomination Committee considers a candidate's: (1) general understanding of elements relevant to the success of a publicly traded company in the current business environment; (2) understanding of our business; and (3) diversity in educational and professional background. The Committee also gives consideration to a candidate's judgment, competence, dedication and anticipated participation in Board activities along with experience, geographic location and special talents or personal attributes. The following are qualifications, experience and skills for Board members which are important to Hemispherx's business and its future:

Leadership Experience: We seek directors who have demonstrated strong leadership qualities. Such leaders bring diverse perspectives and broad business insight to our Company. The relevant leadership experience that we seek includes a past or current leadership role in a large or entrepreneurial company, a senior faculty position at a prominent educational institution or a past elected or appointed senior government position.

Industry or Academic Experience: We seek directors who have relevant industry experience, both with respect to the disease areas where we are developing new therapies as well as with the economic and competitive dynamics of pharmaceutical markets, including those in which our drugs will be prescribed.

Scientific, Legal or Regulatory Experience: Given the highly technical and specialized nature of biotechnology, we desire that certain of our directors have advanced degrees, as well as drug development experience. Since we are subject to substantial regulatory oversight, both here and abroad by the FDA and other agencies, we also desire directors who have legal or regulatory experience.

Finance Experience: We believe that our directors should possess an understanding of finance and related reporting processes, particularly given the complex budgets and long timelines associated with drug development programs.

**THOMAS K. EQUELS, Esq.**, has been a Director and serves as our Executive Vice Chairman (since 2008), Chief Executive Officer (since 2016) and President (since 2015). Mr. Equels is the owner of and former President and Managing Director of the Equels Law Firm headquartered in Miami, Florida that focuses on litigation. For over a quarter century, Mr. Equels has represented national and state governments as well as companies in the banking, insurance, aviation, pharmaceutical and construction industries. Mr. Equels received his Juris Doctor degree with high honors from Florida State University. He is a summa cum laude graduate of Troy University and also obtained his Masters' Degree from Troy. He is a member of the Florida Bar Association and the American Bar Association.

**THOMAS K. EQUELS, Esq.** - Director Qualifications:

- Leadership Experience –Owner and Former President, Managing Director of Equels Law Firm;
- Industry Experience –legal counsel to Hemispherx; and
- Scientific, Legal or Regulatory Experience - Law degree with over 25 years as a practicing attorney specializing in litigation.

**WILLIAM M. MITCHELL, M.D., Ph.D.**, has been a Director since July 1998. On February 17, 2016, Dr. Mitchell was appointed as Chairman of the Board upon Dr. Carter's termination. Dr. Mitchell is a Professor of Pathology at Vanderbilt University School of Medicine and is a board certified physician. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as House Officer in Internal Medicine, followed by a Fellowship at its School of Medicine. Dr. Mitchell has published over 200 papers, reviews and abstracts that relate to viruses, anti-viral drugs, immune responses to HIV infection, and other biomedical topics. Dr. Mitchell has worked for and with many professional societies that have included the American Society of Investigative Pathology, the International Society for Antiviral Research, the American Society of Clinical Oncology, the American Society of Biochemistry and Molecular Biology and the American Society of Microbiology. Dr. Mitchell is a member of the American Medical Association. He has served on numerous government review committees, among them the National Institutes of Health, AIDS and Related Research Review Group. Dr. Mitchell previously served as one of our Directors from 1987 to 1989.

**WILLIAM M. MITCHELL, M.D., Ph.D.** - Director Qualifications:

- Leadership Experience – Professor at Vanderbilt University School of Medicine. He is a member of the Board of Directors for Chronix Biomedical and is Chairman of its Medical Advisory Board. Additionally, he has served on multiple governmental review committees of the National Institutes of Health, Centers for Disease Control and Prevention and for the European Union, including key roles as Chairman;
- Academic and Industry Experience – Well published medical researcher with extensive investigative experience on virus and immunology issues relevant to the scientific business of Hemispherx along with being a Director of an entrepreneurial diagnostic company (Chronix Biomedical) that is involved in next generation DNA sequencing for medical diagnostics; and
- Scientific, Legal or Regulatory Experience - M.D., Ph.D. and professor at a top ranked school of medicine, and inventor of record on numerous U.S. and international patents who is experienced in regulatory affairs through filings with the FDA.

**STEWART L. APPELROUTH, CPA** was appointed as a director and head of the Audit Committee in August 2016 and is a certified public accountant and partner at Appelrouth Farah & Co., P.A., Certified Public Accountants and Advisors. Mr. Appelrouth is also a certified forensic accountant and possesses 40 years of experience in Accounting and Consulting. He is a member of or has affiliations with the AICPA, American College of Forensic Examiners, Association of Certified Fraud Examiners, Florida Bar Grievance Committee, Florida Institute of Certified Public Accountants and InfraGard Member, a national information sharing program between the Federal Bureau of Investigation and the private sector.

Mr. Appelrouth graduated from Florida State University in 1975 and received his Master's Degree in Finance from Florida International University in 1980. The Board has determined Mr. Appelrouth to be an Independent Director as required under Section 803(2) of the NYSE: MKT Company Guide and Rule 10A-3 under the Exchange Act.

**STEWART L. APPELROUTH** - Director Qualifications:

- Leadership Experience –has served in leadership positions on numerous Boards and other organizations;
- Industry Experience – Partner at certified public accounting and advisory firm; Certified Public Accountant and Certified Fraud Examiner;
- Regulatory Experience – FINRA Arbitrator.
- Financial Expert – over 40 years of accounting and audit experience.

**ADAM PASCALE** was promoted to Chief Financial Officer on February 22, 2016. He will continue to be the Company's Chief Accounting Officer. Mr. Pascale has been employed with the Company for 22 years, with more than two decades of public accounting experience and prior public company experience. He earned a Bachelor of Arts degree in Accounting and Finance from Rutgers University. Mr. Pascale served for several years as a CPA prior to joining Hemispherx, and is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants.

**DAVID R. STRAYER, M.D.** has acted as our Medical Director since 1986. On February 19, 2016, Dr. Strayer was appointed as Chief Scientific Officer upon Dr. Carter's termination. He has served as Professor of Medicine at the Medical College of Pennsylvania and Hahnemann University. Dr. Strayer is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders. He has served as principal investigator in studies funded by the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health. Dr. Strayer attended the School of Medicine at the University of California at Los Angeles where he received his M.D. in 1972.

**PETER W. RODINO III** was appointed a Director in July 2013. On September 30, 2016, Mr. Rodino resigned as a member of our Board to permit him to serve us in a new capacity. In this regard, effective October 1, 2016, we retained Mr. Rodino as our Executive Director for Governmental Relations, and as our General Counsel. In that capacity, Mr. Rodino handles all government affairs and litigation matters on a going forward basis. Mr. Rodino was also appointed Secretary of the Company in November 2016. Through September 30, 2016, Mr. Rodino served as Lead Director and Chairman and Financial Expert of the Audit Committee, a member of the Compensation Committee and a member of the Governance and Nomination Committee of the Board of Directors. Mr. Rodino has broad legal, financial, and executive experience. In addition to being President of Rodino Consulting LLC and managing partner at several law firms during his many years as a practicing attorney, he served as Chairman and CEO of Crossroads Health Plan, the first major Health Maintenance Organization in New Jersey. He also has had experience as an investment executive in the securities industry and acted as trustee in numerous Chapter 11 complex corporate reorganizations. For the past 17 years, as founder and president of Rodino Consulting, Mr. Rodino has provided business and government relations consulting services to smaller companies with a focus on helping them develop business plans, implement marketing strategies and acquire investment capital. Mr. Rodino holds a B.S. in Business Administration from Georgetown University and a J.D. degree from Seton Hall University.

**WAYNE S. SPRINGATE** was promoted to Senior Vice President of Operations on May 1, 2011. Mr. Springate joined Hemispherx in 2002 as Vice President of Business Development when Hemispherx acquired Alferon N Injection® and its New Brunswick, NJ manufacturing facilities. He led the consolidation of our Rockville facility to our New Brunswick location as well as coordinated the relocation of manufacturing polymers from South Africa to our production facility in New Brunswick. He was also responsible for preparing and having a successful Preapproval Inspection by the FDA for our New Brunswick manufacturing plant in connection with the filing of our Ampligen® NDA. Currently he is managing a capital improvement budget to enhance our Alferon® facility in accordance with cGMP. Previously, Mr. Springate served as President for World Fashion Concepts in New York and oversaw operations at several locations throughout the United States and overseas. Mr. Springate assists the CEO in details of operations on a daily basis and is involved in all aspects of manufacturing, warehouse management, distribution and logistics.

## **Compliance with Section 16(a) of the Exchange Act**

Section 16(a) of the Exchange Act requires our Officers and Directors, and persons who own more than ten percent of a registered class of equity securities, to file reports with the Securities and Exchange Commission reflecting their initial position of ownership on Form 3 and changes in ownership on Form 4 or Form 5. Based solely on a review of the copies of such Forms received by us, we found that, during the fiscal year ended December 31, 2016, all of our Officers and Directors had complied with all applicable Section 16(a) filing requirements on a timely basis with regard to transactions occurring in 2016, except for Stewart Appelrouth, one of our Directors, who filed a Form 3 and Form 4 late.

### Audit Committee and Audit Committee Expert

The Audit Committee of our Board of Directors consists of William Mitchell, M.D. and Stewart L. Appelrouth. Dr. Mitchell and Mr. Appelrouth are determined by the Board of Directors to be Independent Directors as required under Section 803(2) of the NYSE: MKT Company Guide and Rule 10A-3 under the Exchange Act. The Board has determined that Mr. Appelrouth qualifies as an “audit committee financial expert” as that term is defined by Section 803B(2) of the NYSE: MKT Company Guide and the rules and regulations of the SEC.

We believe Dr. Mitchell and Mr. Appelrouth to be independent of management and free of any relationship that would interfere with their exercise of independent judgment as members of this Committee. The principal functions of the Audit Committee are to (i) assist the Board in fulfilling its oversight responsibility relating to the annual independent audit of our consolidated financial statements and internal control over financial reporting, the engagement of the independent registered public accounting firm and the evaluation of the independent registered public accounting firm’s qualifications, independence and performance; (ii) prepare the reports or statements as may be required by NYSE MKT or the securities laws; (iii) assist the Board in fulfilling its oversight responsibility relating to the integrity of our financial statements and financial reporting process and our system of internal accounting and financial controls; (iv) discuss the financial statements and reports with management, including any significant adjustments, management judgments and estimates, new accounting policies and disagreements with management; and (v) review disclosures by our independent registered public accounting firm concerning relationships with us and the performance of our independent accountants.

This Committee formally met seven times in 2016 with all committee members in attendance. Our General Counsel and Chief Financial Officer support the Audit Committee in its work. The full text of the Audit Committee’s Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the “Investor Relations” tab under “Corporate Governance”.

Prior to his appointment as a Director of the Company, the Audit Committee engaged the services of Stewart L. Appelrouth in 2015. Mr. Appelrouth met the SEC criteria of a Financial Expert to enhance the current structure and expertise of the Committee. Mr. Appelrouth, a Florida and North Carolina licensed Certified Public Accountant, directly supported the efforts of the Audit Committee on an as-needed basis.

#### Scientific Advisory Board

In August 2016, the Company formed the Scientific Advisory Board (the “SAB”). The SAB was established to leverage its member’s scientific and pharmaceutical expertise and advice to advance our drug development programs by providing guidance on steering us forward and capitalizing on business opportunities as well as interactions with the FDA. It is responsible for: (i) reviewing all submissions made by us to the FDA and other regulators to ensure that the submissions fully, accurately, and timely describe the status of any clinical trials, tests, or other studies or analyses of drug safety and efficacy undertaken by us, and any agreements, protocols, or guidance provided by relevant regulatory agencies; and (ii) monitoring and supervising our relationship with the FDA. The SAB shall have free and open access to our scientific and executive personnel, including the Chief Scientific Officer and the members of our Board of Directors. The SAB is comprised of William Mitchell, M.D., Chairman, and Ronald Brus, M.D., W. Neal Burnette, M.D., and Christopher Nicodemus, M.D., all of whom are members. The SAB reports to the independent directors of the Company and closely interacts with the Disclosure Controls Committee.

#### Disclosure Controls Committee

In August 2011, our Board formed the Disclosure Controls Committee (“DCC”). The DCC reports to the Audit Committee and is responsible for procedures and guidelines on managing disclosure information.

The purpose of the DCC is to make certain that information required to be publicly disclosed is properly accumulated, recorded, summarized and communicated to the Board and management. This process is intended to allow for timely decisions regarding communications and disclosures and to help ensure that we comply with related SEC rules and regulations. Wayne Springate one of our Senior Vice Presidents, is the DCC’s Investor Relations Coordinator and Chairperson. The other members of the DCC are Peter Rodino, our General Counsel, William Mitchell, one of our Independent Directors, and Adam Pascale, our Chief Financial and Accounting Officer. Ann Marie Coverly, Director of HR and Administration, serves the DCC as Deputy Investor Relations Coordinator. The DCC also closely interacts with the SAB. The full text of the DCC’s Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the “Investor Relations” tab under “Corporate Governance”.

#### Executive Committee

In February 2016, our Board formed the Executive Committee. The Executive Committee reports to the Board and its purpose is to aid the Board in handling matters which, in the opinion of the Chairman of the Board, should not be postponed until the next scheduled meeting of the Board. Mr. Equels, our Chief Executive Officer is the chairman of the Committee, along with two of our independent directors, Mr. Appelrouth and Dr. Mitchell. The full text of the Executive Committee Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the “Investor Relations” tab under “Corporate Governance”. The Committee met three times in 2016.

## Code of Ethics

Our Board of Directors adopted a revision to the 2003 Code of Ethics and business conduct for officers, directors, employees, agents and consultants on October 15, 2009. The principal amendments included broadening the Code's application to our agents and consultants, adoption of a regulatory compliance policy and adoption of a policy for protection and use of Company computer technology for business purposes only. On an annual basis, this Code is reviewed and signed by each Officer, Director, employee and strategic consultants with none of the amendments constituting a waiver of provision of the Code of Ethics on behalf of our Chief Executive Officer, Chief Financial Officer, Controller, or persons performing similar functions.

You may obtain a copy of this Code by visiting our web site at [www.hemispherx.net](http://www.hemispherx.net) (Investor Relations / Corporate Governance) or by written request to our office at 1617 JFK Boulevard, Suite 500, Philadelphia, PA 19103.

## **ITEM 11. Executive Compensation.**

### **COMPENSATION DISCUSSION AND ANALYSIS**

This discussion and analysis describes our executive compensation philosophy, process, plans and practices as they relate to our "Named Executive Officers" ("NEO") listed below and gives the context for understanding and evaluating the more specific compensation information contained in the narratives, tables and related disclosures that follow. Please note that Dr. Carter's employment was terminated on February 17, 2016 and also that he is no longer a director. For the purposes of discussion and analysis Dr. Carter was included in the narratives, tables and related disclosures that follow:

- Thomas K. Equels, Chief Executive Officer ("CEO") and President;
- Adam Pascale, Chief Financial Officer ("CFO"); and
- Dr. David Strayer, Chief Scientific Officer ("CSO") and Medical Director.

### **Overview of Our Business Environment**

Hemispherx is a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. We were 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.

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

#### **Governance of Compensation Committee**

The Compensation Committee consists of the following two directors, each of whom is "independent" under applicable NYSE MKT rules, a "Non-Employee Director" as defined in Rule 16b-3 under the Exchange Act, and an "Outside Director" as defined under the U.S. Treasury regulations promulgated under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"): Dr. William Mitchell, M.D. (Chair) and Stewart L. Appelrouth. The Compensation Committee makes recommendations concerning salaries and compensation for senior management and other highly paid professionals or consultants to Hemispherx. The full text of the Compensation Committee's Charter, as approved by the Board, is available on our website: [www.hemispherx.net](http://www.hemispherx.net) in the "Investor Relations" tab under "Corporate Governance".

This Committee formally met five times in 2016 and all committee members were in attendance for the meetings with the exception of one meeting. Our General Counsel, Chief Financial Officer and Director of Human Resources support the Compensation Committee in its work.

#### **Results of Stockholder Advisory Vote on Executive Compensation**

At the August 17, 2016 Annual Meeting of Stockholders, the Stockholders approved the annual, non-binding advisory vote on Executive Compensation.

Our Compensation Committee reviews its executive compensation policies annually and takes into account the results of prior say-on-pay advisory votes.

The Committee reviewed the results of the 2015 say-on-pay advisory vote and its executive compensation policies. In January 2016, in an effort to better incentivize top management and align top management's compensation with their performance on behalf of the Company, the Committee created the 2016 Senior Executive Deferred Cash Performance Award Plan. See Item 7-Management's Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources; *The Executive Plan*" in PART II.

## Process

Our Compensation Committee is responsible for determining the compensation of our NEO included in the “Summary Compensation Table” below. For purposes of determining compensation for our NEO, our Compensation Committee takes into account the recommendation of our Chief Executive Officer. The Compensation Committee is also responsible for overseeing our incentive compensation plans and equity-based plans, under which stock option grants have been made to employees, including the NEO, as well as non-employee Directors and strategic consultants.

The following table summarizes the roles of each of the key participants in the executive compensation decision-making process:

Compensation Committee	<ul style="list-style-type: none"><li>• Fulfills the Board of Directors’ responsibilities relating to compensation of Hemispherx’ NEO, other non-officer Executives and non-Executives.</li><li>• Oversees implementation and administration of Hemispherx’ compensation and employee benefits programs, including incentive compensation and equity compensation plans.</li><li>• Reviews and approves Hemispherx’ goals and objectives and, in light of these, evaluates each NEO’s performance and sets their annual base salary, annual incentive opportunity, long-term incentive opportunity and any special/supplemental benefits or payments.</li><li>• Reviews and approves compensation for all other non-officer Executives of Hemispherx including annual base salary, annual incentive opportunity, long-term incentive opportunity and any special/supplemental benefits or payments.</li><li>• In consultation with the CEO and CFO, reviews the talent development process within Hemispherx to ensure it is effectively managed and sufficient to undertake successful succession planning.</li><li>• Reviews and approves employment agreements, severance arrangements, issuances of equity compensation and change in control agreements.</li></ul>
Chairman and CEO	<ul style="list-style-type: none"><li>• Presents to the Compensation Committee the overall performance evaluation of, and compensation recommendations for, each of the NEO and other non-officer Executives.</li></ul>
Chief Financial Officer and Director of Human Resources	<ul style="list-style-type: none"><li>• Reports directly or indirectly to the Chief Executive Officer.</li><li>• Assists the Compensation Committee with the data for competitive pay and benchmarking purposes.</li><li>• Reviews relevant market data and advises the Compensation Committee on interpretation of information, including cost of living statistics, within the framework of Hemispherx.</li><li>• Informs the Compensation Committee of regulatory developments and how these may affect Hemispherx’ compensation program.</li></ul>

## **Objectives and Philosophy of Executive Compensation**

The primary objectives of the Compensation Committee of our Board of Directors with respect to Executive compensation are to attract and retain the most talented and dedicated Executives possible, to tie annual and long-term cash and stock incentives to achievement of measurable performance objectives, and to align Executives' incentives with stockholder value creation. To achieve these objectives, the Compensation Committee expects to implement and maintain compensation plans that tie a substantial portion of Executives' overall compensation to key strategic financial and operational goals such as the establishment and maintenance of key strategic relationships, the development of our products, the identification and advancement of additional products and the performance of our common stock price. The Compensation Committee evaluates individual Executive performance with the goal of setting compensation at levels the Committee believes are comparable with Executives in other companies of similar size and stage of development operating in the biotechnology industry while taking into account our relative performance, our own strategic goals, governmental regulations and the results of Stockholder Advisory Votes regarding executive compensation.

## **Use of Compensation Data**

Our compensation plans are developed by utilizing publicly available compensation data for national and regional companies in the biopharmaceutical industry as well as web sites that specialize in compensation and/or employment data. We believe that the practices of this group of companies and/or data obtained from employment industry organizations, provide us with appropriate compensation benchmarks necessary to review the compensation recommendations by the CEO, CFO and/or Human Resources Department. Prior to 2016, the Committee did not engage the services of an independent compensation consultant, but alternatively utilized web-based organizations and data bases such as Salary.com, to help them analyze compensation data and compare our programs with the practices of similar national and/or regional companies represented in the biopharmaceutical industry. In 2016, the Board of Directors, based upon the recommendation of the Compensation Committee, engaged Steven Hall Partners, an independent compensation consultant, to review and improve executive compensation arrangements and ensure they are in line with industry standards. The Compensation Committee recommended the consultant based upon candidates suggested to it by its independent counsel and will review performance of the independent consultant at least annually.

