HEMISPHERX BIOPHARMA INC
Form 10-K
April 01, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2018

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)

2117 SW Highway 484, Ocala FL	34473
(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 [X]

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 [X]

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 [X] No **[ ]**

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes [X] 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. [X]

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:

[ ]	Large accelerated filer	[ ]	Accelerated filer
[ ]	Non-accelerated filer	[X]	Smaller reporting company
		[ ]	Emerging growth company

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

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

The aggregate market value of Common Stock held by non-affiliates at June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter was $14,981,748.

The number of shares of the registrant's Common Stock outstanding as of March 22, 2019 was 62,290,318.

DOCUMENTS INCORPORATED BY REFERENCE: None.

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PART I

ITEM 1. Business

GENERAL

Hemispherx Biopharma, Inc. and its subsidiaries (collectively, "Hemispherx", "Company", "we" or "us") are an immuno-pharma company headquartered in Ocala, Florida and focused on the research and development of therapeutics to treat multiple types of cancers, as well as immune-deficiency disorders. We have established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of nucleic acids and natural interferon to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain cancers and chronic diseases.

Hemispherx's flagship products include Ampligen® (Rintatolimod), a first-in-class drug of large macromolecular RNA (ribonucleic acid) molecules, and Alferon N Injection® (Interferon Alfa-N3). A first-in-class drug also known as a new chemical entity, is a drug that contains an active moiety that has not been approved by the FDA or marketed in the US.

Ampligen® represents an RNA being developed for globally important cancers, viral diseases and disorders of the immune system. Ampligen® has in the clinic demonstrated the potential for standalone efficacy in a number of solid tumors. We have also seen success in increasing survival rates and efficacy in the treatment of animal tumors when Ampligen® is used in combination with checkpoint blockade therapies. This success in the field of immuno-oncology has guided our focus toward the potential use of Ampligen® as a combinational therapy for the treatment of a variety of solid tumor types. There are currently multiple Ampligen® clinical trials — both underway and planned — at major cancer research centers around the country. Ampligen ® is also being used as a monotherapy to treat pancreatic cancer patients in an Early Access Program (EAP) approved by the Inspectorate of Healthcare in the Netherlands at Erasmus Medical Center.

Ampligen® is also being evaluated for the treatment of myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Hemispherx is currently sponsoring an expanded access program (EAP) for ME/CFS patients in the U.S. In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT) for commercial sale of Ampligen® in the Argentine Republic for the treatment of severe CFS. With regulatory approval in Argentina, Ampligen® is the world's only approved therapeutic for ME/CFS. We continue to pursue our Ampligen New Drug Application, or NDA, for the treatment of CFS with the Food and Drug Administration, or FDA. Please see "Research And Development ("R&D"); Myalgic Encephalomyelitis/Chronic Fatigue Syndrome ("ME/CFS")" below.

Alferon N Injection® is approved for a category of STD infection and patients that are intolerant to recombinant interferon in Argentina. Alferon is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional treatment of refractory (resistant to other treatment) or recurring external Condylomata Acuminata/genital warts (GW) in patients 18 years of age or older. Certain types of human papilloma viruses cause GW. Hemispherx also has approval from ANMAT for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon in Argentina. We have developed and, with proper funding, will be seeking FDA Pre-Approval Inspection of a high-volume, high-efficiency, upgraded manufacturing process to allow for the commercial viability of Alferon®.

We operate a 30,000 sq. ft. facility in New Brunswick, NJ with the objective of producing Ampligen® and Alferon®. 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 Ampligen® and our FDA-approved drug Alferon® N.

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 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.

OUR PRODUCTS

Our primary pharmaceutical product platform consists of Ampligen®, first-in-class drug of large macromolecular double-stranded (ds) RNA (ribonucleic acid) molecules and our FDA approved natural alpha-interferon product, Alferon N Injection®.

Ampligen®

Ampligen® is approved for sale in Argentina for severe Chronic Fatigue Syndrome (CFS) and is an experimental drug in the United States currently undergoing clinical development for the treatment of certain cancers and ME/CFS. Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA and European Medicines Agency ("EMA")), 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) dsRNA 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 designed to act at the molecular level for treatment of many human diseases. There are two forms of nucleic acids, deoxyribonucleic acid ("DNA") and ribonucleic acid ("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 and is a selective TLR3 agonist that is administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I):poly(C_{12}U).