## **Elements of Executive Compensation**

The Compensation Committee has adopted a mix among the compensation elements in order to further our compensation goals. The elements include:

- Base salary (impacted by cost of living adjustments);
- Variable compensation consisting of a cash bonus based upon individual and overall Company performance;
- Performance incentive bonus based on the accomplishment of Company sales milestones or activity;
- Long-term bonus incentive programs consisting of the Employee Bonus Pool Program;
- Stock option grants with exercise prices set in excess of fair market value at the time of grant and, effective December 2011, not vesting sooner than one year from the date of issuance; and
- Adoption of a policy to facilitate compliance with Dodd-Frank's Claw-Back Compensation Recoupment provisions.

Executive compensation consists of the following elements:

**Base Salary**

Base salaries for our Executives are established based on the scope of their responsibilities, taking into account competitive market compensation paid by other companies for similar positions. Generally, we believe that Executive base salaries should be targeted near the median of the range of salaries for executives in similar positions with similar responsibilities at comparable companies, in line with our compensation philosophy. For those NEO with employment agreements, base salary is determined and set forth in the agreement and the Compensation Committee reviews the base salary prior to renewal of such agreement. Base salaries for the other NEO are normally reviewed annually, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. While this review process would normally occur in the fourth quarter of each year, in recent years this review has occurred when NEO's employment agreements required restatement, amendment or replacement. However, after analysis of overall Company compensation, the Committee authorized a non-discriminatory and universally applied cost of living increase to the base salaries of all full-time employees of record effective December 31, 2016, 2015 and 2014 at the rates of 0.0%, 0.0% and 1.5%, respectively. Additional changes to our NEO's base salaries could be undertaken in a future determination by the Compensation Committee at its discretion. During 2016 and 2015, none of the employment contracts of NEOs were created, amended or restated. Mr. Equels employment agreement automatically extended for an additional three-year period upon his original agreement expiring as of December 31, 2016. We are currently in negotiations with Mr. Equels on a new employment agreement. We are utilizing an independent compensation consultant for assistance in negotiating the terms and conditions of this agreement. Dr. Strayer does not currently have an employment agreement with the Company.

**Senior Executive Deferred Cash Performance Award Plan & Voluntary Incentive Stock Award Plan**

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

### The Executive Plan

The Executive Plan was established to both conserve cash and create appropriate incentives for senior executives to be rewarded based upon the performance of the Company. The two participants are Dr. William A. Carter, the Company's former Chairman of the Board, Chief Executive Officer and Chief Scientific Officer, and Thomas K. Equels, the Company's current Chief Executive Officer, President and Executive Vice Chairman of the Board (the "Executives"). Dr. Carter's participation in the Plan ended upon his termination of employment. The Executive Plan provides for a change to the amount to be withheld from salary and director's fees (collectively, "Compensation") of Mr. Equels for the 3-month period commencing February 1, 2016 for the semi-monthly payroll period ended February 15, 2016 (the "Initial Period") and thereafter. For the payroll periods ended on February 15 and 29, 2016, 50% of Mr. Equels' Compensation was withheld. For the remainder of the Initial Period, 100% of Mr. Equels' Compensation was withheld. Following the Initial Period and during any period the Executive Plan is in effect, the percentage withheld from Mr. Equels' Compensation would be at least 50% thereof, provided that any amounts in excess of 50% would be as agreed upon by the Committee and Mr. Equels. Notwithstanding the foregoing, the amount of Compensation to be withheld during any periods commencing on and after March 1, 2016 did not include the amount necessary, on an after-tax basis, to fund applicable FICA, FUTA and other governmental welfare benefit taxes (both federal and state) and any health or other insured benefits for which Mr. Equels contributes to the cost.

The Executive Plan was in effect for three months beginning with the commencement of the Employee Plan described below and may be extended for additional periods of three months thereafter subject to termination by the Company with the approval of the Board. The Executives participated during each three-month period the Executive Plan was in effect (each such period, an "Executive Plan Period"). By participating in the Executive Plan, each Executive authorized the Company to withhold 50% of the sum of his salary, consulting and director's fees on each semi-monthly payroll date (each, a "Withholding Date") occurring during the applicable Executive Plan Period. The Company established and maintained a record of the dollar amount withheld on each Withholding Date (each, a "Withheld Dollar Amount") and the closing price of a share of the Company's common stock (the "Stock") on the NYSE MKT on the last trading day preceding the Withholding Date (each, a "Base Stock Price").

On the 9-month anniversary of each Withholding Date (each, a "Payment Date"), if the Payment Condition, as defined below, in respect of the Withheld Dollar Amount on such Withholding Date is satisfied, the Company would pay the Executive an amount in cash (the "Performance Cash Payment") equal to (a) the product of the applicable Withheld Dollar Amount multiplied by a fraction, the numerator of which was the closing price of the Stock on the NYSE MKT for the last trading date preceding the Payment Date (a "Payment Stock Price"), and the denominator of which was the applicable Base Stock Price, less (b) the minimum withholding taxes due in respect of such payment. The Payment Condition was that the closing price of the Stock for at least five (5) successive trading days during the period beginning on the applicable Withholding Date and ending on the applicable Payment Date must have been at least \$0.20 per share. If the Payment Condition is not fully satisfied with respect to a Withheld Dollar Amount then the Performance Cash Payment will be zero and the Senior Executives will lose the entire amount withheld. In 2016 Mr. Equels earned \$131,000 in accordance with item 5 of the Executive Plan, as the price of our stock has been above \$.20 for 5 successive trading days.

The Company believes that this combination of a large compensation holdback coupled with the Executives' ability to recoup this amount and possibly more aligns the Executives' compensation to their performance and rewards them only if they are able to increase stockholder value and penalizes them if they fail to achieve the minimum floor stock price of \$.20 per share for several successive days. This enhances the incentives related to improving the Company's business and raising its stock price.

The Executive Plan was administered and interpreted by the Compensation Committee. The Compensation Committee had the authority to make appropriate adjustments to the Base Stock Price and the Payment Stock Price to reflect stock splits and stock combinations.

#### The Employee Plan

Pursuant to the Employee Plan, all full-time employees and directors, other than Mr. Equels participated in the plan. The Employee Plan was in effect for three months commencing on February 1, 2016 and may be extended for additional periods of three months thereafter subject to termination by the Company with the approval of the Board. Eligible employees and directors may elect to participate during any three-month period the Employee Plan is in effect (each, an "Employee Plan Period") subject to election prior to the commencement of any such period. Employees and Directors who elect to participate in the Employee Plan (the "Participants") may elect to cease their participation at the end of any Employee Plan Period.

By electing to participate in the Employee Plan, employees authorized the Company to withhold 20% of the employee's salary on each semi-monthly payroll date and the directors authorized the Company to withhold 20% of the director's fee on each semi-monthly payment date (each a "Withholding Date") occurring during the applicable Employee Plan Period. On each Withholding Date, the Participant was issued an Incentive Right for a number of shares of Stock, less applicable withholding taxes. The number of shares (the "Participant's Amount") was computed by dividing the applicable salary/fee withheld for the period by the closing price of the Stock on the NYSE MKT on the trading day immediately preceding the Withholding Date. The Company established and maintained a record of the number of shares of Stock represented by each Incentive Right. Such number of shares of Stock represented by an Incentive Right was subject to appropriate adjustment in the event of a stock split or stock consolidation.

Any employee earning salary at a rate of less than \$75,000 per year made an Election discussed above, to participate by authorizing the Company to withhold, at the employee's option, 10% or 20% of the employee's salary during such Employee Plan Period.

Each Participant made an Election in writing to receive the Participant's Amount, on the 6-month, 9-month or 12-month anniversary of each Withholding Date. In the absence of an election, the Participant was paid on the 6-month anniversary of the applicable Withholding Date.

On the anniversary date on which the Participant was paid in accordance with his or her election (the "Payment Date"), the Company determined, for tax withholding and basis purposes, the value of each Participant's Amount for which payment was made. The value on the Payment Date was based on the closing price of a share of Stock on the NYSE MKT for the trading day preceding the Payment Date. On any date Stock was issued, the number of shares needed for sale to cover the related withholding taxes was determined by the Company and communicated to the Participant. Unless the Participant elects prior to the commencement of the applicable Employee Plan Period to pay the withholding tax dollar amount directly to the Company on or before the Payment Date, the Company will withhold the required minimum withholding tax from any amounts due the Participant on such Payment Date by either, in its discretion, (a) reducing the number of shares of Stock to be issued to the Participant by the number of shares of Stock having a value equal to the applicable withholding taxes or (b) causing to be sold on the open market that number of shares of Stock issued to the Participant which is necessary to fund the payment of the withholding tax.

The Employee Plan was administered and interpreted by the Compensation Committee.

The Company arranged, at its cost, for a registered brokerage firm to establish a trading account for each Participant. Shares of Stock being delivered under the Employee Plan will be transferred to that account. Delivery of shares of Stock under the Employee Plan will constitute taxable income to a Participant at the time the shares of Stock are delivered and will be subject to payroll taxes. The Company will bear all costs related to selling shares of Stock awarded under the Employee Plan in such amount as necessary to pay any withholding taxes. During the period a Participant remains an active employee or a Director, the Company will bear (i) the charges of the brokerage firm for the maintenance of the account, (ii) any transaction costs related to the transfer of shares by the Company into the account and (iii) transaction costs related to the sale of shares of Stock from the account.

All full-time employees opted to participate in the Employee Plan.

#### **Annual Bonus**

Our compensation program includes eligibility for an annual performance-based cash bonus in the case of all NEO and certain senior, non-officer Executives. The amount of the cash bonus depends on the level of achievement of the stated corporate, department, and individual performance goals, with a target bonus generally set as a percentage of base salary. As provided in their respective employment agreements, during the year ended December 31, 2016, the following NEOs were eligible for an annual performance bonus based on their salaries, the amount of which, if any, is determined by the Board of Directors in its sole discretion based on the recommendation of the Compensation Committee:

- Thomas Equels, CEO & President (bonus opportunity up to 25%);
- Adam Pascale, Chief Financial Officer (bonus opportunity up to 25%).

The Compensation Committee utilizes annual incentive bonuses to compensate NEO and certain senior, non-officer executives (the “Executive Team”) for attainment or success towards overall corporate financial and/or operational goals along with achieving individual annual performance objectives. These objectives will vary depending on the individual Executive, but generally relate to strategic factors such as establishment and/or maintenance of key strategic relationships, development of our products, identification, research and/or development of additional products, enhancing financial factors such as raising capital, cost containment and/or improving the results of operations. The Compensation Committee, in light of established individual and Company-wide goals and objectives, evaluated the performance of each NEO, key executive and overall staff in order to determine each respective annual incentive opportunity including an analysis by the Compensation Committee that provides the following information:

1. The Company-wide goals and objectives along with individual performance goals for each NEO used to determine annual bonuses for the fiscal year;
2. How each goal individually or in totality was weighted, if applicable, to the extent that any of the performance goals were quantitatively and/or quantitatively measurable;
3. The threshold, target, and maximum levels of achievement of each performance goal, if applicable;
4. The intended relationship between the level of achievement of Company-wide performance goals and the amount of bonus to be awarded;
5. The intended relationship between the level of achievement of each NEO’s individual performance goals and the amount of bonus to be awarded;
6. The evaluation by the Committee of the level of achievement by each NEO of the Company-wide and individual performance goals applicable to him/her individually;
7. If applicable, whether the Committee reviewed any report(s) from compensation consultant(s) and/or web based organizations and data bases;
8. The adequate disclosure of the percentage of base salary awarded in the form of an incentive bonus to each NEO as a result of their or the Company’s performance; and
9. If applicable, how the Company’s compensation policies and practices relate to the Company’s risk management.

The Compensation Committee also undertook the initial steps to review and reestablish goals and objectives for the Executive Team regarding bonuses. On an overall basis, all bonus eligible member of the Executive Team would share the following Company-wide goals:

- A. Regulatory approval and sales of Ampligen® for the treatment of Chronic Fatigue Syndrome in any country or regional jurisdiction;
- B. Significant regulatory advancement for the approval of Ampligen® for any non-CFS indication in any country jurisdiction. These indications include cancer vaccines, vaccines for infectious indications including bioterror/biowarfare, burns or other inducers of traumatic immunodeficiency;
- C. Regulatory approval and sales of Alferon® for the treatment of any non-CFS indication in any country jurisdiction;
- D. Any merger, acquisition, or partnership that quantitatively improves the value of the company;
- E. Any governmental grant and/or contact, singly or in the aggregate for R & D or commercial product;
- F. Continued productive interaction with the FDA concerning issues necessary for approval of Ampligen® for CFS;
- G. Continued progress towards non-USA approval of Ampligen® for Chronic Fatigue Syndrome;
- H. An overall strategic plan for Ampligen® and Alferon® to be submitted to the Board;
- I. Strategic plans for the marketing and partners for Ampligen® to be submitted to the Board;
- J. Continued development of enhancement of vaccines requiring Ampligen®;
- K. Success in the protection of Company Intellectual Property;
- L. Continued development of Alferon® LDO;
- M. Progress in the return to commercialization of Alferon N Injection®;
- N. Continued development of Ampligen® and Alferon N Injection® for treatment of influenza;
- O. Maintaining the overall financial strength of the Company and operations consistent with the budget;
- P. Implementation of research & development partnerships;
- Q. Implementation of Ampligen® clinical trials in cancer with commercial partner(s);
- R. Implementation of Ampligen® clinical trials in cancer with academic partner(s);
- S. Increase in clinical trials of Alferon N Injection® and additional indications; and,
- T. Acquisition of complimentary pharmaceutical technologies and/or drugs/vaccines.

On an annual basis and at the sole discretion of the Compensation Committee, with input from the CEO or the Executive's direct supervisor, the Committee evaluates the individual performance of each member of the Executive Team as to his/her achievement and/or contribution towards meeting the overall Company-wide goals along with his/her accomplishments specific to his/her job description. The outcome of the Committee's analysis is utilized to determine if a bonus is warranted, and if so, the dollar amount or percentage of the Executive Team member's year-end base pay rate to be awarded.

Prior to year-end or during the first fiscal quarter of the subsequent year, the Compensation Committee would complete their analysis utilizing any internal and external documentation desired, including but not limited to reports from independent analysts and/or corporate benchmarking organizations. Upon analysis completion, the Compensation Committee made formal recommendations to the Board based on their findings with regard to bonuses for the respective year ended. Due to the subjective nature of the Company-wide goals regarding the success and analysis of an Executive in meeting or exceeding elements of his/her specific job duties, the goals were not designed to be weighted in value or quantitative in nature. The bonuses were designed to be awarded based on a subjective cumulative nature of the goals deemed attainable, employee performance and progress towards achievement. The bonus threshold was designed to range from zero percent to twenty-five percent, with a target bonus of approximately twenty or twenty-five percent, calculated from the individual's year-end base pay rate.

In June and July 2014, the Compensation Committee reviewed the Executive Team's Company-wide goals as detailed in the Committee's March 2014 meeting minutes along with specific goals documented in each individual's job description. Upon individual review of each member of the Executive Team, the Committee concluded that the Executive Team members had excelled in meeting their goals and responsibilities as documented in each individual's job description as well as made significant progress in meeting corporate goals with outstanding success. Additionally, the Committee observed that the employees had worked tirelessly over the first half of 2014 and that a performance bonus would be desirable to acknowledge the persistence, loyalty, effort and dedication of the Senior Management team.

The Compensation Committee in light of pre-established individual, along with position appropriate Company-wide goals (A. through T. as disclosed above) and objectives, undertook a weighted-average evaluation of the performance of each key executive in order to determine respective annual incentive opportunities considering base salary and fees, short and long-term incentive opportunity and any special/supplemental benefits or payments. Based upon all the foregoing and the recommendation of the Compensation Committee, the Board approved the following 2014 Performance Bonuses be granted to the following NEO at the rate of 25% of their respective 2014 year-end base compensation:

- Thomas Equels (Executive Vice Chairman, current Chief Executive Officer and President) for \$134,203;
- Adam Pascale (Chief Financial Officer) for \$33,459;
- David Strayer (Chief Scientific Officer & Medical Director) for \$67,369.

There were no Performance Bonuses granted and/or paid to the NEO's for the years ended 2016 and 2015.

#### **Employee Appraisal and Merit Bonus Program**

In 2012, the Compensation Committee approved an Employee Appraisal and Merit Bonus Program for those employees not eligible for the key employee annual bonus. This Program incorporates a team concept by conducting appraisals for eligible employees in each department throughout the calendar year and then averaging the total scores per department in order to determine year-end, department-wide merit bonuses. This Program is annually renewed and at the ultimate discretion of the Compensation Committee based on various factors, including the Company's overall accomplishment of milestones and access to Working Capital.

For the year ended 2016 and 2015, no bonuses related to this program were granted to employees. In 2014, bonuses related to this program were granted to employees amounting to approximately \$58,000.

### **Executive Performance Incentive Bonus**

As an element of his employment contract, Thomas Equels (Executive Vice Chairman, Chief Executive Officer and President) is eligible for a performance incentive bonus based on a percent, 2.5% and 5.0% respectively, of the Gross Proceeds paid to the Company as a result of sales of Alferon N Injection®, Alferon® LDO, Ampligen® or other Company products, or from any joint ventures or corporate partnering arrangements. For bonus purposes, Gross Proceeds is defined as cash amounts paid to the Company by the other parties to the joint venture or corporate partnering arrangement, but shall not include any amounts paid to the Company as reimbursement of expenses incurred; and any amounts paid to the Company in consideration for the Company's assets (i.e., plant, property, equipment, investments, etc.), equity or other securities. After the termination of this Agreement, for any reason, Mr. Equels shall be entitled to receive the incentive bonus based upon Gross Proceeds received by the Company during the three-year period commencing on the termination of their Agreement with respect to any joint ventures or corporate partnering arrangements entered into by the Company during the term of the Agreement. Furthermore, Mr. Equels shall be entitled to a 5% bonus related to any sale of the Company, or any sale of a substantial portion of Company assets not in the ordinary course of its business. The aggregate incentive bonus hereunder as set forth above shall be capped not to exceed \$5,000,000 annually.

During 2012, the Compensation Committee and Board of Directors sought out and received an opinion of independent legal counsel regarding the elements of the Executive Performance Incentive Bonus created by the current employment contracts of William Carter and Thomas Equels in relation to the shares of Company stock sold through the Maxim ATM. It was the opinion of independent counsel that Section 3(c)(ii) of Dr. Carter and Mr. Equels respective agreements could reasonably be interpreted to require the Company to pay them a 5% bonus on the net proceeds resulting from the sale of securities of the Maxim ATM Offering as either (a) constitutes any sale of the Company, or (b) is a sale of substantial portion of Company assets not in the ordinary course of its business. On November 26, 2012, all of the members of the Compensation Committee authorized the payment of bonus for the Company stock sold through the Maxim ATM based on the contractual obligation and opinion of independent counsel. On November 23, 2015, Mr. Equels waived his rights under his respective employment agreement to any future payment of any incentive bonus related to the sale of the Company's stock or other securities by, or on behalf of, the Company pursuant to the Maxim Equity Distribution Agreement or any similar or successor ATM equity distribution agreement including the Chardan Agreement. Mr. Equels provided this waiver due to a litigation settlement in 2016 as well as in an effort to preserve cash and to help the Company to ensure its short term commercialization goals. For the years ended 2016, 2015 and 2014, compensation was granted or paid related to the Executive Performance Incentive Program, as set forth in Section 3(c)(ii) of his respective Employment Agreement, for approximately \$0, \$262,000, and \$641,000 to Mr. Equels. In addition, Mr. Equels received, as set forth in Section 3(c)(ii) of his Employment Agreement, \$39,000 for 5% of the Ampligen® cost recovery sales for the last 5 years.

### **Long-Term Bonus Incentive Programs**

The Compensation Committee believes that team oriented performance by our NEO, non-officer Executive officers and all employees, consistent with our short and long-term goals, can be achieved through the use of goal or result oriented bonus programs. For the year ending 2016, the Employee Bonus Pool Program continued to exist to provide our employees, including our NEO and certain senior, non-officer Executives, with incentives to help align their financial interests with that of Hemispherx and its stockholders. For the year ending 2016, no compensation was granted or paid in relation to Long-Term Bonus Programs.