EAP/clinical trials of Ampligen® that have been conducted or that are ongoing include studies of the potential treatment of patients with renal cell carcinoma, malignant melanoma, non-small cell lung, ovarian, breast, colorectal, urothelial, prostate and pancreatic cancer, CFS, Hepatitis B and HIV.

We have received approval of our NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. Commercialization in Argentina will require, among other things, GP

Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch.

The FDA has authorized an open-label expanded access treatment protocol, ("AMP-511"), allowing patient access to Ampligen® 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 clinical sites provide safety information regarding the use of Ampligen® in patients with CFS. We are establishing an enlarged data base of clinical safety information which we believe will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment. We believe that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support our future filings for Ampligen® and/or the design of future clinical studies that the FDA requested in a complete response letter. The FDA recently approved the increase reimbursement level from $200 to $345 per 200mg vial of Ampligen, due to increased production costs. At this time, we do not plan on passing this adjustment along the patients in this program. As of December 31, 2018, there are 15 patients being treated in this open-label expanded access treatment protocol.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, 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, as amended, myTomorrows also will manage all Early Access Programs and Special Access Programs in Europe, Canada and Turkey to treat pancreatic cancer and ME/CFS patients.

In April 2018, we completed data analysis of an intranasal human safety study of Ampligen® plus FluMist® known as AMP-600. The study was previously closed after the US Centers for Disease Control and Prevention ("CDC") recommended against the use of FluMist®. Intranasal Ampligen® in combination with FluMist® was generally well-tolerated in the study.

In June 2018, Ampligen® was cited as outperforming two other TLR3 agonists, poly IC and natural double stranded RNA, in creating an enhanced tumor microenvironment for checkpoint blockage therapy in the journal of Cancer Research (http://cancerres.aacrjournals.org/content/early/2018/05/31/0008-5472.CAN-17-3985). In a head-to-head study in explant culture models, Ampligen® activated the TLR3 pathway and promoted an accumulation of killer T cells but, unlike the other two TLR3 agonists, it did so without causing regulatory T cell (Treg) attraction. These findings were considered important because they indicate that Ampligen® selectively reprograms the tumor microenvironment by inducing the beneficial aspects of tumor inflammation (attracting killer T cells), without amplifying immune suppressive elements such as regulatory T cells. The study was conducted at the University of Pittsburgh and Roswell Park Comprehensive Cancer Center, as a part of the NIH-funded P01 CA132714 and Ovarian Cancer Specialized Program of Research Excellence (SPORE). Based upon these findings Hemispherx and Roswell Park Comprehensive Cancer Center expanded their existing scientific collaboration to advance the clinical development of Ampligen® which has shown promise in preclinical studies when combined with checkpoint inhibitors (CPIs). The parties executed a Memorandum of Understanding ("MOU") designed to further assess the clinical potential of Ampligen® in treating certain cancers. This phase I/II study will evaluate the potential of Ampligen® to enhance the immune mediated effects of CPIs in patients with advanced solid tumors including bladder, melanoma and renal cell carcinoma.

In 2018, we also reported that we completed production of two commercial-size batches of more than 16,000 vials of Ampligen®, following its "Fill & Finish" at the Contract Manufacturing Organization. These lots passed all required testing for regulatory release for human use and are being used for multiple programs including the product launch in Argentina, for the treatment of ME/CFS, the pancreatic cancer EAP in the Netherlands, ongoing and future clinical studies in oncology, and our ME/CFS EAP in the U.S. and Europe.

Alferon N Injection®

Alferon N Injection® is the registered trademark for our injectable formulation of natural alpha interferon. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. and Argentina 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. Alferon® is also approved in Argentina for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferons. Certain types of human papilloma viruses ("HPV") cause genital warts, a sexually transmitted disease ("STD"). According to the CDC, HPV is the most common sexually transmitted infection, with approximately 79 million Americans — most in their late teens and early 20s — infected with HPV. In fact, the CDC states that "HPV is so common that nearly all sexually active men and women get the virus 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 of treatment, 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®.

PATENTS AND NON-PATENT EXCLUSIVITY RIGHTS

As of December 31, 2018, we had 57 patents worldwide with 6 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.

In 2016, we received a new Ampligen® composition of matter patent in the US (#9,315,538). In 2015, we were granted a new composition of matter patent (#2340307) by the European Patent Office and we received twenty-eight new patents in various EU countries. In 2014, we were granted a new composition of matter patent in the United States (#8722874) covering Ampligen® formulations.

The Ampligen® U.S. CFS treatment patent (#6130206) expired October 10, 2017 (we believe that the expiration of this patent will have minimal impact on us; see details on U.S. #9315538, U.S. #8722874 and information on the FDA has granted “orphan drug status” to the drug for CFS below). Our U.S. Ampligen® Trademark (#73617687) has been renewed through December 6, 2028. New therapeutic use patent applications are pending. On May 13, 2014, the United States Patent Office issued patent U.S. #8722874 titled “Double-Stranded Ribonucleic Acids with Rugged Physiochemical Structure and Highly Specific Biologic Activity,” with all rights assigned to 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. Patents #9315538 and #8722874 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 #9315538, with all rights assigned to 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 #7943147 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.

With respect to Alferon®, the composition is 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 that not having patent protection 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.

RESEARCH AND DEVELOPMENT ("R&D")

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

Cancer

We have been working with the University of Pittsburgh's chemokine modulation research initiative which includes the use of Ampligen® as a potential adjuvant to modify the tumor microenvironment (TME) with the goal of increasing anti-tumor responses to check point inhibitors (CPI). As part of this collaboration, Hemispherx has supplied Ampligen® (rintatolimod) to the University. The study, under the leadership of Robert P. Edwards, MD, chair of gynecologic services at Magee-Women's Hospital of the University of Pittsburgh School of Medicine, and Professor of Surgery Pawel Kalinski, M.D., Ph.D., at Roswell Park Comprehensive Cancer Center, Buffalo, N.Y., involved the chemokine modulatory regimen developed by Dr. Kalinski's group and successfully completed the Phase 1 dose escalation in patients with resectable colorectal cancer. In the 1st quarter of 2017, Dr. Kalinski relocated to Roswell Park Comprehensive Cancer Center ("RPCCC") in Buffalo, NY and has established a cancer program which will continue to require a supply of Ampligen®.

In October 2018, we signed a clinical trial agreement with Roswell Park Comprehensive Cancer Center to evaluate Ampligen® in combination with checkpoint inhibitors (CPIs). The Phase IIa clinical trial will evaluate the immune-mediated effects of cytokine modulation in combination with CPIs in patients with primary resistance to CPI therapy. The protocol will seek to evaluate the combination of Ampligen® and CPIs in patients with advanced urothelial carcinoma, renal cell carcinoma and melanoma. Ampligen® is our investigational immune-enhancing TLR3 agonist that has demonstrated a robust anti-cancer effect in preclinical models when combined with CPIs. This new agreement expands the extensive prior clinical and preclinical work into the clinical checkpoint blockade arena and offers the opportunity to begin evaluation of this combination therapy in patients with a variety of solid tumors where large numbers of patients do not respond or progress following treatment with standard CPI-based therapy.

Currently, four Ampligen® clinical trials are underway at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint inhibitors:

Recurrent Ovarian Cancer - Phase 1 / 2 study of intraperitoneal chemo-immunotherapy in recurrent ovarian cancer at University of Pittsburgh Medical Center. Dr. R. Edwards, PI. Study underway. An interim report from Dr. Edwards' team is expected within thirty days and a summary of same will be disclosed upon receipt. See: https://clinicaltrials.gov/ct2/show/NCT02432378

Colorectal Cancer - Phase 2a study of Ampligen as component of chemokine modulatory regimen on colorectal cancer metastatic to liver at Roswell Park Comprehensive Cancer Center. Dr. P. Boland, PI. Study underway. See: https://clinicaltrials.gov/ct2/show/NCT03403634

Metastatic Triple Negative Breast Cancer - Open label study of metastatic triple-negative breast cancer using chemokine modulation therapy, including Ampligen and pembrolizumab, at Roswell Park Comprehensive Cancer Center. Dr. M. Opyrchal, PI. Initiation of study is expected in the near future and will be announced forthwith. See: https://www.clinicaltrials.gov/ct2/show/NCT03599453