### **Base Pay Supplement and Employee Bonus Pool Programs**

All Participants in the Employee Plan and Executive Plan created in January 2016 will be awarded an amount (the “Approval Award”) equal to 30% of the pre-tax amount of their base annual salary as then in effect upon FDA Approval of Ampligen® (the “Approval”). The Approval Award will be paid within three months following the Approval. In addition, all Participants in either plan will be awarded an amount (the “Pre-Approval Award”) equal to 30% of the pre-tax amount of their annual salary as then in effect upon the successful pre-approval inspection by the FDA of the Alferon® facility (the “Pre-Approval”). The Pre-Approval Award will be paid within three months following the Pre-Approval. A Participant will not qualify for the Approval or Pre-Approval Award if the Participant’s employment is terminated prior to such Approval or Pre-Approval due to (i) termination by the Company for Cause or (ii) voluntary termination by the Participant. See Item 7-Management’s Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources; *Base Pay Supplement*” in PART II.

An element of the prior 2009’s Employee Wage or Hours Reduction Program was the establishment of a Bonus Pool (the “Pool”) in the case of FDA Approval (“Approval”) of Ampligen®. This bonus is to award to each employee of record at January 1, 2009 a pretax sum of 30% in wages, calculated on their base salary per annum compensation at the time of the Approval, and awarded within three months of Approval. Participants who terminate their employment prior to the Approval will not qualify for this bonus. For the year ended 2016, no compensation was granted or paid related to the Employee Bonus Pool Program.

### **Stock Options**

The Compensation Committee believes that long-term performance is achieved through an ownership culture that encourages such performance by our NEO, non-officer Executives and all employees through the use of stock and stock-based awards. Our stock plans have been established to provide our employees, including our NEO and senior non-officer Executives, with incentives to help align their interests with the interests of stockholders. Accordingly, the Compensation Committee believes that the use of stock and stock-based awards offers the best approach to achieving long-term performance goals because:

- Stock options align the interests of Executives and employees with those of the stockholders, support a pay-for-performance culture, foster employee stock ownership, and focus the management team on increasing value for the stockholders;
- Stock options are performance based. All the value received by the recipient of a stock option is based on the growth of the stock price; and
- Stock options help to provide a balance to the overall executive compensation program as base salary and our discretionary annual bonus program focus on short-term compensation.

We have historically elected, and continue to use, stock options as the primary long-term equity incentive vehicle. We have adopted stock ownership guidelines and our stock compensation plans have provided the principal method, other than through direct investment for our executives to acquire equity in our Company. The Compensation Committee believes that the annual aggregate value of these awards should be set near competitive median levels for comparable companies. However, in the early stage of our business, we provided a greater portion of total compensation to our Executives through our stock compensation plans than through cash-based compensation.

In determining the number of stock options to be granted to NEO, non-officer Executives and employees, we take into account the individual's position, scope of responsibility, ability to affect profits and stockholder value and the individual's historic and recent performance and the value of stock options in relation to other elements of the individual's total compensation.

Our stock plans authorize us to grant options to purchase shares of common stock to our NEO, employees, Directors and consultants. Our Compensation Committee oversees the administration of our stock option plan. The Compensation Committee reviews and recommends approval by our Board of Directors of stock option awards to NEO based upon a review of competitive compensation data, its assessment of individual performance, a review of each Executive's existing long-term incentives and retention considerations. Periodic stock option grants are made at the discretion of the Board of Directors upon recommendation of the Compensation Committee to eligible NEO and employees and, in appropriate circumstances, the Compensation Committee considers the recommendations of the CEO.

As a reinforcement to employees that one of the Company's priorities continues to be that of increasing shareholder value, the Compensation Committee and Board have historically granted the replacement of expired stock options to all current employees at the same number of shares and exercise price as had been originally issued.

Effective as of December 2011, the Compensation Committee mandated that the standard terms of options to be issued to individuals in their role as Company employees to require that such options not vest sooner than one year from the date of issuance and that, to the extent that any such options have not vested on the date of an Executive's termination, the options shall be void as to such unvested portion.

The following Options were issued to NEO in their role as employees during 2016:

- On June 8, 2016, we granted options to Thomas K. Equels, Chief Executive Officer, consistent with his employment agreement 25,000 ten year options to purchase common stock at \$1.68 per share which vest in entirety in one year; and

- On June 21, 2016, we granted 12,500 ten year options to purchase common stock at \$1.56 per share which vest in entirety in one year options to Dr. Strayer, Chief Scientific Officer and Chief Medical Officer; and
- On June 21, 2016, we granted 12,500 ten year options to purchase common stock at \$1.56 per share which vest in entirety in one year options to Adam Pascale, Chief Financial Officer;

The following Options were issued to NEO in their role as employees during 2015:

- On June 6, 2015, we granted options to Thomas K. Equels, Chief Executive Officer consistent with his employment agreement 25,000 ten year options to purchase common stock at \$3.00 per share which vest in entirety in one year;

The following Options were issued to NEO in their role as employees during 2014:

- On June 6, 2014, we granted options to Thomas K. Equels, Chief Executive Officer consistent with his employment agreement 25,000 ten year options to purchase common stock at \$4.32 per share which vest in entirety in one year; and

The Equity Incentive Plan of 2009 authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 1,250,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. In September 2015, the Company's stockholders approved the following amendments to the 2009 Plan: (1) increased the number of shares authorized to be issued under the Equity Incentive Plan from 1,250,000 to 1,833,333; (2) required a gradual vesting period of options issued under the Equity Incentive Plan over a one year period; (3) revised the definition of "change in control" to make it less "liberal" by amending the provision that a change in control occurs upon stockholder approval of a merger, consolidation or sale or disposition by the Company of all or substantially all of its assets (a "Business Combination") to state that such a change in control occurs upon the consummation of the Business Combination; and (4) clarified that the definition of change in control has a double trigger – For a Participant to get the benefit resulting from a change in control, such Participant must have been terminated other than for cause within a two year period. Unless sooner terminated, the Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date.

#### **Claw-Back Compensation Recoupment Provisions**

Effective December 2011, all Executive compensation including and without limitation to base salary, bonuses, stock options, and fringe benefits, shall be subject to recoupment from the Employee by the Company pursuant to the Company's Executive Compensation Recoupment Policies adopted December 1, 2011, as may be amended by the Company's Board of Directors from time to time to remain in compliance with the claw-back compensation recoupment provisions of the Dodd-Frank Act.

### **Other Compensation**

We provide the following benefits to our NEO generally on the same bases as benefits provided to all full-time employees:

- Health, vision and dental insurance;
- Life insurance;
- Short and long-term disability insurance; and
- 401(k) with Company's ability to match of up to 6% of employee's contribution or to the extent of IRS regulations, whichever is lower.

The Compensation Committee believes that these benefits are consistent with those offered by other companies, specifically those provided by our peers. Occasionally, certain Executives separately negotiate other benefits in addition to the benefits described above. The following additional benefits were provided in 2012 NEO as an element of their respective employment:

Thomas Equels, General Counsel:

- Automobile allowance;
- Predetermined allowance for the Company's utilization of Florida offices of Equels Law Firm;
- Reimbursement of home office, computer, internet, phone and telefax expenses;
- Health, vision and dental insurance fully paid by the Company; and
- Supplementary life and disability insurance policies.

### **401(k) Plan**

In December 1995, we established a defined contribution plan, effective January 1, 1995, entitled the Hemispherx Biopharma employees 401(k) Plan and Trust Agreement. All of our full-time employees are eligible to participate in the 401(k) plan following one year of employment. Subject to certain limitations imposed by Federal Tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Through March 14, 2008, Participants' contributions to the 401(k) plan were matched by Hemispherx at a rate determined annually by the Board of Directors. Each participant immediately vests in his or her deferred salary contributions, while our contributions will vest over one year.

Effective March 15, 2008 and continuing through December 31, 2009, we halted our matching of 401(k) contributions provided to the account for each eligible participant. Effective January 1, 2010, our Compensation Committee reestablished Hemispherx' 100% matching of up to 6% of the 401(k) contributions provided to the account for each eligible participant, to the dollar extent permitted by IRS regulations, including without exception each eligible Named Executive Officer. We halted our matching of 401(k) contributions as of January 1, 2016.

## **Severance**

In determining whether to approve and setting the terms of severance arrangements, the Compensation Committee recognizes that Executives, especially highly ranked Executives, often face challenges securing new employment following termination. Upon termination of employment, the following NEO currently are entitled to receive severance payments under their employment and/or engagement agreements:

- Thomas K. Equels, Executive Vice Chairman of the Board, Chief Executive Officer and President.

The Compensation Committee believes that severance agreements provided to these individuals are generally in line with severance packages offered to executive officers of companies of similar size. Alternately, Dr. David Strayer and Adam Pascale are currently not covered under an existing severance agreement. Any severance benefits payable to them under similar circumstances would be determined by the Compensation Committee in its discretion. See “Estimated Payments Following Severance — Named Executive Officers”.

## **Conclusion**

Our compensation policies are designed to retain and motivate our Executive Officers, other non-officer Executives and non-Executives and to ultimately reward them for outstanding individual and corporate performance.

## **COMPENSATION COMMITTEE REPORT**

The Compensation Committee of our Board of Directors oversees our compensation program on behalf of the Board. In fulfilling its oversight responsibilities, the Committee reviewed and discussed with Management the Executive Compensation Discussion and Analysis set forth in this Form 10-K for the fiscal year ended December 31, 2016.

In reliance on the review and discussions referred to above, the Committee recommended to the Board that the Compensation Discussion and Analysis be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and Hemispherx’ Proxy Statement to be filed in connection with Hemispherx’ 2017 Annual Meeting of Stockholders.

**COMPENSATION COMMITTEE**  
Dr. William M. Mitchell, Committee Chairman  
Stewart L. Appelrouth

The foregoing Compensation Committee report shall not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act, and shall not otherwise be deemed filed under these acts, except to the extent we incorporate by reference into such filings.

**Compliance with Internal Revenue Code Section 162(m) and 409A & 409(b)**

One of the factors the Compensation Committee considers in connection with compensation matters is the anticipated tax treatment to Hemispherx and to the Executives of the compensation arrangements. The deductibility of certain types of compensation depends upon the timing of an executive's vesting in, or exercise of, previously granted rights. Moreover, interpretation of, and changes in, the tax laws and other factors beyond the Compensation Committee's control also affect the deductibility of compensation. Accordingly, the Compensation Committee will not necessarily limit executive compensation to that deductible under Section 162(m) or 409A & 409(b) of the Code. The Compensation Committee will consider various alternatives to preserving the deductibility of compensation payments and benefits to the extent consistent with its other compensation objectives.

**COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION**

Our Compensation Committee of the Board of Directors, consisting of Dr. William M. Mitchell, the Committee Chair, and Stewart L. Appelrouth are independent directors. There are no interlocking relationships.

**EXECUTIVE COMPENSATION**

The following table provides information on the compensation during the fiscal years ended December 31, 2016, 2015 and 2014 of our Chief Executive Officer, Chief Financial Officer, and Chief Scientific Officer/Medical Director constituting the Company's Named Executive Officers, based on the year ended 2016 for each fiscal year.

**Summary Compensation Table**

Name & Principal Position	Year	Salary / Fees (3)	Bonus	Stock Awards	Option Awards (3) (9)	Non-Equity Incentive Plan Compensation	Change in Pension Valued and NQDC Earnings (\$)	All Other Compensation	Total (3)
Thomas K. Equels CEO & President	2016	\$ 503,081	\$ 170,261(3)	—	\$ 27,297(1)	—	—	\$ 84,521(6)	\$ 785,160
(2) (3)	2015	\$ 719,273	\$ 262,092(3)	—	\$ 45,518(1)	—	—	\$ 94,971(6)	\$ 1,121,854
	2014	\$ 719,273	\$ 774,990(3)(5)	—	\$ 69,199(3)	—	—	\$ 104,987(6)	\$ 1,668,449
Adam Pascale CFO	2016	\$ 190,767	\$ —	\$ —	\$ 12,590	—	—	\$ 32,037(8)	\$ 235,394
	2015	\$ 154,000	\$ —	\$ —	\$ —	—	—	\$ 38,264(8)	\$ 192,264
	2014	\$ 143,917	\$ 33,459(5)	\$ —	\$ 10,339	—	—	\$ 36,027(8)	\$ 223,742
David Strayer CSO & Medical Director	2016	\$ 284,575	\$ —	—	\$ 12,590	—	—	\$ 32,235(7)	\$ 329,400
	2015	\$ 269,475	\$ —	—	\$ —	—	—	\$ 44,865(7)	\$ 314,340
	2014	\$ 269,475	\$ 67,369(7)	—	\$ 746(4)	—	—	\$ 29,744(7)	\$ 367,334

Notes:

- (1) Mr. Equels transitioned from the role of external to internal General Counsel and Litigation Counsel effective June 1, 2010 with an Employment Agreement of June 11, 2010, which was amended on July 15, 2010, then amended and restated December 6, 2011, that granted him the annual Option to purchase 25,000 shares of Hemispherx common stock as an element of his Employment Agreement.
- (2) For Named Executive Officers, who are also Directors that receive compensation for their services as a Director, the Salary/Fees and Option Awards columns include compensation that was received by them for their role as a member of the Board of Directors. As is required by Regulation S-K, Item 402(c), compensation for services as a Director have been reported within the "Summary Compensation Table" (above) for fiscal years of 2016, 2015 and 2014 as well as reported separately in the "Compensation of Directors" section (see below) for calendar year 2016.
- (3) On November 26, 2012, the Compensation Committee authorized the payment of a bonus of 5% on the net dollar proceeds resulting from the sale of Company stock sold through the Maxim ATM to Mr. Equels based on the contractual obligation and opinion of independent legal counsel, as set forth in Section 3(c)(ii) of their respective Employment Agreements. Amounts include for 2014, 2015 and 2016, compensation was granted or paid to Mr. Equels, pursuant to this bonus. On November 23, 2015, he waived his rights to any future payments of any incentive bonuses related to the sale of the Company's stock pursuant to any ATM equity distribution agreement. In December 2016, the Compensation Committee authorized the payment of \$39,419 for 5% of Ampligen® sales for the last 5 years, as stated in Thomas Equels' employment contract and the payment of \$130,842, as stated in the 2016 Senior Executive Deferred Cash Performance Award Plan for achieving the Company stock price of \$0.20 for 5 successive trading days

- (4) On December 8, 2014, the Compensation Committee granted 10 year term replacement options to purchase 833 shares of our common stock at an exercise price of \$22.80 per share that vest over a 12 month period to Dr. Strayer.
- (5) On July 3, 2014, our Compensation Committee of the Board of Directors awarded bonuses to certain NEO and senior, non-officer Executives in recognition for their achievement towards our Company-wide and individual goals in 2014.
- (6) Mr. Equels' All Other Compensation consists of:

	2016	2015	2014
Life and Disability Insurance	\$ 36,640	\$ 31,429	\$ 35,280
Healthcare Insurance	29,881	29,942	36,107
Car Expenses / Allowance	18,000	18,000	18,000
401(k) Matching Funds	—	15,600	15,600
	<u>\$ 84,521</u>	<u>\$ 94,971</u>	<u>\$ 104,987</u>

- (7) Dr. Strayer's All Other Compensation consists of:

	2016	2015	2014
Life and Disability Insurance	\$ 3,571	\$ —	\$ —
Healthcare Insurance	28,664	29,265	14,144
401(k) Matching Funds	—	15,600	15,600
	<u>\$ 32,235</u>	<u>\$ 44,865</u>	<u>\$ 29,744</u>

- (8) Mr. Pascale's All Other Compensation consists of:

	2016	2015	2014
Life and Disability Insurance	\$ 3,373	\$ 3,353	\$ 3,187
Healthcare Insurance	28,664	25,671	22,178
401(k) Matching Funds	-	9,240	10,641
	<u>\$ 32,037</u>	<u>\$ 38,264</u>	<u>\$ 36,027</u>

**Grants of Plan Based Awards**

Name	Grant Date (2)	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Underlying Options (#)(2)	Exercise Price of Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
		Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (\$)	Target (\$)	Maximum (\$)				
Thomas Equels, CEO & President	6/6/2016	—	100,616	125,770	—	15,403(3)	—	25,000	\$ 1.68	\$27,297	
Adam Pascale, CFO		—	38,153	47,692	—	—	—	12,500	\$ 1.56	\$12,590	
David Strayer, CSO & Medical Director		—	56,915	71,144	—	—	—	12,500	\$ 1.56	\$12,590	

Notes:

- (1) For 2016, the Compensation Committee continued its practice of not establishing or estimating possible future payouts to the NEO under a Cash Bonus Plan. All Bonuses are at the discretion of the Compensation Committee. Utilizing existing Employment Agreements as a benchmark and the respective employees' Base Salary at January 1, 2016, the "Target" was estimated at 20% of the Base Salary and "Maximum" was estimated at 25% of Base Salary.
- (2) Consists of stock options granted during 2016 under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the NYSE MKT closing market price of our common stock on the date of grant. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).
- (3) Consists of stock options contractually required per the NEO's respective Employment Agreement to be granted during 2017 under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the NYSE MKT closing market price of our common stock on the date of grant. For the purpose of this schedule, a NYSE MKT closing price at December 31, 2016 of \$0.69 was assumed with an estimated exercise price of \$0.76 for Mr. Equels. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

**Outstanding Equity Awards at Fiscal Year End**

Name	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#)	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)	Equity Incentive Plan Awards: Number of Units or Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Rights that Have Not Vested (#)
Thomas Equels,	25,000	—	—	7.92	6/11/2020	—	—	—	—
President and Chief Executive Officer	25,000	—	—	4.92	6/24/2021	—	—	—	—
	8,333	—	—	3.48	6/6/2022	—	—	—	—
	25,000	—	—	3.72	6/11/2022	—	—	—	—
	25,000	—	—	3.72	6/6/2023	—	—	—	—
	12,500	—	—	3.00	8/2/2023	—	—	—	—
	25,000	—	—	4.32	6/6/2024	—	—	—	—
	25,000	—	—	3.00	6/8/2025	—	—	—	—
	—	25,000	—	1.68	6/8/2026	—	—	—	—
Adam Pascale,	83	—	—	28.44	1/23/2017	—	—	—	—
Chief Financial Officer	1,250	—	—	15.60	12/6/2017	—	—	—	—
	417	—	—	48.00	9/17/18	—	—	—	—
	500	—	—	48.36	4/13/2022	—	—	—	—
	4,167	—	—	3.96	7/8/2024	—	—	—	—
	—	12,500	—	1.56	6/21/2026	—	—	—	—
David Strayer,	4,167	—	—	24.00	9/9/2017	—	—	—	—
CSO & Medical Director	4,167	—	—	48.00	2/18/2018	—	—	—	—
	833	—	—	48.36	4/13/2022	—	—	—	—
	1,667	—	—	28.44	1/23/2017	—	—	—	—
	833	—	—	22.80	12/8/2024	—	—	—	—
	2,083	—	—	15.60	12/6/2017	—	—	—	—
	—	12,500	—	1.56	6/21/2026	—	—	—	—

**Option Exercises and Stock Vested**

Name and Principal Position	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting (\$)
Thomas K. Equels, CEO & President	—	—	—	—
Adam Pascale, CFO	—	—	—	—
David Strayer, CSO and Medical Director	—	—	—	—

**Payments on Disability**

At December 31, 2016, we had an employment agreement with Mr. Equels which entitled him Base Salary and applicable benefits otherwise due and payable through the last day of the month in which disability occurs and for an additional twelve-month period. Each current NEO, including Mr. Pascale and Dr. Strayer, has the same short and long-term disability coverage which is available to all eligible employees. The coverage for short-term disability provides up to six months of full salary continuation up to 60% of weekly pay, less other income, with a \$1,500 weekly maximum limit. The coverage for group long-term disability provides coverage at the exhaustion of short-term disability benefits of full salary continuation up to 60% of monthly pay, less other income, with a \$10,000 monthly maximum limit. The maximum benefit period for the group long-term disability coverage is 60 months for those age 60 and younger at the time of the claim with the coverage period proportionately reduced with the advanced age of the eligible employee to a minimum coverage period of 12 months for those of 69 years old and older as of the date of the claim. For the period June 2010 through 2016 pursuant to his respective employment agreement and payable by us, Mr. Equels is entitled to receive total disability coverage of \$400,000.

**Payments on Death**

At December 31, 2016, we had an employment agreement with Mr. Equels which entitled him Base Salary and applicable benefits otherwise due and payable through the last day of the month in which death occurs and for an additional twelve-month period. Each NEO, including Mr. Pascale and Dr. Strayer, has coverage of group life insurance, along with accidental death and dismemberment benefits, consistent to the dollar value available to all eligible employees. The benefit is equal to two times current salary or wage with a maximum limit of \$300,000, plus any supplemental life insurance elected and paid for by the NEO. For the period June 2010 and through 2016 pursuant to his respective employment agreements and payable by us, Mr. Equels is entitled to receive total death benefit coverage of \$3,000,000.

**Estimated Payments Following Severance — Named Executive Officers**

At December 31, 2016, we had an employment agreement with Mr. Equels which entitled him to severance benefits on certain types of employment terminations not related to a change in control. Dr. Strayer and Mr. Pascale are not covered by an employment severance agreement and therefore would only receive severance as determined by the Compensation Committee in its discretion.

The dollar amounts below assume that the termination occurred on January 1, 2017. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from Hemispherx based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

Name	Event	Cash Severance (\$)	Value of Stock Awards That Will Become Vested (1) (\$)	Continuation of Medical Benefits (\$)	Additional Life Insurance (\$)	Total (\$)
Thomas K. Equels, CEO & President	Involuntary (no cause)	554,811	6,737	—	—	561,548
	Termination (for cause)	—	—	—	—	—
	Death or disability	554,811	6,737	—	—	561,548
	Termination by employee or retirement	554,811	6,737	—	—	561,548
Adam Pascale CFO	Involuntary (no cause)	—	—	—	—	—
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—
David Strayer CSO & Medical Director	Involuntary (no cause)	—	—	—	—	—
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—

Notes:

- (1) Consists of stock options contractually required per the employee's respective Employment Agreement to be granted during each calendar year of the term under our 2009 Equity Incentive Plan. The stock options have a ten-year term and an exercise price equal to 110% of the closing market price of our common stock on the date of grant. For the purpose of this schedule, a NYSE MKT closing price at December 31, 2016 of \$0.69 was utilized with an estimated exercise price of \$0.76. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).

#### Payments On Termination in Connection with a Change in Control Named Executive Officers

At December 31, 2016, we had an employment agreement with Mr. Equels which entitled him to severance benefits on certain types of employment terminations related to a change in control whereby the term of his respective agreement would automatically be extended for three additional years. Dr. Strayer and Mr. Pascale are not covered by employment severance agreement and therefore would only receive severance from a change in control as determined by the Compensation Committee in its discretion. Any specific benefits for these two NEO would be determined by the Compensation Committee in its discretion.

The dollar amounts in the chart below assume that change in control termination occurred on January 1, 2017, based on the employment agreements that existed at that time. The actual dollar amounts to be paid can only be determined at the time of the NEO's separation from Hemispherx based on their prevailing compensation and employment agreements along with any determination by the Compensation Committee in its discretion.

#### Estimated Benefits on Termination Following a Change in Control — December 31, 2016

The following table shows potential payments to the NEO if employment terminates following a change in control under contracts, agreements, plans or arrangements at December 31, 2016. The amounts assume a January 1, 2017 termination date regarding base pay and use of the opening price of \$0.69 on the NYSE MKT for our common stock at that date.

Name	Aggregate Severance Pay (\$)	PVSU Acceleration (2) (\$)	Early Vesting of Restricted Stock (4) (5) (\$)	Early Vesting of Stock Options and SARs (3) (\$)	Acceleration and Vesting of Supplemental Award (5) (\$)	Welfare Benefits Continuation (\$)	Outplacement Assistance (\$)	Parachute Tax Gross-up Payment (\$)	Total (\$)
	2,219,244								
Thomas K. Equels	(1)	—	—	—	55,243 (4)	—	—	—	2,274,487
Adam Pascale	—	—	—	—	—	—	—	—	—
David Strayer	—	—	—	—	—	—	—	—	—

Notes:

- (1) This amount represents the base salary and benefits for remaining term of the NEO's employment agreement plus a three-year extension in the term upon the occurrence of a termination from a change in control. The existing employment agreement with Mr. Equels has a term through December 31, 2016; however, this was automatically extended for an additional three-year period through December 31, 2019.
- (2) This amount represents the payout of all outstanding performance-vesting share units ("PVSU") awarded on a change in control at the target payout level with each award then pro-rated based on the time elapsed for the applicable three-year performance period.
- (3) This amount is the intrinsic value [fair market value on January 1, 2017 (\$0.69 per share) minus the per share exercise price of 110%] of all unvested stock options for each NEO, including Stock Appreciation Rights ("SAR"). Any option with an exercise price of greater than fair market value was assumed to be cancelled for no consideration and, therefore, had no intrinsic value.
- (4) This amount represents the options to be issued annually for the remaining term of the NEO's employment agreement plus a three-year extension in the occurrence of termination from a change in control. The calculation was based on a NYSE MKT closing price for December 31, 2016 of \$0.69 with an estimated exercise price of \$0.76 (110% prior NYSE MKT closing value). The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718 (formerly SFAS 123R).
- (5) Any purchase rights represented by the Option not then vested shall, upon a change in control, shall become vested.

**Definition of "Change in Control"** for each agreement, a "Change in Control" is defined generally as any such event that requires a report to the SEC, but includes any of the following:

- Any person or entity other than Hemispherx, any of our current Directors or Officers or a Trustee or fiduciary holding our securities, becomes the beneficial owner of more than 50% of the combined voting power of our outstanding securities;
- An acquisition, sale, merger or other transaction that results in a change in ownership of more than 50% of the combined voting power of our stock or the sale/transfer of more than 75% of our assets;
- A change in the majority of our Board of Directors over a two-year period that is not approved by at least two-thirds of the Directors then in office who were Directors at the beginning of the period; or
- Execution of an agreement with Hemispherx, which if consummated, would result in any of the above events.

**Definition of “Constructive Termination”.** A “Constructive Termination” generally includes any of the following actions taken by Hemispherx without the Executive’s written consent following a change in control:

- Significantly reducing or diminishing the nature or scope of the executive’s authority or duties;
- Materially reducing the executive’s annual salary or incentive compensation opportunities;
- Changing the executive’s office location so that he must commute more than 50 miles, as compared to his commute as of the date of the agreement;
- Failing to provide substantially similar fringe benefits, or substitute benefits that were substantially similar taken as a whole, to the benefits provided as of the date of the agreement; or
- Failing to obtain a satisfactory agreement from any successor to Hemispherx to assume and agree to perform the obligations under the agreement.

However, no constructive termination occurs if the executive:

- Fails to give us written notice of his intention to claim constructive termination and the basis for that claim at least 10 days in advance of the effective date of the executive’s resignation; or
- We cure the circumstances giving rise to the constructive termination before the effective date of the executive’s resignation.

**Available Information**

Our Internet website is [www.hemispherx.net](http://www.hemispherx.net) and you may find our SEC filings in the “Investor Relations” under “SEC Filings”. We provide access to our filings with the SEC, free of charge through [www.sec.gov](http://www.sec.gov), as soon as reasonably practicable after filing with the SEC. Our Internet website and the information contained on that website, or accessible from our website, is not intended to be incorporated into this Annual Report on Form 10-K or any other filings we make with the SEC.

**Post-Employment Compensation**

We have an agreement with the following NEO who has benefits upon termination as a condition of his respective employment agreement: Thomas K. Equels, our CEO.

The following is a description of post-employment compensation payable to the respective NEO. If a NEO does not have a specific benefit, they will not be mentioned in the subsection. In such event, the NEO does not have any such benefits upon termination unless otherwise required by law.

**Termination for Cause**

All of our NEOs can be terminated for cause. For Mr. Equels, “Cause” means willful engaging in illegal conduct, gross misconduct or gross violation of the Company’s Code of Ethics and Business Conduct for Officers which is demonstrably and materially injurious to the Company. For purposes of his respective agreement, no act, or failure to act, on employee’s part shall be deemed “willful” unless done intentionally by employee and not in good faith and without reasonable belief that employee’s action or omission was in the best interest of the Company. Notwithstanding the foregoing, employee shall not be deemed to have been terminated for Cause unless and until the Company delivers to the employee a copy of a resolution duly adopted by the affirmative vote of not less than three-quarters of the Directors of the Board at a meeting of the Board called and held for such purpose (after reasonable notice to employee and an opportunity for Employee, together with counsel, to be heard before the Board) finding that, in the good faith opinion of the Board, employee was guilty of conduct set forth above and specifying the particulars thereof in detail. In the event that his employment is terminated for Cause, the Company shall pay him, at the time of such termination, only the compensation and benefits otherwise due and payable to them through the last day of their actual employment by the Company.

**Termination Without Cause**

Mr. Equels is entitled to the compensation and benefits otherwise due and payable to him through the last day of the then current term of their respective agreements. In the event that he is terminated at any time without "Cause" the Company shall pay to him, at the time of such termination, the compensation and benefits otherwise due and payable through the last day of the then current term of their Agreement. However, benefit distributions that are made due to a "separation from service" occurring while he is a Named Executive Officer shall not be made during the first six months following separation from service. Rather, any distribution which would otherwise be paid to him during such period shall be accumulated and paid to him in a lump sum on the first day of the seventh month following the "separation from service". All subsequent distributions shall be paid in the manner specified.

**Death or Disability**

Mr. Equels can be terminated for death or disability. For each, "Disability" means the inability to effectively carry out substantially all of his duties under their agreement by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted for a continuous period of not less than 12 months. In the event the employment is terminated due to his death or disability, the Company will pay (or their respective estate as the case may be), at the time of such termination, the Base Salary and applicable benefits otherwise due and payable through the last day of the month in which such termination occurs and for an additional 12 month period.

**Termination by Officer and Employee**

All NEO employment agreements have the right to terminate their respective agreement upon thirty (30) days or less of prior written notice of termination. In such event, Mr. Equels is specifically entitled to fees due to him through the last day of the month in which such termination occurs and for 12 months thereafter. All other NEOs are entitled to the fees due to them through the last day of the month in which such termination occurs.

### **Change in Control**

As an element of his employment agreement, Mr. Equels is entitled to benefits upon a Change in Control or Constructive Termination that include that any unvested Options immediately vest and the term of his respective employment agreement automatically extend for an additional three years. In the event of a Change in Control, the Company is responsible for the base salary or benefits for remaining term of the NEO's employment agreement plus an automatic three-year extension in the term of the agreement. The existing employment agreement with Mr. Equels had a term through December 31, 2016; however, this employment agreement automatically extended for an additional three-years through December 31, 2019.

### **Compensation of Directors**

Our Compensation, Audit and Corporate Governance and Nomination Committees, consist of Dr. William M. Mitchell, Compensation and Corporate Governance and Nomination Committee Chair, and Stewart L. Appellrouth, Audit Committee Chair, both of whom are independent Board of Director members.

Hemispherx reimburses Directors for travel expenses incurred in connection with attending board, committee, stockholder and special meetings along with other Company business-related expenses. Hemispherx does not provide retirement benefits or other perquisites to non-employee Directors under any current program.

Commencing as of January 1, 2014, a 1.5% cost of living increase was granted to Board member Directors' fee compensation, increasing 2014's annual retainer from \$176,766 to \$182,462 for 2014. There was no cost of living increase granted in 2015 or 2016. Directors' fees will continue to be paid semi-monthly in cash.

All Directors have been granted options to purchase common stock under our Stock Option Plans and/or Warrants to purchase common stock. We believe such compensation and payments are necessary in order for us to attract and retain qualified outside directors. To the extent that share compensation would exceed 83,333 shares in the aggregate for the ten-year period commencing January 1, 2003, as previously approved by Resolution of the Board of September 9, 2003, shares for share compensation were issued under the our 2007 and 2009 Equity Incentive Plans.

## Director Compensation – 2016

Name and Title of Director	Fees Earned or Paid in Cash (\$)	Stock Award (\$)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation As Director (\$)	Total (\$)
T. Equels, Executive Vice Chairman	20,410(2)	—	—	—	—	—	20,410
W. Mitchell, Chairman of the Board (1)	182,462	—	12,590	—	—	—	195,052
Stewart L. Appelrouth, Director (1)	68,423	—	—	—	—	—	68,423

Notes:

- (1) Independent Director of the Company.
- (2) Only includes compensation received in the role as member of the Board of Directors and does not include compensation received in the capacity of a Named Executive Officer. As is required by Regulation S-K, Item 402(c), compensation as a Director has also been reported within the “Summary Compensation Table” regarding Named Executive Officer Compensation during fiscal years of 2016, 2015 and 2014 (see above). Mr. Equels stopped receiving Board fees in March 2016.

### ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth as of March 10, 2017, the number and percentage of outstanding shares of common stock beneficially owned by:

- Each person, individually or as a group, known to us to be deemed the beneficial owners of five percent or more of our issued and outstanding common stock;
- Each of our Directors and the Named Executives Officers; and
- All of our officers and directors as a group.

Name and Address of Beneficial Owner	Shares Beneficially Owned	% Of Shares Beneficially Owned
Thomas K. Equels	457,222 (1)	1.73%
Peter W. Rodino III 17400 Sterling Lake Drive Fort Myers, FL 33967	25,000 (2)	*
William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21st and Garland Nashville, TN 37232	72,169 (3)	*
Stewart L. Appelrouth 999 Ponce de Leon., Suite 625 Coral Gables, FL 33134	15,750 (8)	*
Wayne S. Springate 783 Jersey Ave. New Brunswick, NJ 08901	44,613 (4)	*
David R. Strayer, M.D.	48,558 (5)	*
Adam Pascale	23,369 (6)	*
Sabby Management LLC	1,391,286 (7)	5.31%
All directors and executive officers as a group (6 persons)	686,681	2.58%

\* Ownership of less than 1%

- (1) Mr. Equels is Executive Vice Chairman of our Board of Directors, Chief Executive Officer and President, who beneficially owns 220,456 shares of common stock and beneficially owns 195,833 shares issuable or issued upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2009	6/11/2010	\$ 7.92	25,000	6/11/2020
	2009	6/24/2011	\$ 4.92	25,000	6/24/2021
	2009	6/5/2012	\$ 3.48	8,333	6/6/2022
	2009	6/11/2012	\$ 3.72	25,000	6/11/2022
	2009	6/6/2013	\$ 3.72	25,000	6/6/2023
	2009	8/2/2013	\$ 3.00	12,500	8/2/2023
	2009	6/6/2014	\$ 4.32	25,000	6/6/2024
	2009	6/6/2015	\$ 3.00	25,000	6/6/2025
	2009	6/8/2016	\$ 1.68	25,000	6/6/2025
Total Options				<u>195,833</u>	
Warrants	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
Total Warrants	2009	2/1/2009	\$ 6.12	<u>40,933</u>	2/1/2019

- (2) Mr. Rodino is our General Counsel, Exec. Dir. of Governmental Relations and Secretary who beneficially owns 25,000 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2009	8/2/2013	\$ 3.00	12,500	8/2/2023
	2009	6/21/2016	\$ 1.56	12,500	6/21/2026
<b>Total Options</b>				<b>25,000</b>	

- (3) Dr. Mitchell is our Chairman of the Board who owns 8,697 shares of common stock and beneficially owns 46,833 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	9/10/2007	\$ 24.00	8,333	9/9/2017
	2004	9/17/2008	\$ 72.00	1,000	9/17/2018
	2009	6/5/2012	\$ 3.48	8,333	6/6/2022
	2009	8/2/2013	\$ 3.00	12,500	8/2/2023
	2009	9/9/2014	\$ 31.20	4,167	9/9/2024
	2009	9/9/2014	\$ 1.56	12,500	9/9/2024
<b>Total Options</b>				<b>46,833</b>	

Dr. Mitchell beneficially owns 16,639 shares of common stock of which 8,318 shares are held by Shirley Mitchell (Spouse), 4,098 shares are held by the Aesclepius Irrevocable Trust (Shirley Mitchell Trustee), and 4,223 shares are held by the Aesclepius Irrevocable Trust II (William Mitchell Trustee).

- (4) Mr. Springate is our Senior Vice President of Operations and owns 8,627 shares of common stock and beneficially owns 35,986 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Price	Number Of Shares	Expiration Date
	2004	5/1/2007	\$ 21.36	1,667	5/1/2017
	2004	12/6/2007	\$ 15.60	1,667	12/6/2017
	2009	5/31/2011	\$ 6.60	7,500	5/31/2021
	2009	6/5/2012	\$ 3.48	4,167	6/5/2022
	2009	5/9/2013	\$ 2.88	4,167	5/9/2023
	2009	6/6/2014	\$ 4.32	4,167	6/6/2024
	2009	12/8/2014	\$ 22.80	151	12/8/2024
	2009	6/21/2016	\$ 1.56	12,500	6/21/2026
<b>Total Options</b>				<b>35,986</b>	

- (5) Dr. Strayer is our Chief Scientific Officer and Chief Medical Director that has ownership of 23,975 shares of common stock and beneficially owns 24,583 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Issued	Number Of Shares	Expiration Date
	2004	9/10/2007	\$ 24.00	4,167	9/9/2017
	2004	12/6/2007	\$ 15.60	2,083	12/6/2017
	2004	2/18/2008	\$ 48.00	4,167	2/18/2018
	2009	4/13/2012	\$ 48.36	833	4/13/2022
	2009	12/8/2014	\$ 22.80	833	12/8/2024
	2009	6/21/2016	\$ 1.56	12,500	12/8/2024
<b>Total Options</b>				<b>24,583</b>	

- (6) Mr. Pascale is our Chief Financial Officer that has ownership of 4,535 shares of common stock and beneficially owns 18,834 shares issuable upon exercise of:

Options	Plan	Date Issued	Exercise Issued	Number Of Shares	Expiration Date
	2004	12/6/2007	\$ 15.60	1,250	12/6/2017
	2004	9/17/2008	\$ 48.00	417	9/17/2018
	2009	4/13/2012	\$ 48.36	500	4/13/2022
	2009	7/8/2014	\$ 3.96	4,167	7/8/2024
	2009	6/21/2016	\$ 1.56	12,500	6/21/2026
<b>Total Options</b>				<b>18,834</b>	

- (7) Sabby Management, LLC beneficially owns 1,391,286 shares of common stock of which 850,769 shares are held by Sabby Healthcare Master Fund, Ltd. and 540,517 shares are held by Sabby Volatility Warrant Master Fund, Ltd

- (8) Mr. Appelrouth is a Director and has ownership of 15,750 shares of common stock.

### ITEM 13. Certain Relationships and Related Transactions, and Director Independence.

#### Review, Approval or Ratification of Transactions with Related Persons

Our policy is to require that any transaction with a related party required to be reported under applicable SEC rules, other than compensation related matters and waivers of our code of business conduct and ethics, be reviewed and approved or ratified by a majority of independent, disinterested Directors. We have adopted procedures in which the Audit Committee shall conduct an appropriate review of all related party transactions for potential conflict of interest situations on an annual and case-by-case basis with the approval of this Committee required for all such transactions.

We have employment agreements with certain of our executive officers and have granted such Officers and Directors options and warrants to purchase our common stock, as discussed under the headings, "ITEM 11. Executive Compensation", and "ITEM 12. Security Ownership of Certain Beneficial Owners and Management", as noted above.

Thomas Equels was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008 and joined the Company as General Counsel effective June 1, 2010. Mr. Equels had provided external legal services for several years through May 31, 2010 and Equels Law Firm ceased providing external legal services in 2016. In 2015 and 2014, the Company paid Equels Law Firm approximately \$42,000 and \$303,000, respectively, for services rendered. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the hourly rates charged by Equels Law to the Company were reasonable when compared to the fee structure of a possible arms-length transaction from comparable firms in practice in the same market and of the similar size. The hourly rate fees from Equels Law Firm remained the same 2014 and 2015. For his Board fees, Mr. Equels received approximately \$20,000, \$182,000 and \$182,000, respectively, for 2016, 2015 and 2014.

For the years ended 2016, 2015 and 2014, compensation was granted or paid related to the Executive Performance Incentive Program related to the ATM, as set forth in Section 3(c)(ii) of his Employment Agreement, for approximately \$0, \$262,000, and \$641,000 to Mr. Equels. Mr. Equels' compensation related to this program was classified entirely as general and administrative expense.