Recurrent Ovarian Cancer – This is a Phase 2 investigator-sponsored trial being conducted in advanced recurrent ovarian cancer at the University of Pittsburgh Medical Center that will evaluate Ampligen in combination with pembrolizumab. Patient enrollment has been initiated in this study designed for 45 subjects. Dr. Robert Edwards, world renowned expert in ovarian cancer is the lead investigator. For more important details see: https://clinicaltrials.gov/ct2/show/NCT03734692

In addition, five Ampligen clinical trials are planned for initiation in 2019, subject to funding:

Phase 2 study that will evaluate Ampligen in combination with pembrolizumab in refractory metastatic colorectal carcinoma at Roswell Park Comprehensive Cancer Center. Dr. P. Boland, PI. Study design and budget being developed.

Phase 2 study of advanced urothelial (bladder), melanoma and renal cell carcinoma, resistant to checkpoint blockade, that will evaluate Ampligen in combination with a checkpoint blockade therapy at Roswell Park Comprehensive Cancer Center. Dr. M. Opyrchal, PI. Protocol design currently being finalized. Hemispherx Biopharma signed a clinical trial agreement with Roswell Park Comprehensive Cancer Center to study Ampligen in combination with checkpoint inhibitors in a phase 2a study in urothelial carcinoma, renal cell carcinoma and melanoma. This Phase 2a study will be led by Mateusz Opyrchal, MD, PhD, Assistant Professor of Medicine and Associate Director of the Early Phase Clinical Trial Program at Roswell Park, in collaboration with Dr. Kalinski.

First-line therapy for non-small cell lung cancer with SOC chemotherapy that will evaluate Ampligen in combination with pembrolizumab at University of Nebraska Medical Center. Dr. V. Ernani, PI. Study design and budget being developed.

Phase 2 study in advanced pancreatic cancer using checkpoint blockade plus Ampligen at University of Nebraska Medical Center. Dr. K. Klute, PI. Protocol and budget being developed. Based upon success in the initial animal studies, an additional round of more extensive and comprehensive pre-clinical animal pancreatic cancer studies are being conducted at University of Nebraska to reconfirm results, test additional PC tumor types, examine anti-PD-1 in addition to the prior anti-PD-L1 analysis, then fine tune the focus of the proposed future pancreatic cancer clinical trial and reduce the chances of error in clinical trial design. This information will also be used to formulate proposed future combination therapy clinical activity in the Kingdom of the Netherlands.

Phase 2 study of neoadjuvant conditioning of prostate cancer using Ampligen as a component of chemokine modulation at Roswell Park Comprehensive Cancer Center. Dr. G. Chatta, PI. This protocol is under review by the FDA.

In January 2017, the EAP through our agreement with myTomorrows designed to enable access of Ampligen® to ME/CFS patients had been extended to pancreatic cancer patients beginning in the Netherlands. myTomorrows is our exclusive service provider in Europe and Turkey and will manage all EAP activities relating to the pancreatic cancer extension of the program. In February 2018, the agreement with myTomorrows was extended to cover Canada to treat pancreatic cancer patients, pending government approval.

As of December 31, 2018, 40 pancreatic cancer patients have received treatment with Ampligen® immuno-oncology therapy under the EAP program at Erasmus University in the Netherlands.

Supervised by Prof. Casper van Eijck, MD, a world-renowned specialist in this dread malignancy, and Diba Latifi, MD, the team at Erasmus is making progress. As disclosed recently, the Dutch government has approved and extended the therapeutic program for an additional year. Early progress was reported in a published abstract from Erasmus, and a copy of the abstract can be found at http://ir.hemispherx.net/Events_Presentations. The abstract was part of a larger original report covering a variety of medical topics, which can be found at https://www.pancreasclub.com/wp-content/uploads/2018/06/Poster-Abstracts.pdf.

As of today, we are pleased to report that four out of 24 patients with either locally advanced or metastatic disease have survived for more than one year on the Ampligen protocol without additional therapy. Another four patients have survived for more than one year since the start of the Ampligen protocol with palliative chemotherapy. However, in this group of patients 15 died within seven months since start of Ampligen. Of the five resected patients two died on Ampligen, 24 and 27 months after resection. The other three patients are still alive with a mean survival of 26 months after resection and adjuvant Ampligen treatment.