**ITEM 14. Principal Accountant Fees and Services.**

All audit and professional services are approved in advance by the Audit Committee to assure such services do not impair the auditor's independence from us. The total fees by RSM US LLP ("RSM") for 2016 and 2015 were \$279,500 and \$327,000 respectively. The following table shows the aggregate fees for professional services rendered during the year ended December 31, 2016 and 2015.

Description of Fees:	Amount (\$)	
	2016	2015
Audit Fees	\$ 272,000	\$ 269,000
Audit-Related Fees	7,500	58,000
Tax Fees	—	—
All Other Fees	—	—
<b>Total</b>	<b>\$ 279,500</b>	<b>\$ 327,000</b>

*Audit Fees*

Audit fees include the audit of our annual financial statements and the review of our financial statements included in our quarterly reports and services in connection with statutory and regulatory filings.

*Audit-Related Fees*

Represents the fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements. Audit-related fees include professional services related to the Company's filing of SEC Form S-3 and S-8 (i.e., stock shelf offering procedures).

The Audit Committee has determined that RSM's rendering of these audit-related services and all other fees were compatible with maintaining auditor's independence. The Board of Directors considered RSM to be well qualified to serve as our independent public accountants. The Committee also pre-approved the charges for services performed in 2015 and 2014.

The Audit Committee pre-approves all auditing and accounting services and the terms thereof (which may include providing comfort letters in connection with securities underwriting) and non-audit services (other than non-audit services prohibited under Section 10A(g) of the Exchange Act or the applicable rules of the SEC or the Public Company Accounting Oversight Board) to be provided to us by the independent auditor; provided, however, the pre-approval requirement is waived with respect to the provisions of non-audit services for us if the “de minimus” provisions of Section 10A (i)(1)(B) of the Exchange Act are satisfied. This authority to pre-approve non-audit services may be delegated to one or more members of the Audit Committee, who shall present all decisions to pre-approve an activity to the full Audit Committee at its first meeting following such decision.

#### **PART IV**

##### **ITEM 15. Exhibits and Financial Statement Schedules.**

- (a) Financial Statements and Schedules - See index to financial statements on page F-1 of this Annual Report. All other schedules called for under regulation S-X are not submitted because they are not applicable or not required, or because the required information is included in the financial statements or notes thereto.
- (i) Exhibits - See exhibit index below. Except as disclosed in the footnotes, the following exhibits were filed with the Securities and Exchange Commission as exhibits to our Form S-1 Registration Statement (No. 33-93314) or amendments thereto and are hereby incorporated by reference:

Exhibit No.	Description
1.1	July 23, 2012 Equity Distribution Agreement with Maxim Group LLC (1)
3.1	Amended and Restated Certificate of Incorporation of the Company, as amended, along with Certificates of Designations. (2)
3.3	Amended and Restated By-Laws of Registrant (35)
4.1	Specimen certificate representing our Common Stock.
4.2	Amended and Restated Rights Agreement, dated as of November 2, 2012, between the Company and Continental Stock Transfer & Trust Company. The Amended and Restated Right Agreement includes the Form of Certificate of Designation, 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. (3)
4.4	Form of Indenture filed with Form S-3 Universal Shelf Registration Statement. (4)
4.5	Form of Series I common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (5)
4.6	Form of Series II common stock purchase warrant pursuant to May 10, 2009 Securities Purchase Agreement. (5)
4.7	Form of common stock purchase warrant pursuant to May 18, 2009 Securities Purchase Agreement. (6)
4.8	Form of Warrant pursuant to August 30, 2016 Securities Purchase Agreement. (38)
4.9	Form of Warrant pursuant to February 1, 2017 Securities Purchase Agreement. (40)
10.1	Form of Confidentiality, Invention and Non-Compete Agreement.
10.2	Form of Clinical Research Agreement.
10.3	Employee Wage or Hours Reduction Program. (7)
10.4	Form of Securities Purchase Agreement entered into on May 10, 2009. (1)
10.5	Form of Securities Purchase Agreement entered into on May 18, 2009. (5)
10.6	Amended and Restated Employment Agreement with Robert Dickey IV, dated September 1, 2010. (8)
10.7	Supply Agreement with Hollister-Stier Laboratories LLC dated December 5, 2005. (9)
10.8	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC dated February 25, 2010. (10)
10.9	Amended and Restated Employment Agreement of Dr. William A. Carter dated June 11, 2010 (11)
10.10	Vendor Agreement with Bio Ridge Pharma, LLC dated August 11, 2011. (33).
10.11	Vendor Agreement with Armada Healthcare, LLC dated August 11, 2011. (33).
10.12	Amended and restated employment agreement with Wayne Springate dated May 1, 2011. (13)
10.13	Amended and restated employment agreement with Ralph Christopher Cavalli dated September 15, 2011. (15)
10.14	Amended and restated employment agreement with William A. Carter dated December 6, 2011. (16)
10.15	Amended and restated employment agreement with Thomas K. Equels dated December 6, 2011. (16)
10.16	Amended and restated employment agreement with Charles T. Bernhardt dated December 6, 2011. (16)
10.17	Second Amended and Restated Advisor's Agreement with The Sage Group dated December 14, 2011. (17)
10.18	Amendment to Supply Agreement with Hollister-Stier Laboratories LLC executed September 9, 2011. (17)
10.19	Vendor Agreement extension with Bio Ridge Pharma, LLC dated August 14, 2012. (18)

10.20	Vendor Agreement extension with Armada Healthcare, LLC dated August 14, 2012. (18)
10.21	Advisor’s Agreement with The Sage Group dated June 15, 2013. (20)
10.22	Vendor Agreement extension with Armada Healthcare, LLC dated July 19, 2013. (21)
10.23	Vendor Agreement extension with Bio Ridge Pharma, LLC dated July 19, 2013. (21)
10.24	Vendor Agreement extension with Bio Ridge Pharma, LLC and Armada Healthcare, LLC dated August 8, 2014.(22)
10.25	Sales, Marketing, Distribution, and Supply Agreement with Emerge Health Pty Ltd. dated March 9, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (22)
10.26	August 4, 2015 Amendment to Equity Distribution Agreement between the registrant and Maxim Group LLC. (24)
10.27	Vendor Agreement extension with Armada Healthcare, LLC dated July 29, 2015. (26)
10.28	Vendor Agreement extension with Bio Ridge Pharma, LLC dated July 29, 2013. (26)
10.29	Early Access Agreement with Impatiens N.V. dated August 3, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (27)
10.30	Sales, Marketing, Distribution, and Supply Agreement with Emerge Health Pty Ltd. dated August 6, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (26)
10.31	Addendum to Early Access Agreement with Impatiens N.V. dated October 16, 2015. (Confidential Treatment granted with respect to portions of the Agreement) (27)
10.32	Letter agreement between Dr. Carter and the Company dated September 28, 2015 extending the period for notice of non-renewal to December 1, 2015 within the June 11, 2010 Amended and Restated Engagement Agreement entered into between the Company and Dr. Carter. (27)
10.33	November 23, 2015 William A. Carter Employment Agreement Waiver. (28)
10.34	November 23, 2015 Thomas K. Equels Employment Agreement Waiver. (28)
10.35	Equity Distribution Agreement, dated December 15, 2015 with Chardan Capital Markets, LLC. (29)
10.36	December 23, 2015 letter to Dr. Carter related to non-renewal of his consulting agreement and continued consulting services. (30)
10.37	2016 Senior Executive Deferred Cash Performance Award Plan. (31)
10.38	2016 Voluntary Incentive Stock Award Plan. (31)
10.39	Amended and Restated 2016 Senior Executive Deferred Cash Performance Award Plan. (32)
10.40	Sales, Marketing, Distribution and Supply Agreement (the “Agreement”) with Scientific Products Pharmaceutical Co. LTD dated March 3, 2016 (Confidential Treatment granted with respect to portions of the Agreement). (34)
10.41	Agreement between Avrio Biopharmaceuticals (“Avrio”) and the Company dated July 20, 2016 (Confidential Treatment granted with respect to portions of the Agreement). (36)
10.42	Licensing Agreement dated April 13, 2016 with Lonza Sales AG (Confidential Treatment granted with respect to portions of the Agreement). (37)
10.43	Form of Securities Purchase Agreement entered into on August 30, 2016. (38)
10.44	Amended and Restated Early Access Agreement with Impatiens N.V. dated May 20, 2016. (Confidential portions of this exhibit have been redacted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request in accordance with Rule 24b-2 of the Securities Exchange Act of 1934, as amended). (39)
10.45	Form of Securities Purchase Agreement entered into on February 1, 2017. (40)
21	Subsidiaries of the Registrant. *
23.1	RSM US LLP consent. *
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’ Annual Report on Form 10-K for the year ended December 31, 2015, formatted in eXtensible Business Reporting Language (“XBRL”): (i) the Condensed Consolidated Statements of Income; (ii) the Condensed Consolidated Balance Sheets; (iii) the Condensed Consolidated Statements of Cash Flows; and (iv) Notes to Condensed Consolidated Financial Statements.

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\* Filed herewith.

- (1) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed July 23, 2012 and is hereby incorporated by reference.
- (2) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed June 24, 2011 and is hereby incorporated by reference.
- (3) Filed with the Securities and Exchange Commission on November 2, 2012 as an exhibit to the Company's Registration Statement on Form 8-A12G/A (No. 0-27072) and is hereby incorporated by reference.
- (4) Filed with the Securities and Exchange Commission as an exhibit to the Company's Form S-3 Registration Statement (No. 333-182216) on June 19, 2012 and is hereby incorporated by reference.
- (5) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended March 31, 2009 and is hereby incorporated by reference.
- (6) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) dated May 18, 2009 and is hereby incorporated by reference.
- (7) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2008 and is hereby incorporated by reference.
- (8) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2010 and is hereby incorporated by reference.
- (9) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2005 and is hereby incorporated by reference.
- (10) Filed with the Securities and Exchange Commission as an exhibit to the Company's Annual Report on Form 10-K (No. 000-27072) for the year ended December 31, 2009 and is hereby incorporated by reference.
- (11) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) dated June 15, 2010 and is hereby incorporated by reference.
- (12) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) dated May 28, 2010 and is hereby incorporated by reference.
- (13) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended March 31, 2011 and is hereby incorporated by reference.
- (14) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2011 and is hereby incorporated by reference.
- (15) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed September 23, 2011 and is hereby incorporated by reference.
- (16) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed December 12, 2011 and is hereby incorporated by reference.

- (17) Filed with the Securities and Exchange Commission as an exhibit to the Company's Annual Report on Form 10-K (No. 000-27072) for the year ended December 31, 2011 and is hereby incorporated by reference.
- (18) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed August 15, 2012 and is hereby incorporated by reference.
- (19) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended September 30, 2015 and is hereby incorporated by reference.
- (20) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2013 and is hereby incorporated by reference.
- (21) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2013 and is hereby incorporated by reference.
- (22) Filed with the Securities and Exchange Commission as an exhibit to the Company's annual report on Form 10-K (No. 000-27072) for the year ended December 31, 2014 and is hereby incorporated by reference.
- (23) Intentionally left blank.
- (24) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed June 23, 2015 and is hereby incorporated by reference.
- (25) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed August 4, 2015 and is hereby incorporated by reference.
- (26) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q (No. 000-27072) for the period ended June 30, 2015 and is hereby incorporated by reference.
- (27) Intentionally left blank
- (28) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed November 23, 2015 and is hereby incorporated by reference.
- (29) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed December 15, 2015 and is hereby incorporated by reference.
- (30) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed January 14, 2016 and is hereby incorporated by reference.
- (31) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed February 4, 2016 and is hereby incorporated by reference.
- (32) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K (No. 000-27072) filed March 1, 2016 and is hereby incorporated by reference.
- (33) Filed with the Securities and Exchange Commission as an exhibit to the Company's amended quarterly report on Form 10-Q/A (No. 000-27072) for the period ended September 30, 2011 and is hereby incorporated by reference.
- (34) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q for the period ended March 31, 2016 and is hereby incorporated by reference.
- (35) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed June 10, 2016 and is hereby incorporated by reference.
- (36) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q for the period ended June 30, 2016 and is hereby incorporated by reference.

- (37) Filed with the Securities and Exchange Commission as an exhibit to the Company's quarterly report on Form 10-Q/A for the period ended March 31, 2016 and is hereby incorporated by reference.
- (38) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed September 1, 2016 and is hereby incorporated by reference.
- (39) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed January 17, 2017 and is hereby incorporated by reference.
- (40) Filed with the Securities and Exchange Commission as an exhibit to the Company's Current Report on Form 8-K filed February 1, 2017 and is hereby incorporated by reference.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ Thomas K. Equels  
Thomas K. Equels  
Chief Executive Officer

March 31, 2017

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange of 1934, as amended, this report has been signed below by the following persons on behalf of this Registrant and in the capacities and on the dates indicated.

<u>/s/ Thomas K. Equels</u> Thomas K. Equels	Executive Vice Chairman of the Board, Chief Executive Officer and Director	March 31, 2017
<u>/s/ William Mitchell</u> William Mitchell, M.D., Ph.D.	Chairman of the Board and Director	March 31, 2017
<u>/s/ Stewart L. Appelrouth</u> Stewart L. Appelrouth	Director	March 31, 2017
<u>/s/ Adam Pascale</u> Adam Pascale	Chief Financial Officer	March 31, 2017

**HEMISPHERx BIOPHARMA, INC AND SUBSIDIARIES**  
**Index to Consolidated Financial Statements**

	<u>Page</u>
<a href="#"><u>Report of Independent Registered Public Accounting Firm</u></a>	F-2
<a href="#"><u>Consolidated Balance Sheets at December 31, 2016 and 2015</u></a>	F-3
<a href="#"><u>Consolidated Statements of Comprehensive Loss for each of the years in the three-year period ended December 31, 2016</u></a>	F-4
<a href="#"><u>Consolidated Statements of Changes in Stockholders' Equity for each of the years in the three-year period ended December 31, 2016</u></a>	F-5
<a href="#"><u>Consolidated Statements of Cash Flows for each of the years in the three-year period ended December 31, 2016</u></a>	F-6
<a href="#"><u>Notes to Consolidated Financial Statements</u></a>	F-7

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Stockholders  
Hemispherx Biopharma, Inc.

We have audited the accompanying consolidated balance sheets of Hemispherx Biopharma, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Hemispherx Biopharma, Inc. and Subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

*/s/ RSM US LLP*

Blue Bell, Pennsylvania  
March 31, 2017

**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES**  
**Consolidated Balance Sheets**  
**December 31, 2016 and 2015**  
(in thousands, except for share and per share amounts)

	2016	2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,408	\$ 2,115
Marketable securities- unrestricted	3,460	6,795
Assets held for sale	764	—
Work-In-Process inventory	—	1,326
Prepaid expenses and other current assets	309	335
Total current assets	<u>6,941</u>	<u>10,571</u>
Property and equipment, net	9,514	11,237
Patent and trademark rights, net	872	862
Other assets	1,546	134
Total assets	<u>\$ 18,873</u>	<u>\$ 22,804</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 887	\$ 1,213
Accrued expenses	1,548	1,219
Current portion of capital lease	—	1
Total current liabilities	<u>2,435</u>	<u>2,433</u>
Redeemable warrants	940	—
Commitments and contingencies (Notes 9,11,12,14 and 15)		
Stockholders' equity:		
Preferred stock, par value \$0.01 per share, authorized 5,000,000; issued and outstanding: none	—	—
Common stock, par value \$0.001 per share, authorized 350,000,000 shares; issued and outstanding 24,202,921 and 20,629,957, respectively	24	21
Additional paid-in capital	315,980	313,446
Other comprehensive loss	(5)	(97)
Accumulated deficit	<u>(300,501)</u>	<u>(292,999)</u>
Total stockholders' equity	<u>15,498</u>	<u>20,371</u>
Total liabilities and stockholders' equity	<u>\$ 18,873</u>	<u>\$ 22,804</u>

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)

	Years ended December 31,		
	2016	2015	2014
<b>Revenues:</b>			
Clinical treatment programs	\$ 92	\$ 133	\$ 197
<b>Total Revenues</b>	<u>92</u>	<u>133</u>	<u>197</u>
<b>Costs and Expenses:</b>			
Production costs	1,108	1,598	1,251
Research and development	5,107	8,038	8,988
General and administrative	7,681	7,147	9,057
<b>Total Costs and Expenses</b>	<u>13,896</u>	<u>16,783</u>	<u>19,296</u>
<b>Operating loss</b>	<u>(13,804)</u>	<u>(16,650)</u>	<u>(19,099)</u>
Interest and other income	129	364	665
Impairment loss on investments	-	(315)	(145)
Interest expense	-	(3)	(11)
Litigation settlement net insurance proceeds	1,626	-	-
Gain from sale of income tax operating losses	2,870	1,374	1,126
Redeemable warrants valuation adjustment	1,677	-	14
<b>Net loss</b>	<u>(7,502)</u>	<u>(15,230)</u>	<u>(17,450)</u>
<b>Other Comprehensive Income (Loss)</b>			
Unrealized gain (loss) on securities	35	(252)	(191)
Reclassification adjustments for realized loss on sales of short-term marketable securities and for impairment losses on investments included in net loss	57	315	145
<b>Net comprehensive loss</b>	<u>\$ (7,410)</u>	<u>\$ (15,167)</u>	<u>\$ (17,496)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.34)</u>	<u>\$ (0.77)</u>	<u>\$ (1.11)</u>
Weighted average shares outstanding basic and diluted	<u>21,818,206</u>	<u>19,679,315</u>	<u>15,690,998</u>

See accompanying notes to consolidated financial statements.

**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Changes in Stockholders' Equity**  
(in thousands except share data)

	Common Stock Shares	Common Stock .001 Par Value	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders Equity
Balance December 31, 2013	14,055,031	\$ 14	\$ 289,717	\$ (114)	\$ (260,319)	\$ 29,298
Shares issued for:						
Settlement of accounts payable	19,086	—	59	—	—	59
Shares sold at the market	2,926,285	3	12,814	—	—	12,817
Equity-based compensation	—	—	326	—	—	326
Net comprehensive loss	—	—	—	(46)	(17,450)	(17,496)
Balance December 31, 2014	17,000,402	17	302,916	(160)	(277,769)	25,004
Shares issued for:						
Settlement of accounts payable	213,232	—	672	—	—	672
Shares sold at the market	3,416,323	4	9,677	—	—	9,681
Equity-based compensation	—	—	181	—	—	181
Net comprehensive loss	—	—	—	63	(15,230)	(15,167)
Balance December 31, 2015	20,629,957	21	313,446	(97)	(292,999)	20,371
Shares issued for:						
Shares sold at the market	114,394	—	174	—	—	174
Common stock issuance	3,333,334	3	4,517	—	—	4,520
Other issuance	78,879	—	50	—	—	50
Equity-based compensation	46,357	—	410	—	—	410
Redeemable warrants	—	—	(2,617)	—	—	(2,617)
Net comprehensive loss	—	—	—	92	(7,502)	(7,410)
Balance December 31, 2016	24,202,921	\$ 24	\$ 315,980	\$ (5)	\$ (300,501)	\$ 15,498

See accompanying notes to consolidated financial statements

**HEMISPHERx BIOPHARMA, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Cash Flows**  
(in thousands)

	Years ended December 31,		
	2016	2015	2014
<b>Cash flows from operating activities:</b>			
Net loss	\$ (7,502)	\$ (15,230)	\$ (17,450)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>			
Depreciation of property and equipment	1,119	941	665
Amortization and abandonment of patent and trademark rights	184	249	477
Redeemable warrants valuation adjustment	(1,677)	—	(14)
Equity-based compensation	410	181	326
Other-than-temporary impairment of marketable securities	-	315	145
Realized gain (loss) on securities	57	63	(46)
<b>Changes in assets and liabilities:</b>			
Inventories	—	(1,326)	—
Prepaid expenses and other assets	26	64	(41)
Accounts payable	(326)	(196)	869
Accrued expenses	329	(1,114)	1,105
Net cash used in operating activities	<u>(7,380)</u>	<u>(16,053)</u>	<u>(13,964)</u>
<b>Cash flows from investing activities:</b>			
Purchases of property, equipment and construction in progress	(160)	(240)	(504)
Additions to patent and trademark rights	(294)	(250)	(258)
Sales and maturities of short-term and long-term marketable securities	3,370	6,842	3,294
Net cash provided by investing activities	<u>2,916</u>	<u>\$ 6,352</u>	<u>\$ 2,532</u>
<b>Cash flows from financing activities:</b>			
Proceeds from sale of common stock, net of issuance costs	4,744	9,681	12,817
Deposits on capital leases refunded	14	—	2
Payments on capital leases	(1)	(21)	(34)
Net cash provided by financing activities	<u>4,757</u>	<u>9,660</u>	<u>12,785</u>
Net (decrease) increase in cash and cash equivalents	293	(41)	1,353
Cash and cash equivalents at beginning of year	2,115	2,156	803
Cash and cash equivalents at end of year	<u>\$ 2,408</u>	<u>\$ 2,115</u>	<u>\$ 2,156</u>
<b>Supplemental disclosures of non-cash investing and financing cash flow information:</b>			
Issuance of common stock for accounts payable and accrued expenses	\$ -	\$ 672	\$ 59
Unrealized gain (loss) on marketable securities	\$ 92	\$ 63	\$ (46)
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest expense	\$ -	\$ 3	\$ 11

See accompanying notes to consolidated financial statements.