All patients reported improvement in quality of life during treatment. We expect within 60 days a more comprehensive update from the Erasmus team on the immunological response in relation to survival. Hemispherx hopes to work with Dr. Van Eijck, Dr. Latifi, and Erasmus M.C. to initiate a combination therapy program to extend the results seen thus far in the Netherlands by combining Ampligen with checkpoint blockade therapy.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (“ME/CFS”)

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (“ME/CFS”), also known as Chronic Fatigue Immune Dysfunction Syndrome (“CFIDS”) and Chronic Fatigue Syndrome (“CFS”), is a serious and debilitating chronic illness and a major public health problem. ME/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 https://www.cdc.gov/me-cfs/ that “*Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a serious, long-term illness that affects many body systems. People with ME/CFS are often not able to do their usual*

activities. At times, ME/CFS may confine them to bed. People with ME/CFS have severe fatigue and sleep problems. ME/CFS may get worse after people with the illness try to do as much as they want or need to do. This symptom is known as post-exertional malaise (PEM). Other symptoms can include problems with thinking and concentrating, pain, and dizziness."

Many severe ME/CFS patients become completely disabled or totally bedridden and are afflicted with severe pain and mental confusion even at rest. ME/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.

In October 2016, an analysis of a subset of CFS patients from the AMP-516 Phase 3 study was performed and presented at the IACFS/ME annual meeting in Fort Lauderdale, FL. The ITT Population (n=208) was separated into two subsets based primarily on baseline CFS symptom duration (2-8 years (n=75) and <2 years plus >8 years (n=133)). Responder analyses of the ITT Population and both subsets were performed. Responder analyses of rintatolimod vs. placebo patients improving ET duration from baseline by ≥25% shows over twice the % of patients with clinical enhancement in ET effect in the rintatolimod cohort compared to placebo for the 2-8 year subset vs. the ITT population. This subset may assist in the design of future clinical studies of Ampligen® in the treatment for ME/CFS patients.

Other Diseases

In Europe, the EMA has approved the Orphan Medicinal Products Designation for rintatolimod (Ampligen®) as a potential treatment of Ebola virus disease and for Alferon® N Injection, also known as interferon alfa-n3, as a potential treatment of MERS.

We concluded our series of collaborations designed to determine the potential effectiveness of Ampligen® and Alferon® N as potential preventative and/or therapeutic treatments for Ebola related disorders. Although we believe that the threat of both MERS and Ebola globally may reemerge in the future, it appears that the spread of these disorders has somewhat diminished. As a result, we have elected to focus our research and development efforts on other areas at this time.

MANUFACTURING

In January 2017, Hemispherx approved a quote and provided a purchase order commitment with Jubilant Hollister-Stier LLC (“Jubilant”) pursuant to which Jubilant will manufacture commercial size batches of Ampligen®. Additional orders will be placed upon approved quotes and purchase orders provided by Hemispherx to Jubilant. Jubilant was approved by the FDA as a manufacture of Ampligen by the successful completion of a previous preapproval inspection by the agency. The National Administration of Drugs, Food and Medical Devices (A.N.M.A.T) in Argentina has approved Ampligen for commercial distribution for the treatment of Chronic Fatigue Syndrome (CFS). Shipment of the drug product to Argentina was initiated in 2018 to complete the release testing by A.N.M.A.T. needed for commercial distribution.

Since the commencement of the 2017 commitment between Jubilant and Hemispherx, two lots of Ampligen consisting of more than 16,000 units have been manufactured and released. The first lot was designated for human use in the US in the cost recovery CFS program and for expanded oncology clinical trials. The second lot has been designated for these programs in addition to commercial distribution in Argentina for the treatment of CFS. Additional lots of Ampligen are being planned for manufacture at Jubilant. The production of additional polymer (Ampligen intermediates) at our New Brunswick facility is required to produce the additional lots of Ampligen. Polymer manufacture is on schedule to provide the intermediates needed for the Ampligen manufacture planned at Jubilant

Alferon® is approved by the FDA for commercial sales in the US for the treatment of genital warts. It is also approved by A.N.M.A.T in Argentina for commercial sales for the treatment of genital warts and in patients refractory to treatment with recombinant interferons. While the Hemispherx facility in New Brunswick is approved by the FDA under the Biologic License Application (BLA) for Alferon®, this status will need to be reaffirmed by an FDA pre-approval inspection which will not occur until new batches of commercial filled and finished product are

produced and released by the FDA. Currently, the manufacturing process is on hold and there is no definitive timetable to have the facility back online until additional funding is obtained.

Licensing/Collaborations/Joint Ventures

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

MARKETING/DISTRIBUTION

In May 2016, we entered into a five-year exclusive Renewed Sales, Marketing, Distribution and Supply Agreement (the “Agreement”) with GP Pharm. Under this Agreement, GP Pharm was responsible for gaining regulatory approval in Argentina for Ampligen® to treat severe 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.

In January 2017, the ANMAT granted a five-year extension to a previous approval to sell and distribute Alferon N Injection® (under the brand name “Naturaferon”) in Argentina. This extends the approval until 2022. In February 2013, we received the ANMAT approval for the treatment of refractory patients that failed or were intolerant to treatment with recombinant interferon, with Naturaferon® in Argentina.

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

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

In February 2018, we signed an amendment to the EAP with myTomorrows. This amendment extended the territory to cover Canada to treat pancreatic cancer patients, pending government approval.

In March 2018, we signed an amendment to the EAP with myTomorrows, pursuant to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen® for the treatment of ME/CFS.

In August 2017, we extended our agreement with Asembia, formerly Armada Healthcare, LLC, to undertake the marketing, education and sales of Alferon N Injection® throughout the United States.

COMPETITION

The major pharmaceutical competitors for Ampligen 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.

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 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 intralesional 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 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, with adequate funding, it will again be able to obtain FDA approval.

For more information about the current status of Alferon N Injection® and Ampligen® please see “Our Products” above.

HUMAN RESOURCES

As of February 1, 2019, we had personnel consisting of 31 full-time employees and two part-time employees. Seventeen of the combined personnel are engaged in our research, development, clinical, and manufacturing effort with 16 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.

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. Please see “Special Note Regarding Forward Looking Statements” below.

Risks Associated with Our General Business

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

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.

We will require additional financing which may not be available.

The development of our products requires the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. As of December 31, 2018, we had approximately $1,825,000 in cash, cash equivalents and marketable securities (inclusive of approximately $1,526,000 in Marketable Securities). However, if we are unable to commercialize and sell Ampligen® and/or recommence material sales of Alferon N Injection®, our operations, financial position and liquidity may be adversely impacted.

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 FDA approval of Ampligen® along with the manufacturing, marketing and distribution of our products, including Alferon N Injection®. Due to the high cost estimates to bring the facility back online, we will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. We also will need additional capital to eventually commercialize and sell Ampligen® and/or recommence and increase sales of Alferon N Injection® or our other products. We anticipate considering multiple options in an attempt to secure funding, including but not limited to such methods as the sales of additional equity, licensing agreements, partnering with other organizations, debt financing or other sources of capital. If we are unable to obtain additional funding, through an Equity Distribution Agreement (“EDA”) or other sales of securities and/or otherwise, our ability to develop our products, commercially produce inventory or continue our operations may be materially adversely affected.

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

As of December 31, 2018, our accumulated deficit was approximately $318,573,000. As with many biotechnology companies 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.

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 AdministracionNacional de Medicamentos, Alimentos y TecnologiaMedica ("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.

While we received approval of our Argentinian NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe ME/CFS, 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 would be able to commence commercial sales in Argentina.

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. The FDA issued a Complete Response Letter ("CRL") in February 2013 for this NDA and provided recommendations to address certain outstanding issues before they could approve Ampligen for

Commercial Sales. 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. The FDA indicated that we needed to conduct additional work. Therefore, ultimate FDA approval, if any, may be delayed indefinitely 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.

If we are unable to gain necessary FDA approvals related to Ampligen® and Alferon® on a timely basis, or 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 operations most likely will be materially and/or adversely affected.

Generally, 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.

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® and Alferon N Injection®, 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.

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, and flammable solvents. 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. However, we have obtained insurance coverage to mitigate any potential significant loss in this area.

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.

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.

Risks Associated with Our Products

In addition to the risks disclosed above, the development of Ampligen® 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.

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.

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.

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®. Although Alferon N Injection® is approved for marketing in the United States for 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.