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

**(1) Business**

Hemispherx Biopharma, Inc. ("Company") is 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. The Company was founded in the early 1970s doing contract research for the National Institutes of Health. Since that time, the Company has 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.

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

The 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 December 31, 2016, our accumulated deficit was approximately \$300,501,000. 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. During 2016, 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 and exploring the possibility of mortgaging its facility or selling it if the Company can obtain a long term lease back on the facility on acceptable terms. 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.

The consolidated financial statements include the financial statements of Hemispherx Biopharma, Inc. and its wholly-owned subsidiaries. The Company has two domestic subsidiaries BioPro Corp. and BioAegean Corp., all of which are incorporated in Delaware and are dormant. The Company's foreign subsidiary, Hemispherx Biopharma Europe N.V./S.A., was established in Belgium in 1998. All significant intercompany balances and transactions have been eliminated in consolidation.

## (2) Summary of Significant Accounting Policies

### (a) Cash and Cash Equivalents

Cash and Cash Equivalents consist of cash and money market accounts and total \$2,408,000 and \$2,115,000 at December 31, 2016 and 2015, respectively.

### (b) Marketable Securities

The Company's securities are classified as available for sale and are stated at fair value. Unrealized gains and losses on securities available for sale are excluded from results of operations and are reported as other comprehensive income (loss) on the Statements of Comprehensive Loss, net of taxes. Securities classified as available for sale include securities that may be sold in response to changes in interest rates, changes in prepayment risks or for portfolio management purposes. The cost of securities sold is determined on a specific identification basis. Gains and losses on sales of securities are recognized in the statements of comprehensive loss on the date of sale.

### (c) Property and Equipment

	(in thousands) December 31,	
	2016	2014
Land, buildings and improvements	\$ 10,530	\$ 11,603
Furniture, fixtures, and equipment	5,630	5,490
Leasehold improvements	-	85
Total property and equipment	16,160	17,178
Less: accumulated depreciation and amortization	(6,646)	(5,941)
Property and equipment, net	<u>\$ 9,514</u>	<u>\$ 11,237</u>

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.

### (d) Patent and Trademark Rights

Patents and trademarks are stated at cost (primarily legal fees) and are amortized using the straight line method over the established useful life of 17 years. The Company reviews its patents and trademark rights periodically to determine whether they have continuing value or their value has become impaired. Such review includes an analysis of the patent and trademark's ultimate revenue and profitability potential. Management's review addresses whether each patent continues to fit into the Company's strategic business plans.

(e) Revenue

Revenue from the sale of Ampligen® under a cost recovery, open-label treatment protocols approved by the FDA is recognized when the treatment is provided to the patient.

Revenues from the sale of Alferon N Injection® are recognized when the product is shipped and title is transferred to the customer. The Company has no other obligation associated with its products once shipment has been shipped to the customer.

(f) Accounting for Income Taxes

Deferred income tax assets and liabilities are determined based on differences between the financial statement reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws in effect when the differences are expected to reverse. The measurement of deferred income tax assets is reduced, if necessary, by a valuation allowance for any tax benefits which are not expected to be realized. The effect on deferred income tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The Company applies the provisions of Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 740-10 Uncertainty in Income Taxes. There has been no material change to the Company’s tax position as they have not paid any corporate income taxes due to operating losses. All tax benefits will likely not be recognized due to the substantial net operating loss carryforwards which will most likely not be realized prior to expiration. With no tax due for the foreseeable future, the Company has determined that a policy to determine the accounting for interest or penalties related to the payment of tax is not necessary at this time.

(g) Comprehensive loss

Comprehensive loss consists of net loss, net unrealized gains (losses) on securities and is presented in the consolidated statements of comprehensive loss.

(h) Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. Accounts requiring the use of significant estimates include valuation allowances for inventory, determination of other-than-temporary impairment on securities, valuation of deferred taxes, patent and trademark valuations, stock-based compensation calculations, building valuation, fair value of warrants and contingency accruals.

(i) Recent Accounting Standards and Pronouncements

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

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

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

In February 2016, the FASB issued ASU 2016-02 - *Leases*, which amends the existing accounting standards for lease accounting, including requiring lessees to recognize most leases on their balance sheets and making targeted changes to lessor accounting. ASU 2016-02 will be effective for annual reporting periods beginning after December 15, 2018, and early adoption of is permitted as of the standard’s issuance date. ASU 2016-02 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 may not have a material impact on the Company's financial statement presentation or disclosures.

In 2016, the FASB also issued Accounting Standards Updates ("ASU") 2016-03 through 2016-20 and in 2017 the FASB issued 2017-01 through 2017-07. These updates did not have a significant impact on the financial statements.

(j) Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, "Compensation – Stock Compensation", which requires recognition of compensation expense related to stock-based compensation awards over the period during which an employee is required to provide service for the award. Compensation expense is equal to the fair value of the award at the date of grant, net of estimated forfeitures.

(k) Accounts Receivable

Concentration of credit risk, with respect to accounts receivable, is limited due to the Company's credit evaluation process. The Company does not require collateral on its receivables. The Company did not have any receivables as of December 31, 2016 and 2015.

(l) Common Stock Per Share Calculation

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 related to 4,032,851, 1,316,204 and 1,457,245 shares, are excluded from the calculation of diluted net loss per share for the years ended December 31, 2016, 2015 and 2014, respectively, since their effect is antidilutive.

(m) Long-Lived Assets

The Company assesses long-lived assets for impairment when events or changes in circumstances indicate that the carrying value of the assets or the asset grouping may not be recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant under-performance of a business or product line in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in its use of the assets. The Company measures the recoverability of assets that it will continue to use in its operations by comparing the carrying value of the asset grouping to our estimate of the related total future undiscounted net cash flows. If an asset grouping's carrying value is not recoverable through the related undiscounted cash flows, the asset grouping is considered to be impaired.

The Company measures the impairment by comparing the difference between the asset grouping's carrying value and its fair value. Long-lived assets are considered a non-financial asset and are recorded at fair value only if an impairment charge is recognized. Impairments are determined for groups of assets related to the lowest level of identifiable independent cash flows. The Company makes subjective judgments in determining the independent cash flows that can be related to specific asset groupings. In addition, as the Company reviews its manufacturing process and other manufacturing planning decisions, the Company must make subjective judgments regarding the remaining useful lives of assets. When the Company determines that the useful lives of assets are shorter than the Company had originally estimated, it accelerates the rate of depreciation over the assets' new, shorter useful lives.

**(3) 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)	
	2016	2015
Inventory Work-In-Process, January 1	\$ 1,326	\$ —
Production	—	1,443
Transfer to other assets	(1,326)	—
Spoilage	—	(117)
Inventory Work-In-Process, December 31	<u>\$ —</u>	<u>\$ 1,326</u>

Commercial sales of Alferon® will not resume until new batches of commercial filled and finished product are produced and released by the FDA. The Company is continuing the validation of Alferon® production and production of new Alferon® API inventory commenced in February 2015. While the facility is approved by the FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection. The Company will also need the FDA's approval to release commercial product once it has submitted satisfactory stability and quality release data. Due to the Company extending the timeline of Alferon® production to an excess of one year, the Company reclassified Alferon® Work-In-Process inventory to other assets within the Company's balance sheet as of December 31, 2016.

#### (4) Marketable Securities

Marketable securities consist of Mutual Funds. For the twelve months ended December 31, 2016 and 2015, it was determined that some of the Marketable Securities had other than temporary impairments of approximately \$0 and \$315,000, respectively. At December 31, 2016 and 2015, all securities were classified as available for sale investments and were measured as Level 1 instruments of the fair value measurements standard (see Note 17: Fair Value).

Securities classified as available for sale consisted of:

Securities	December 31, 2016 (in thousands)					
	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	<u>\$ 3,465</u>	<u>\$ —</u>	<u>\$ (5)</u>	<u>\$ 3,460</u>	<u>\$ 3,460</u>	<u>\$ —</u>

Securities	December 31, 2015 (in thousands)					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value	Short-Term Investments	Long Term Investments
Mutual Funds	\$ 6,892	\$ —	\$ (97)	\$ 6,795	\$ 6,795	\$ —
Totals	<u>\$ 6,892</u>	<u>\$ —</u>	<u>\$ (97)</u>	<u>\$ 6,795</u>	<u>\$ 6,795</u>	<u>\$ —</u>

#### 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:

December 31, 2016  
(in thousands)

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

December 31, 2015  
(in thousands)

Securities	Total Number In Loss Position	Less Than 12 Months		12 Months or Greater		Totals	
		Fair Values	Unrealized Losses	Fair Values	Unrealized Losses	Total Fair Value	Total Unrealized Losses
Mutual Funds	2	\$ 2,834	\$ (159)	\$ 2,041	\$ (21)	\$ 4,875	\$ (180)
Totals	2	\$ 2,834	\$ (159)	\$ 2,041	\$ (21)	\$ 4,875	\$ (180)

**(5) Patents, Trademark Rights and Other Intangibles (FASB ASC 350-30 General Intangibles Other than Goodwill)**

During the years ended December 31, 2016, 2015 and 2014, the Company decided not to pursue certain patents in various countries for strategic reasons and recorded abandonment charges of \$134,000, \$215,000 and \$446,000, respectively, which are included in research and development. Amortization expense was \$50,000, \$34,000 and \$31,000 in 2016, 2015 and 2014, respectively. The total cost of the patents was \$1,065,000 and \$1,005,000 as of December 31, 2016 and 2015, respectively. The accumulated amortization as of December 31, 2016 and 2015 is \$193,000 and \$143,000, respectively. For the year ended December 31, 2016 and 2015, additions to patents costs were \$294,000 and \$250,000, respectively.

Amortization of patents and trademarks for each of the next five years is as follows: 2017 - \$50,000; 2018 - \$50,000; 2019 - \$50,000; 2020 - \$50,000 and 2021 - \$50,000. No amortization expense is recognized related to patents that are pending.

## (6) Accrued Expenses

Accrued expenses at December 31, 2016 and 2015 consists of the following:

	(in thousands)	
	December 31,	
	2016	2015
Compensation	\$ 297	\$ 229
Professional fees	604	619
Clinical Trial expenses	158	143
Other Expenses	489	228
	<u>\$ 1,548</u>	<u>\$ 1,219</u>

## (7) 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 at December 31, 2016 and 2015.

### (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 on December 8, 2011. This amendment increased the Company's authorized shares from 200,000,000 to 350,000,000 with specific limitations and restrictions on the usage of 75,000,000 of the 150,000,000 newly authorized shares.

On September 16, 2015, the Company's stockholders removed the limitations and restrictions on 5,583,000 shares. The Company's stockholders approved up to an additional 5,000,000 shares for use in capital raising transactions and 583,000 shares for use in the Equity Plan of 2009. On August 29, 2016, the company effected a 12 to 1 reverse stock split on the outstanding shares, in order to become compliant with the NYSE regulations. This did affect the number of authorized shares.

As of December 31, 2016 and 2015, 24,202,921 and 20,629,957 shares were outstanding, respectively, which reflect the 12 to 1 reverse stock split.

### (c) Equity Financings

On July 23, 2012, the Company entered into an equity distribution agreement with Maxim (the "EDA") pursuant to which we may sell up to \$75,000,000 worth of our shares of common stock from time to time through Maxim, as sales agent. Under the EDA, Maxim is entitled to a fixed commission rate of 4.0% of the gross sales price of Shares sold under the EDA, up to aggregate gross proceeds of \$10,000,000, and thereafter, at a fixed commission rate of 3.0% of the gross sales price of Shares sold under the EDA. Sales of the Shares, if any, may be made in transactions that are deemed to be "at-the-market" offerings as defined in Rule 415 under the Securities Act of 1933, as amended, including sales made by means of ordinary brokers' transactions, including on the NYSE MKT, at market prices or as otherwise agreed with Maxim. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the EDA or terminate the EDA. Up until August 4, 2015, the shares were being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on July 2, 2012. Since August 4, 2015, the shares are being sold pursuant to the Company's Universal Shelf Registration Statement on Form S-3, declared effective by the Securities and Exchange Commission on August 4, 2015 (the "2015 Universal Shelf").

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

On August 5, 2015, the Company filed an updated Prospectus Supplement to reflect that sales under the EDA are now being conducted pursuant to the 2015 Universal Shelf. In addition, On September 16, 2015, the Company's stockholders 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.

Through December 15, 2015, the Company sold an aggregate of shares that resulted in net cash proceeds of approximately \$45,930,000 after commissions paid to Maxim for approximately \$1,524,000. On December 15, 2015, the Company filed a Prospectus Supplement reducing all offerings pursuant to its existing equity distribution agreement with Maxim Group LLC to \$0.

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

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

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

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

Pursuant to an engagement agreement dated July 26, 2016, the Company engaged Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC (“Wainwright”), to act as its exclusive placement agent in connection with the Offering. Pursuant to the engagement agreement, the Company paid Wainwright an aggregate fee equal to 7% of the gross proceeds received by the Company from the sale of the securities in the Offering and granted to Wainwright or its designees warrants to purchase up to 5% of the aggregate number of shares sold in the transactions (the “Wainwright Warrants”) amounting to 166,667 warrants. The Wainwright Warrants have substantially the same terms as the Warrants, except that the Wainwright Warrants will expire on September 1, 2021 and have an exercise price equal to \$1.875 per share of Common Stock. The Wainwright Warrants and the shares issuable upon exercise of the Wainwright Warrants will be issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act as transactions not involving a public offering and in reliance on similar exemptions under applicable state laws. The Wainwright Warrants, upon issuance, were recorded at a fair value of approximately \$164,000. The Company also paid Wainwright placement agent fees of \$70,000 plus a management fee equal to 1.0% of the gross proceeds raised in the Offering.

(d) Common Stock Options and Warrants

*(i) Stock Options*

The Equity Plan of 2004, effective May 1, 2004, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 8,000,000 shares of common stock was reserved for potential issuance pursuant to awards under the Equity Plan of 2004. The Equity Plan of 2004 continued in effect for a period of 10 years from its effective date. The plan terminated on May 1, 2014.

The Equity Incentive Plan of 2007, effective June 20, 2007, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 750,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2007. Unless sooner terminated, the Equity Incentive Plan of 2007 will continue in effect for a period of 10 years from its effective date.

The Equity Incentive Plan of 2009, effective June 24, 2009, authorizes the grant of non-qualified and incentive stock options, stock appreciation rights, restricted stock and other stock awards. A maximum of 1,250,000 shares of common stock is reserved for potential issuance pursuant to awards under the Equity Incentive Plan of 2009. In September 2015, the Company's shareholders approved the following amendments to the 2009 Plan: (1) increased the number of shares authorized to be issued under the Equity Incentive Plan from 1,250,000 to 1,833,333; (2) required a gradual vesting period of options issued under the Equity Incentive Plan over a three year period; (3) revised the definition of "change in control" to make it less "liberal" by amending the provision that a change in control occurs upon stockholder approval of a merger, consolidation or sale or disposition by the Company of all or substantially all of its assets (a "Business Combination") to state that such a change in control occurs upon the consummation of the Business Combination; and (4) clarified that the definition of change in control has a double trigger. For a Participant to get the benefit resulting from a change in control, such Participant must have been terminated other than for cause within a two-year period. Unless sooner terminated, the Equity Incentive Plan of 2009 will continue in effect for a period of 10 years from its effective date.

The Equity Plan of 2004 and the Equity Incentive Plans of 2007 and 2009 are administered by the Board of Directors. The Plans provide for awards to be made to such Officers, other key employees, non-employee Directors, consultants and advisors of the Company and its subsidiaries as the Board may select.

Stock options awarded under the Plans may be exercisable at such times (not later than 10 years after the date of grant) and at such exercise prices (not less than fair market value at the date of grant) as the Board may determine. The Board may provide for options to become immediately exercisable upon a "change in control", which is defined in the Plans to occur upon any of the following events: (a) the acquisition by any person or group, as beneficial owner, of 20% or more of the outstanding shares or the voting power of the outstanding securities of the Company; (b) either a majority of the Directors of the Company at the annual stockholders meeting has been nominated other than by or at the direction of the incumbent Directors of the Board, or the incumbent Directors cease to constitute a majority of the Company's Board; (c) the Company's stockholders approve a merger or other business combination pursuant to which the outstanding common stock of the Company no longer represents more than 50% of the combined entity after the transaction; (d) the Company's stockholders approve a plan of complete liquidation or an agreement for the sale or disposition of all or substantially all of the Company's assets; or (e) any other event or circumstance determined by the Company's Board to affect control of the Company and designated by resolution of the Board as a change in control.

The fair value of each option and equity warrant award is estimated on the date of grant using a Black-Scholes-Merton pricing option 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, life and forfeiture rates. The expected life of the options and equity warrants was estimated based on historical option and equity warrant holders' behavior and represents the period of time that options and equity warrants are expected to be outstanding. The fair values of the options and equity warrants granted, were estimated based on the following weighted average assumptions:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	0.71%-1.23%	1.32%-1.72%	1.66%-1.72%
Expected dividend yield	0	0	0
Expected life	2.5-5 years	2.5-5 years	5 years
Expected volatility	85.18%-94.81%	83.840%-85.220%	84.497%-92.631%
Weighted average grant date fair value for options and equity warrants issued	\$0.99 per option/warrant for 281,250 options/equity warrants	\$1.80 per option for 68,750 options	\$2.16 per option/warrant for 109,524 options/equity warrants

For stock options or equity warrants granted to employees and non-employees, the Company measures fair value of the equity instruments utilizing the Black-Scholes-Merton pricing method. The Company amortizes such cost over the related period of service.

The exercise price of all stock options and equity warrants granted was equal to or greater than the fair market value of the underlying common stock on the date of the grant.

Information regarding the options approved by the Board of Directors under Equity Plan of 2004 is summarized below:

	2014			2015			2016		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	540,078	15.60-72.00	\$ 32.16	488,719	15.60-72.00	\$ 32.28	388,225	15.60-72.00	\$ 34.56
Granted	—	—	—	—	—	—	—	—	—
Forfeited	(51,359)	22.80-41.28	\$ 30.96	(100,493)	19.56-34.44	\$ 23.40	(104,698)	25.32-46.32	\$ 38.08
Exercised	—	—	—	—	—	—	—	—	—
Outstanding, end of year	<u>488,719</u>	15.60-72.00	\$ 32.28	<u>388,225</u>	15.60-72.00	\$ 34.56	<u>283,527</u>	15.60-72.00	\$ 33.20
Exercisable, end of year	<u>488,719</u>	15.60-72.00	\$ 32.28	<u>388,225</u>	15.60-72.00	\$ 34.56	<u>283,527</u>	15.60-72.00	\$ 33.20
Weighted average remaining contractual life (years)	1-4 years			1-3 years			1-2 years		
Available for future grants	—			—			—		

Information regarding the options approved by the Board of Directors under Equity Plan of 2007 is summarized below:

	2014			2015			2016		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	129,167	8.64-36.60	26.04	129,167	8.64-36.60	26.04	129,167	8.64-36.60	26.04
Granted	—	—	—	—	—	—	—	—	—
Forfeited	—	—	—	—	—	—	—	—	—
Exercised	—	—	—	—	—	—	—	—	—
Outstanding, end of year	<u>129,167</u>	8.64-36.60	26.04	<u>129,167</u>	8.64-36.60	26.04	<u>129,167</u>	8.64-36.60	26.04
Exercisable, end of year	<u>129,167</u>	8.64-36.60	26.04	<u>129,167</u>	8.64-36.60	26.04	<u>129,167</u>	8.64-36.60	26.04
Weighted average remaining contractual life (years)	4-6 years			3-5 years			2-4 years		
Available for future grants	<u>250</u>			<u>250</u>			<u>250</u>		

Information regarding the options approved by the Board of Directors under Equity Plan of 2009 is summarized below:

	2014			2015			2016		
	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price	Shares	Option Price	Weighted Average Exercise Price
Outstanding, beginning of year	559,081	2.52-48.36	7.32	639,438	2.52-48.36	6.60	651,628	2.52-48.36	\$ 5.52
Granted	109,524	3.96-31.20	4.80	66,667	3.00	3.00	247,917	1.56-48.36	\$ 1.59
Forfeited	(29,167)	3.72-33.72	17.40	(54,477)	3.00-48.36	20.88	(204,483)	1.56-22.80	\$ 3.53
Exercised	—	—	—	—	—	—	—	—	—
Outstanding, end of year	<u>639,438</u>	2.52-48.36	6.60	<u>651,628</u>	2.52-48.36	5.52	<u>695,061</u>	1.56-48.36	\$ 4.70
Exercisable, end of year	<u>577,445</u>	2.52-48.36	6.60	<u>623,850</u>	2.52-48.36	5.52	<u>578,047</u>	1.56-48.36	\$ 5.32
Weighted average remaining contractual life (years)	5-10 years			4-10 years			3-10 years		
Available for future grants	<u>123,962</u>			<u>695,106</u>			<u>532,920</u>		

Stock option activity during the years ended December 31, 2014, 2015 and 2016 is as follows:

Stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2013	884,290	\$ 20.76	4.92	—
Granted	105,357	11.64	—	—
Forfeited	(48,990)	21.36	—	—
Outstanding December 31, 2014	940,657	\$ 19.68	4.61	—
Granted	66,667	3.00	—	—
Forfeited	(113,553)	15.72	—	—
Outstanding December 31, 2015	893,771	\$ 18.96	4.02	—
Granted	185,417	1.58	—	—
Forfeited	(242,932)	13.06	—	—
Outstanding December 31, 2016	836,256	\$ 16.82	4.47	—
Vested and expected to vest at December 31, 2016	836,256	\$ 16.82	\$ 4.47	—
Exercisable at December 31, 2016	745,630	\$ 17.39	3.03	—

The weighted-average grant-date fair value of employee options granted during the year 2016 was \$189,000 for 185,417 options at \$0.99 per option, during the year 2015 was \$121,000 for 66,667 options at \$1.80 per option, and during the year 2014 was \$230,000 for 105,357 options at \$2.16 per option.

Unvested stock option activity for employees:

	Number of Options	Weighted Average Exercise Price	Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2013	43,750	\$ 3.48	8.38	—
Granted	105,357	11.64	—	—
Vested	(89,891)	4.56	—	—
Forfeited	—	—	—	—
Outstanding December 31, 2014	59,216	\$ 16.56	8.76	—
Granted	66,667	3.00	—	—
Vested	(98,106)	11.04	—	—
Forfeited	—	—	—	—
Outstanding December 31, 2015	27,777	\$ 3.48	7.82	—
Granted	185,417	1.58	—	—
Vested	(122,569)	1.72	—	—
Forfeited	—	—	—	—
Outstanding December 31, 2016	90,625	\$ 1.72	9.33	—

The weighted-average grant-date fair value of employee unvested stock options granted during the year 2016 was \$92,000 for 185,417 option at \$0.50 per option, during the year 2015 was \$51,000 for 66,667 options at \$0.76 per option, and during the year 2014 was \$230,000 for 105,357 options at \$2.16 per option.

Stock option activity for non-employees during the year:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2013	344,036	\$ 17.76	5.01	—
Granted	4,167	31.20	—	—
Exercised	—	—	—	—
Forfeited	(31,536)	33.36	—	—
Outstanding December 31, 2014	316,667	\$ 16.32	4.75	—
Granted	—	—	—	—
Exercised	—	—	—	—
Forfeited	(41,417)	22.32	—	—
Outstanding December 31, 2015	275,250	\$ 15.48	4.31	—
Granted	62,500	1.64	—	—
Exercised	—	—	—	—
Forfeited	(66,250)	23.22	—	—
Outstanding December 31, 2016	271,500	\$ 10.41	4.66	—
Vested and expected to vest at December 31, 2016	271,500	\$ 10.41	4.66	—
Exercisable at December 31, 2016	244,417	\$ 11.36	4.05	—

The weighted-average grant-date fair value of non-employee options granted during the year 2016 was \$63,000 for 62,500 options at \$1.01 per option, during the year 2015 was zero, as no options were granted to non-employees in 2015, and during the year 2014 was \$5,000 for 4,167 options at \$1.20 per option.

Unvested stock option activity for non-employees:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contracted Term (Years)	Aggregate Intrinsic Value
Outstanding December 31, 2013	39,236	\$ 3.00	9.61	—
Granted	4,167	31.20	—	—
Vested	(40,625)	3.96	—	—
Forfeited	—	—	—	—
Outstanding December 31, 2014	2,778	\$ 31.20	9.08	—
Granted	—	—	—	—
Vested	(2,778)	31.20	—	—
Forfeited	—	—	—	—
Outstanding December 31, 2015	—	\$ —	—	—
Granted	62,500	1.62	—	—
Vested	(23,611)	1.63	—	—
Forfeited	(12,500)	1.56	—	—
Outstanding December 31, 2016	26,389	\$ 1.65	8.61	—

Stock-based compensation expense was approximately \$410,000, \$181,000 and \$326,000 for the year ended December 31, 2016, 2015, and 2014, respectively resulting in an increase in general and administrative expenses with no effect on earnings per share

As of December 31, 2016 and 2015, there was \$266,000 and \$199,000, respectively, of unrecognized stock-based compensation cost related to options granted under the Equity Incentive Plans. Stock-based compensation related to options granted under the Equity Incentive Plans will be recorded over the vesting period which is typically one year or upon reaching agreed upon company and/or individual performance milestones being met which is indefinite.

(ii) Stock Warrants

Stock warrants are issued as needed by the Board of Directors and have no formal plan.

The fair value of each warrant award is estimated on the date of grant using a Black-Scholes-Merton pricing option 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 warrant. The Company uses historical data to estimate expected dividend yield, life and forfeiture rates. The expected life of the warrants was estimated based on historical option holder's behavior and represents the period of time that options are expected to be outstanding. There were 2,083 warrants granted during 2015 at \$1.08 per warrant, and 2,700,000 granted in 2016 at \$1.56 to \$2.00 per warrant.

Information regarding warrants outstanding and exercisable into shares of common stock is summarized below:

	2014			2015			2016		
	Shares	Warrant Price	Weighted Average Exercise Price	Shares	Warrant Price	Weighted Average Exercise Price	Shares	Warrant Price	Weighted Average Exercise Price
Outstanding, beginning of year	1,102,354	3.00-24.00	\$ 15.12	199,922	3.00-24.00	\$ 6.72	147,183	1.08-24.00	\$ 5.73
Granted	—	—	\$ —	2,083	1.08	\$ 1.08	2,700,000	1.56-2.00	\$ 1.99
Forfeited	(902,432)	3.48-19.80	16.92	(54,822)	6.12-18.60	9.24	(16,667)	6.00	6.00
Exercised	—	—	—	—	—	—	—	—	—
Outstanding, end of year	<u>199,922</u>	<u>3.00-24.00</u>	<u>\$ 6.72</u>	<u>147,183</u>	<u>3.00-24.00</u>	<u>\$ 5.76</u>	<u>2,830,516</u>	<u>1.08-24.00</u>	<u>\$ 2.16</u>
Exercisable	<u>199,922</u>	<u>3.00-24.00</u>	<u>\$ 6.72</u>	<u>147,183</u>	<u>3.00-24.00</u>	<u>\$ 5.76</u>	<u>2,830,516</u>	<u>1.08-24.00</u>	<u>\$ 2.16</u>
Weighted average remaining contractual life	4.8 years			4.4 years			4.6 years		
Years exercisable	2014-2023			2017-2023			2017-2023		

Stock warrants are issued at the discretion of the Board. In 2016, there were 2,666,667 warrants issued in conjunction with the August 2016 offering at an average exercise price of \$1.99 per share. In 2015, there were no warrants issued. In 2016, 33,333 warrants were issued at an average exercise price of \$1.74 per share. Certain of the stock warrants outstanding are subject to adjustments for stock splits and dividends. No warrants were exercised during 2014, 2015 or 2016.

(e) Rights Offering

On November 19, 2002, the Board of Directors of the Company 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"). 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 \$30.00 per Unit, subject to adjustment. The description and terms of the Rights are set forth in a Rights Agreement (the "Rights Agreement") between the Company and Continental Stock Transfer & Trust Company, as Rights Agent.

On November 2, 2012, the Company executed an Amended and Restated Rights Agreement amending and restating the November 19, 2002 Rights Agreement between the Company and Continental Stock Transfer & Trust Company, as Rights Agent (as amended, the “Amended Rights Agreement”). The Amended Rights Agreement extends the term of the Rights Plan to November 18, 2017 and amends certain other provisions, as described in the Company’s Amended Registration Statement on Form 8-A/A, filed on November 2, 2012 (the “Amended Form 8-A”). The Amended Rights Plan entitles holders to buy one-hundredth unit of preferred stock for \$30.00 and may be redeemed prior to November 19, 2017, the expiration date, at \$0.001 per Right under certain circumstances. The Rights generally are not transferable apart from the common stock and will not be exercisable unless and until a person or group acquires or commences a tender or exchange offer to acquire, beneficial ownership of 15% or more of our common stock.

#### **(8) Segment and Related Information**

The Company operates in one segment, which performs research and development activities related to Ampligen® and other drugs under development, and sales and marketing of Alferon®. The Company’s revenues for the three-year period ended December 31, 2016, were earned in the United States.

The Company employs an insignificant amount of net property and equipment in its foreign operations.

#### **(9) Research, Consulting and Supply Agreements**

On October 2, 2011, the Company finalized their Fourth Amendment to a Supply Agreement, effective through March 11, 2014, 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. The Company is working towards an amendment to the existing Supply Agreement, which may contain additional fees as part of entering into the extension. In October 2014, the Company entered into a purchase commitment with Jubilant for approximately \$700,000 for the manufacture of clinical batches of Ampligen® and no fees were incurred for the years ended 2015 and 2016, respectively, pursuant to this agreement. On January 3, 2017, the Company entered into a purchase order to replace the previous purchase commitment with Jubilant pursuant to which Jubilant will manufacture a commercial batch of Ampligen® for the Company. Pursuant to the order, Jubilant will perform tooling and validation activities as well as final fill and finish services.

On July 27, 2016, the Company reached an agreement with Avecia to serve as an additional contract manufacturer of Hemispherx’s experimental drug, Ampligen®. The first cGMP lot was completed in December and was released in January 2017 for use in the Company’s Early Access Program (“EAP”) in Europe and Turkey to treat pancreatic cancer patients.

To formulate, fill, finish and package (“fill and finish”) Alferon N Injection® Drug Product, the Company requires a FDA approved third party Contract Manufacturing Organization (“CMO”). In January 2012, the Company 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, the Company entered into a purchase commitment with Althea for approximately \$622,000 for the production of validation batches of Alferon® N Injection for emergency use and/or commercial sale. The Company has paid approximately \$210,000 to Althea with regard to this open purchase commitment as of December 31, 2016 and has recorded this amount within Work-In-Process inventory.

On September 6, 2011, the Company executed an amended agreement with Asembia, formerly Armada Healthcare, LLC to undertake the marketing, education and sales of Alferon N Injection® throughout the United States. This agreement also provides start-up along with ongoing sales and marketing support to the Company. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. The Company previously extended this agreement for the previous three years also under the same terms and conditions. The Company incurred no fees for the years ended December 31, 2016, 2015 and 2014, pursuant to original and amended agreements. Due to the Company’s manufacturing process for Alferon® being on hold and there being no definitive timetable to have the facility back online, the Company will review its expiring agreement on August 14, 2017 with Asembia.

On September 6, 2011, the Company executed a new agreement with specialty distributor, BioRidge Pharma, LLC (“BioRidge”) to warehouse, ship, and distribute Alferon N Injection® on an exclusive basis in support of U.S. sales. On July 31, 2015, it was mutually agreed upon to extend this agreement through August 14, 2017 subject to the same terms and conditions. The Company previously extended this agreement for the previous three years also under the same terms and conditions. The Company incurred approximately fees of \$0, \$2,000 and \$21,000 for the years ended December 31, 2016, 2015 and 2014, respectively, pursuant to the agreement. Due to the Company’s manufacturing process for Alferon® being on hold and there being no definitive timetable to have the facility back online, the Company will review its expiring agreement on August 14, 2017 with BioRidge.

On March 9, 2015, the Company executed an agreement with Emerge Health Pty Ltd. (“Emerge”) to seek approval of Ampligen® for CFS in Australia and New Zealand and to commence distribution of Ampligen® in both countries on a named-patient basis, where deemed appropriate. The parties intend to collaborate on seeking regulatory approval from Australia’s Therapeutic Goods Administration (“TGA”) and New Zealand’s Medicines and Medical Devices Safety Authority (“Medsafe”). Under this five year exclusive license to sell, market, and distribute Ampligen® in Australia and New Zealand to treat CFS, Emerge will implement regulatory-compliant programs to educate physicians about Ampligen® for CFS and seek orphan drug designation and approval of Ampligen® to treat CFS. Hemispherx will support these efforts and will supply Ampligen® at a predetermined transfer price. The Company has the right to buy out of the agreement at a price equal to three times Ampligen® sales for the preceding 12 months if exercised within the first two years or two times such sales if exercised after year three. The Company has determined to maintain local expertise in handling the regulatory aspects of treating patients with an unapproved product and has elected not to pursue individual patient use in these territories and has subsequently terminated the agreement in 2017.

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

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

On May 24, 2016, the Company entered into an amended and restated five year agreement (the “Impatients Agreement”) with Impatients, N.V. (“Impatients”), a Netherlands based company doing business as myTomorrows, for the commencement and management of an Early Access Program (“EAP”) in Europe and Turkey (the “Territory”) related to CFS. Pursuant to the agreement, Impatients, 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 Impatients at a predetermined transfer price. In the event that the Company receives Marketing Authorization in any country in the Territory, the Company will pay Impatients 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 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.

The Company has entered into agreements for consulting services, which are performed at medical research institutions and by medical and clinical research individuals. The Company’s obligation to fund these agreements can be terminated after the initial funding period, which generally ranges from one to three years or on an as-needed monthly basis. During the years ending December 31, 2016, 2015 and 2014, the Company incurred approximately \$285,000, \$1,668,000 and \$1,286,000, respectively, of consulting service fees under these agreements. These costs are charged to research and development expense as incurred.

#### **(10) 401(k) Plan**

The Company has a defined contribution plan, entitled the Hemispherx Biopharma Employees 401(k) Plan and Trust Agreement (the “401(k) Plan”). Full time employees of the Company are eligible to participate in the 401(k) Plan following one year of employment. Subject to certain limitations imposed by federal tax laws, participants are eligible to contribute up to 15% of their salary (including bonuses and/or commissions) per annum. Participants’ contributions to the 401(k) Plan may be matched by the Company at a rate determined annually by the Board of Directors.

Each participant immediately vests in his or her deferred salary contributions, while Company contributions will vest over one year. A 6% Company matching contribution was established, effective as of January 1, 2010 through December 31, 2015. As of January 1, 2016, the matching has been terminated. For 2016, 2015 and 2014, the Company contributions towards the 401(k) Plan were \$0, \$167,000 and \$170,000 respectively.

### **(11) Royalties, License and Employment Agreements**

The Company had contractual agreements with Named Executive Officers (“Officers”) in 2016, 2015 and 2014. The aggregate annual base compensation for these Officers under their respective contractual agreements for 2016, 2015 and 2014 was \$983,000, \$2,259,000 and \$2,249,000 respectively. In addition, certain of these Officers were entitled to receive performance bonuses of up to 25% or 20% of their respective annual base salary, at the sole discretion of the Compensation Committee of the Board of Directors. In 2016, 2015 and 2014, Officers’ bonuses of \$0, \$0 and \$386,000 respectively were granted.

On November 23, 2015, Mr. Equels waived his rights under his employment agreement to any future payment of any incentive bonus related to the sale of the Company’s stock or other securities by, or on behalf of, the Company pursuant to the Maxim Equity Distribution Agreement or any similar or successor ATM equity distribution agreement. Mr. Equels voluntarily provided his waiver in an effort to preserve cash and to help the Company to ensure its short term commercialization goals.

In 2016, equity was granted as a form of compensation to these Officers:

- Chief Executive Officer was granted 25,000 ten year options to purchase common stock at \$1.68 per share which vest in entirety in one year; and
- Chief Financial Officer was granted 12,500 ten year options to purchase common stock at \$1.56 per share which vest in entirety in one year.
- Chief Scientific Officer was granted 12,500 ten year options to purchase common stock at \$1.56 per share which vest in entirety in one year.

In 2015, equity was granted as a form of compensation to these Officers:

- Chief Executive Officer was granted 25,000 ten year options to purchase common stock at \$3.00 per share which vest in entirety in one year.

In 2014, equity was granted as a form of compensation to these Officers:

- Chief Executive Officer was granted 25,000 ten year options to purchase common stock at \$4.32 per share which vest in entirety in one year.

The Company recorded stock compensation expense of approximately \$52,000, \$121,000 and \$223,000, respectively, during the years ended December 31, 2016, 2015 and 2014 respectively with regard to these issuances.

**(12) Leases**

The Company has a non-cancelable escalating operating lease as amended, for the space in which its principal office is located. The term of the lease for the Philadelphia, Pennsylvania offices is currently through July 1, 2018. Approximate future minimum payments under these operating lease obligations are as follows:

For The Years Ending December 31,	(In Thousands)
2017	161
2018	68
	<u>\$ 229</u>

Rent expense charged to operations for the years ended December 31, 2016, 2015 and 2014 amounted to approximately \$178,000, \$166,000 and \$163,000 respectively.

**(13) Income Taxes (FASB ASC 740 Income Taxes)**

The Company applies the provisions of FASB ASC 740-10 Uncertainty in Income Taxes. As a result of the implementation, there has been no material change to the Company's tax position as they have not paid any corporate income taxes due to operating losses. All tax benefits will likely not be recognized due to the substantial net operating loss carryforwards which will most likely not be realized prior to expiration.

As of December 31, 2014, the Company has approximately \$151,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2034) 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 \$28,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2033 and 2034) available to offset future state taxable income. In January 2015, the Company effectively sold \$14,300,000 of its New Jersey state net operating loss carryforward for the year 2013 for approximately \$1,374,000.

As of December 31, 2015, the Company has approximately \$166,000,000 of federal net operating loss carryforwards (expiring in the years 2018 through 2035) available to offset future federal taxable income. The Company also has approximately \$36,000,000 of Pennsylvania state net operating loss carryforwards (expiring in the years 2018 through 2033) and approximately \$29,000,000 of New Jersey state net operating loss carryforwards (expiring in the years 2034 and 2035) available to offset future state taxable income. In January 2016, the Company effectively sold \$16,000,000 of its New Jersey state net operating loss carryforward for the year 2014 for approximately \$1,320,000, and also sold New Jersey research and development credits for \$241,000.

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 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 a policy to determine the accounting for interest or penalties related to the payment of tax is not necessary at this time.

Under the Tax Reform Act of 1986, the utilization of a corporation's net operating loss carryforward is limited following a greater than 50% change in ownership. Due to the Company's prior and current equity transactions, the Company's net operating loss carryforwards may be subject to an annual limitation generally determined by multiplying the value of the Company on the date of the ownership change by the federal long-term tax exempt rate. Any unused annual limitation may be carried forward to future years for the balance of the net operating loss carryforward period.

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts used for income tax purposes. In assessing the realizability of deferred tax assets, Management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Due to the uncertainty of the Company's ability to realize the benefit of the deferred tax asset, the deferred tax assets are fully offset by a valuation allowance at December 31, 2016 and 2015.

The components of the net deferred tax assets and liabilities as of December 31, 2016 and 2015 consist of the following:

	(in thousands)	
	December 31,	
	2016	2015
Deferred tax assets:		
Net operating losses	\$ 59,200	\$ 56,300
Amortization & depreciation	132	88
Research and development costs	-	691
Stock compensation	139	62
Total deferred tax assets	<u>59,741</u>	<u>57,141</u>
Deferred tax liabilities:		
Research and development costs	(375)	-
Deferred tax assets, net	59,096	57,141
Less: Valuation allowance	(59,096)	(57,141)
Deferred tax assets, net	<u>—</u>	<u>—</u>

(14) Contingencies

- (a) *Mark Zicherman v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Iraj E. Kiani, William M. Mitchell, Richard C. Piani, David Strayer and Charles T. Bernhardt, U.S. District Court for Eastern District of Pennsylvania, Case No. 2:13-cv-00243-WY.*
  - (b) *Michael Desclos v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, March 2013 Term, No. 110.*
  - (c) *Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., William A. Carter, Charles T. Bernhardt, Thomas K. Equels, David R. Strayer, Richard C. Piani, William M. Mitchell, and Iraj E. Kiani, First Judicial District of Pennsylvania, Court of Common Pleas of Philadelphia, April 2013 Term, No. 3458.*
  - (d) *Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., William A. Carter, Thomas K. Equels, Richard C. Piani, William M. Mitchell, Iraj E. Kiani and Robert E Peterson, Chancery Court of the State of Delaware, June 18, 2013, Case No. 8657.*
  - (e) *Cato Capital, LLC v. Hemispherx Biopharma, Inc., U.S. District Court for the District of Delaware, Case No. 9-549-GMS.*
- (a) On January 15, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the United States District Court for the Eastern District of Pennsylvania. Purporting to assert claims on behalf of the Company, the Complaint in this action, Mark Zicherman v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On February 22, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On July 3, 2013, Plaintiff filed an Amended Complaint, adding David R. Strayer, M.D., as a Defendant. On July 18, 2013, the Court entered an order staying the case as against Dr. Strayer pending the outcome of the motion to dismiss the securities class action. On January 24, 2014, the Court denied the defendants' motion to dismiss the securities class action. On March 26, 2014, the Court entered an order to continue the temporary stay, and on March 27, 2014, the Court entered an order placing the action in the Civil Suspense File. On April 11, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On January 28, 2015, on request of the parties, the Court entered an Order continuing the temporary stay, subject to the requirement that the parties submit an updated joint status report within ten days of the court's entry of an order granting or denying the securities class action parties' motion for preliminary approval of their settlement agreement. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' Settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court entered an Order granting final approval of the parties' settlement, awarding the plaintiffs' counsel \$660,000 in attorneys' fees, and dismissing the action and all claims alleged therein against all defendants with prejudice. The Settlement resolves all claims asserted in this action ("Zicherman") and the two related consolidated state-court actions referenced below, Michael Desclos v. Hemispherx Biopharma, Inc. et al., and Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al. The Settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies.

(b) On March 4, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, Michael Desclos v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On April 10, 2013, the Court entered an order temporarily staying this case pending the outcome of the securities class action defendants' motion to dismiss that action. On January 24, 2013, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the court entered an order consolidating this action with the shareholder derivative action, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., described below. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement in principle to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court in Zicherman entered an Order granting final approval of the parties' settlement and awarding the plaintiffs' counsel \$660,000 in attorneys' fees. The Settlement, which resolves all claims asserted in this action ("Desclos") and the two related actions, Zicherman, referenced above, and the state court action referenced below, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies. On December 2, 2016, the Court in this action removed the case from deferred status, and on December 5, 2016, the prothonotary entered the plaintiffs' praecipe to mark the case settled, discontinued, and ended in its entirety, and with prejudice.

(c) On April 23, 2013, a Shareholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the First Judicial District of Pennsylvania of the Court of Common Pleas of Philadelphia. Purporting to assert claims on behalf of the Company, the Complaint in this action, Richard J. Sussman and Douglas T. Lowe v. Hemispherx Biopharma, Inc., et al., alleges violations of state law, including breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment, arising from the alleged federal securities violations asserted in the securities class action. On May 10, 2013, the Court entered an order staying this case pending the outcome of the ruling on the Federal Securities Class Action Defendants' motion to dismiss. On January 24, 2014, the court in the federal securities class action denied the defendants' motion to dismiss. On January 29, 2014, the Court entered an order consolidating this action with the shareholder derivative action, Michael Desclos v. Hemispherx Biopharma, Inc., et al., described above. On March 26, 2014, the Court entered an order to continue the temporary stay. On June 9, 2014, the Court entered a Stipulated Protective Order, which will govern all confidential documents produced in discovery. On or about January 13, 2016, the parties agreed to attempt to resolve the action through mediation. On February 11, 2016, the parties engaged in a mediation and, at that mediation, reached an agreement to settle all claims. On April 27, 2016, the parties executed a Stipulation and Agreement of Settlement ("Settlement"). On May 27, 2016, the Court in Zicherman entered an order preliminarily approving the parties' Settlement. On September 29, 2016, the Court held a final approval hearing to determine whether the parties' settlement is fair, reasonable, adequate and in the best interests of Hemispherx. On October 4, 2016, the Court in Zicherman entered an Order granting final approval of the parties' settlement and awarding the plaintiffs' counsel \$660,000 in attorneys' fees. The Settlement, which resolves all claims asserted in this action and the two related actions, Zicherman and Desclos, referenced above, does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants. No Company funds were used to pay attorneys' fees award, which was funded by Hemispherx's insurance companies. On December 2, 2016, the Court in this action removed the case from deferred status, and on December 8, 2016, the prothonotary entered the plaintiffs' praecipe to mark the case settled, discontinued, and ended in its entirety, and with prejudice.

- (d) On June 18, 2013, a Stockholder Derivative Complaint was filed against the Company, as nominal defendant, and certain of its current and former Officers and Directors in the Court of Chancery of the State of Delaware. The Complaint in this action, Rena A. Kastis and James E. Conroy v. Hemispherx Biopharma, Inc., et al., alleges breaches of fiduciary duties, waste of corporate assets and unjust enrichment. The Company's Board of Directors appointed a Special Litigation Committee ("SLC") to review the allegations set forth in the Complaint. On September 10, 2013, the Court entered a Stipulation and Order staying all proceedings in this action pending the SLC's review and recommendation concerning the allegations contained in the Complaint. On December 20, 2013, the SLC issued its Report, in which it concluded that dismissing the Complaint would be in the best interests of Hemispherx and its stockholders. On January 20, 2014, the SLC moved to dismiss the Complaint. Following briefing and oral argument on the motion to dismiss, the Court denied the SLC's motion on August 18, 2015, but did dismiss the claims against former officer Robert E. Peterson. On October 13, 2015, Plaintiffs filed a Verified Amended Derivative and Class Action Complaint (the "Amended Complaint"), asserting additional claims for breach of fiduciary duty against Board member Peter W. Rodino, declaratory judgment with respect to certain bonuses paid to officers of the Company, and a class action claim for breach of fiduciary duty against the current Board in connection with the solicitation of votes in advance of the Company's 2015 annual meeting. The Amended Complaint also removed all of the dismissed claims against Mr. Peterson. The Company and all individual defendants except former Board member Richard C. Piani answered the Amended Complaint on November 19, 2015. The Court entered a scheduling order on December 2, 2015, but on January 5, 2016, the parties agreed to suspend all litigation for 60 days and to attempt to resolve the action through mediation. The parties engaged in a mediation on February 10, 2016, and reached an agreement in principle to settle all claims on April 27, 2016. That agreement was memorialized in a Stipulation and Agreement of Settlement (the "Settlement Stipulation") which was filed with the Court on June 8, 2016. The settlement was subject to the Court's finally approving the terms of the parties' settlement agreement in all material respects. On June 8, 2016, concurrent with the filing of the Settlement Stipulation, the parties filed a joint proposed scheduling order, which the Court entered the same day (the "Scheduling Order"). The Scheduling Order preliminarily certified the class for settlement purposes, directed the Company to issue notice (in the form approved by the Court) to Company stockholders and members of the putative class, and scheduled a settlement approval hearing (the "Settlement Approval Hearing") to occur on September 9, 2016. At the Settlement Approval Hearing on September 9 and September 19, 2016, the Court approved the settlement, awarded plaintiffs' counsel \$1.25 million in attorneys' fees and expenses, and dismissed the action with prejudice. No stockholders or members of the putative class objected to the settlement. No Company funds were used to pay the settlement or attorneys' fees award; the settlement and fee award were funded by Hemispherx's insurance policies. The final settlement does not constitute any admission of fault or wrongdoing by Hemispherx or any of the individual defendants.
- (e) Cato Capital, LLC ("Cato") brought suit against the Company on July 31, 2009, in the United States District Court for the District of Delaware (the "Court"), alleging that under a November 2008 agreement between Cato and Hemispherx, Hemispherx owed Cato a placement fee arising from subsequent Hemispherx financing and investment transactions. Hemispherx disputed these allegations, asserting that Cato failed to comply with the provisions of its own contract. The Amended Complaint sought damages in the amount of \$9,830,000.00 plus attorneys' fees and punitive damages. Pursuant to an indemnification responsibility, Hemispherx has also retained this firm to undertake the defense of the Sage Group.

The Parties had a Non-Jury trial on March 4, 5 and 6, 2013 before the United States District Court for the District of Delaware. On September 29, 2014, the Court found in favor of Hemispherx and Sage on all counts, and dismissed Cato's claims in their entirety. On January 13, 2015, the Court granted the Company's motion for attorney's fees and costs and awarded the Company \$770,852.76.

On October 24, 2014, Cato filed a notice of appeal of the Court's September 29, 2014 decision in the United States Court of Appeals for the Third Circuit (the "Third Circuit"). On March 3, 2015, Cato filed its Brief in the Third Circuit. The Company's Brief in Response was filed on April 6, 2015, with a Reply Brief by Cato filed on April 19, 2015. The Court of Appeals conducted Oral Argument on July 16, 2015. On August 21, 2015 the Court of Appeals affirmed the judgment of the District Court. On September 9, 2015 Cato sought reconsideration of the decision through re-argument or re-hearing by the en banc Court of Appeals. On September 17, 2015 the Court of Appeals denied Cato's requests. On October 1, 2015 Hemispherx filed for additional costs and fees to be added to its existing judgment. On February 10, 2016 the Court increased Hemispherx' judgment by an additional \$48,725.75 to reflect the costs of defending the Cato appeal. On February 11, 2016 the Court of Appeals returned the mandate to the District Court. The Company is pursuing collection of its judgment in the amount of \$829,578.51

### **(15) Certain Relationships and Related Transactions**

The Company has employment agreements with certain of their Executive Officers and has granted such officers and directors options and warrants to purchase their common stock. Please see details of these Employment Agreements in Note 11 - Royalties, License and Employment Agreements.

Thomas Equels our CEO, was elected to the Board of Directors at the Annual Stockholders Meeting on November 17, 2008 and joined the Company as General Counsel effective June 1, 2010. Mr. Equels had provided external legal services for several years through May 31, 2010 and Equels Law Firm continued to support the Company through 2015. In 2016, 2015 and 2014, the Company paid Equels Law Firm approximately \$0, \$42,000 and \$303,000, respectively, for services rendered. Upon analysis in the Fall of 2011 by the Audit Committee's Financial Expert, it was deemed that the hourly rates charged by Equels Law to the Company were reasonable when compared to the fee structure of a possible arms-length transaction from comparable firms in practice in the same market and of the similar size. The hourly rate fees from Equels Law Firm remained the same for 2014 and 2015. There were no legal fees paid in 2016 to Equels Law Firm. For his Board fees, Mr. Equels received approximately \$20,000, \$182,000 and \$182,000 for 2016, 2015 and 2014, respectively. Mr. Equels stopped receiving Board fees in March 2016.

For the years ended 2016, 2015 and 2014, compensation was granted or paid related to the Executive Performance Incentive Program related to the ATM, as set forth in Section 3(c)(ii) of his Employment Agreement, for approximately \$0, \$262,000, and \$641,000 to Mr. Equels. Mr. Equels' compensation related to this program was classified entirely as general and administrative expense. Mr. Equels has agreed not to receive any compensation in relation to current or future ATM sales.

In 2016 Mr. Equels also earned, as set forth in Section 3(c)(ii) of his Employment Agreement, \$39,000 for 5% of the Ampligen® cost recovery sales for the last 5 years, and \$131,000 in accordance with item 5 of the 2016 Senior Executive Deferred Cash Performance Award Plan, as the price of our stock has been above \$.20 for 5 successive trading days.

## (16) Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, cash equivalents, investments and accounts receivable. The Company places its cash with high-quality financial institutions and, at times, such amounts in non-interest bearing accounts may be in excess of Federal Deposit Insurance Corporation insurance limits. There was no credit based sales for 2016, 2015 or 2014.

## (17) Fair Value

The Company is required under GAAP to disclose information about the fair value of all the Company's financial instruments, whether or not these instruments are measured at fair value on the Company's consolidated balance sheets.

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

The Company recomputes the fair value of the Warrants at the issuance date and the end of each quarterly reporting period. Such value computation includes subjective input assumptions that are consistently applied each period. If the Company were to alter its assumptions or the numbers input based on such assumptions, the resulting fair value could be materially different.

The Company utilized the following assumptions to estimate the fair value of the August 2016 warrants:

	December 31, 2016	September 6, 2016
Underlying price per share	\$0.69 to \$1.26	\$ 1.39
Exercise price per share	\$1.88 - \$2.00	\$1.88 - \$2.00
Risk-free interest rate	1.86%	1.21%
Expected holding period	4.70	5.00
Expected volatility	85%	90%
Expected dividend yield	-	-

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

- (i) *Risk-Free Interest Rate.* The risk-free interest rates for the Warrants are based on U.S. Treasury constant maturities for periods commensurate with the remaining expected holding periods of the warrants.
- (ii) *Expected Holding Period.* The expected holding period represents the period of time that the Warrants are expected to be outstanding until they are exercised. The Company utilizes the remaining contractual term of the Warrants at each valuation date as the expected holding period.
- (iii) *Expected Volatility.* Expected stock volatility is based on daily observations of the Company's historical stock values for a period commensurate with the remaining expected holding period on the last day of the period for which the computation is made.
- (iv) *Expected Dividend Yield.* Expected dividend yield is based on the Company's anticipated dividend payments over the remaining expected holding period. As the Company has never issued dividends, the expected dividend yield is \$-0- and this assumption will be continued in future calculations unless the Company changes its dividend policy.
- (v) *Expected Probability of a Fundamental Transaction.* The possibility of the occurrence of a Fundamental Transaction triggering a Put right is extremely remote. As discussed above, a Put right would only arise if a Fundamental Transaction 1) is an all cash transaction; (2) results in the Company going private; or (3) is a transaction involving a person or entity not traded on a national securities exchange. The Company believes such an occurrence is highly unlikely because:
  - a. The Company only has one product that is FDA approved but which will not be available for commercial sales for at least approximately 18 months;
  - b. The Company may have to perform additional clinical trials for FDA approval of its flagship product;
  - c. Industry and market conditions continue to include a global market recession, adding risk to any transaction;
  - d. Available capital for a potential buyer in a cash transaction continues to be limited;
  - e. The nature of a life sciences company is heavily dependent on future funding and high fixed costs, including Research & Development;
  - f. The Company has minimal revenues streams which are insufficient to meet the funding needs for the cost of operations or construction at their manufacturing facility; and
  - g. The Company's Rights Agreement and Executive Agreements make it less attractive to a potential buyer.

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

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

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

- (vi) *Expected Timing of Announcement of a Fundamental Transaction.* As the Company has no specific expectation of a Fundamental Transaction, for reasons elucidated above, the Company utilized a discrete uniform probability distribution over the Expected Holding Period to model in the potential announcement of a Fundamental Transaction occurring during the Expected Holding Period.
- (vii) *Expected 100 Day Volatility at Announcement of a Fundamental Transaction.* An estimate of future volatility is necessary as there is no mechanism for directly measuring future stock price movements. Daily observations of the Company's historical stock values for the 100 days immediately prior to the Warrants' grant dates, with a floor of 100%, were utilized as a proxy for the future volatility.
- (viii) *Expected Risk-Free Interest Rate at Announcement of a Fundamental Transaction.* The Company utilized a risk-free interest rate corresponding to the forward U.S. Treasury rate for the period equal to the time between the date forecast for the public announcement of a Fundamental Transaction and the Warrant expiration date for each simulation.
- (ix) *Expected Time Between Announcement and Consummation of a Fundamental Transaction.* The expected time between the announcement and the consummation of a Fundamental Transaction is based on the Company's experience with the due diligence process performed by acquirers, and is estimated to be six months. The Monte Carlo Simulation approach incorporates this additional period to reflect the delay Warrant Holders would experience in receiving the proceeds of the Put.

While the assumptions remain consistent from period to period (e.g., utilizing historical stock prices), the numbers input change from period to period (e.g., the actual historical prices input for the relevant period). The carrying amount and estimated fair value of the above warrants was approximately \$940,000 at December 31, 2016 and \$2,617,000 at September 6, 2016, the date of issuance.

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

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

- Level 1 – Quoted prices are available in active markets for identical assets or liabilities at the reporting date. Generally, this includes debt and equity securities that are traded in an active market.
- Level 2 – Observable inputs other than Level 1 prices such as quote prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities. Generally, this includes debt and equity securities that are not traded in an active market.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or other valuation techniques, as well as instruments for which the determination of fair value requires significant management judgment or estimation. As of September 30, 2016, the Company has classified the warrants with cash settlement features as Level 3. Management evaluates a variety of inputs and then estimates fair value based on those inputs. As discussed above, the Company utilized the Monte Carlo Simulation Model in valuing these warrants.

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

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

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

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

	(in thousands)		
	2016	2015	2014
Balance at December 31, 2015	\$ -	\$ -	\$ 14
Issuance of warrants	2,617	-	(14)
Fair value adjustments	(1,677)	-	-
Balance at December 31, 2016	\$ 940	\$ -	\$ -

**(18) Subsequent Events**

The Company evaluated subsequent events through the date on which these financial statements were issued.

The Company entered into definitive agreements with several institutional investors for an offering of shares of common stock with net proceeds of approximately \$850,000 in a registered direct offering. In connection with the offering, the Company issued registered shares of common stock at a purchase price of \$0.55 per share. Concurrently in a private placement, for each share of common stock purchased by an investor, such investor received from the Company an unregistered warrant to purchase 0.75 of a share of common stock. 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. The Company also issued placement agent warrants for the purchase of an aggregate of 90,909 shares of our common stock. Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC, acted as the exclusive placement agent in connection with this offering.

The Company intends to use the net proceeds from the offering for preparation for technology transfer opportunities, expenses related to Ampligen® manufacturing and for other working capital and general corporate purposes.

**Subsidiaries**

<b>US Subsidiaries:</b>	<b>Status</b>
BioPro Corp.	Dormant
BioAegean Corp.	Dormant
Foreign Subsidiaries:	
Hemispherx Biopharma Europe N.V./S.A. (Belgium)	

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**Consent of Independent Registered Public Accounting Firm**

Hemispherx Biopharma, Inc.  
Philadelphia, Pennsylvania

We consent to the incorporation by reference in Registration Statements (No. 333-160499, 333-57134, 118903, 333-155528 and 333-209060) on Form S-8 and Registration Statements (No. 333-182216, 333-152727, 333-126804, 333-130008, 333-159856, 333-151696 and 333-205228) on Form S-3 of Hemispherx Biopharma, Inc. and Subsidiaries of our report dated March 31, 2017 relating to our audit of the consolidated financial statements which appears in this Annual Report on Form 10-K of Hemispherx Biopharma, Inc. for the year ended December 31, 2016.

*/s/ RSM US LLP*

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RSM US LLP  
Blue Bell, Pennsylvania  
March 31, 2017

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**CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

I, Thomas K. Equels certify that:

1. I have reviewed this annual report on Form 10-K of Hemispherx Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2017

/s/ Thomas K. Equels  
Thomas K. Equels, Esq.  
Chief Executive Officer

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**CERTIFICATIONS PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002**

I, Adam Pascale, certify that:

1. I have reviewed this annual report on Form 10-K of Hemispherx Biopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: March 31, 2017

/s/ Adam Pascale  
Adam Pascale  
Chief Financial Officer

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**CERTIFICATION PURSUANT TO**  
**18 U.S.C. SECTION 1350,**  
**AS ADOPTED PURSUANT TO**  
**SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Hemispherx Biopharma, Inc. (the "Company") on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas K. Equels, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 31, 2017

/s/ Thomas K. Equels  
Thomas K. Equels, Esq.  
Chief Executive Officer

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