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, provided recommendations to address certain outstanding issues before they could approve Ampligen for Commercial Sales. The Agency stated that the submitted 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.

Risks Associated with Our Intellectual Property

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 once we have had a successful FDA Pre Approval Inspection. 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 1 – “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 processes 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.

Risks Associated with Our R&D

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, 2018, we had approximately $1,825,000 in Cash, Cash Equivalents and Marketable Securities, (inclusive of approximately $1,526,000 in Marketable Securities). Please see “*We will require additional financing which may not be available*” above.

Risks Associated with Our Manufacturing

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.

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.

If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon® inventory, our operations most likely will be materially and/or adversely affected. For more information on Alferon N Injection® regarding potential commercial sales, please see PART I, Item 1 - "Business; Manufacturing".

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®. In January 2017, we approved a quote and provided a purchase order with Jubilant Hollister-Stier LLC ("Jubilant") pursuant to which Jubilant manufactured batches of Ampligen® for us. We anticipate that additional orders will be placed upon approved quotes and purchase orders provided by Hemispherx to Jubilant. If we are unable to place adequate acceptable purchase orders with Jubilant in the future at acceptable prices upon acceptable terms, we will need to find another manufacturer. If we need to find another contract manufacturer to produce Ampligen, it would create a significant delay and expense to get the manufacturer up and running. The costs and availability of products and materials we would 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.

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.

Currently, the Alferon manufacturing process is on hold until additional funding is attained; there is no definitive timetable to have the facility back online. If we are unable to gain the necessary funding and 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 I, Item 1 - “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 2017, we approved a quote and provided a purchase order with Jubilant Hollister-Stier LLC (“Jubilant”) pursuant to which Jubilant manufactured batches of Ampligen® for us. We anticipate that additional orders will be placed upon approved quotes and purchase orders provided by Hemispherx to Jubilant. If we are unable to place adequate acceptable purchase orders with Jubilant in the future at acceptable prices upon acceptable terms our business would be materially and adversely affected. Please see the prior risk factor.

Should there be an unanticipated delay in receiving new product or should we experience an unexpected demand for Ampligen®, 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 1 - “Business; Our Products; Manufacturing” above.

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.

Ampligen® has been produced to date in limited quantities for use in our clinical trials and Early Access Programs. 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.

Risks Associated with Our Licensing/Collaborations/Joint Ventures

If we are unable to achieve licensing, collaboration and/or joint ventures, our marketing strategy for Ampligen will be part of the differing health care systems around the world along with the different marketing and distribution systems that are used to supply pharmaceutical products to those systems.

We have received approval of our NDA from ANMAT for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. Commercialization in Argentina will require, among other things, GP Pharm to establish disease awareness, medical education, creation of an appropriate reimbursement level, design of marketing strategies and completion of manufacturing preparations for launch.

Risks Associated with Our Marketing and Distribution

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®, 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 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.

Risks Associated with Our Competition

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 Food and Drug Administration (FDA), The Health Protection Branch of the Canada Department of National Health and Welfare (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 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®), Perrigo Company (Imiquimod Cream - Generic Equivalent to 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.

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.

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 American 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 American. For the year ended December 31, 2018, the trading price of our common stock has ranged from $0.18 to $0.65 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 completed a rights offering to our stockholders and certain option and warrant holders in March 2019, pursuant to which we issued Preferred stock convertible into an aggregate of 26,560,000 shares of common stock and warrants exercisable for up to an additional 26,560,000 shares of common stock. All of these shares of common stock have been registered for public sale. In addition, 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. Since December 5, 2017, we have sold an aggregate of 2,970,273 shares under our under our equity distribution agreements with Maxim Group LLC. In September 2016, we sold 3,333,334 shares of our common stock and issued warrants to purchase 2,500,000 shares of common stock. The warrants were exercised in June and July 2017. In February 2017 we sold 1,818,185 shares of our common stock and issued warrants. In February 2017, these warrants were exchanged for warrants to purchase an aggregate of 5,300,000 shares of common stock at an exercise price of $0.45 per share, most exercisable commencing December 1, 2017. We have registered the shares issuable upon exercise of these warrants for public sale and, should the market price of our common stock exceed the exercise price of these warrants, some or all of these warrants may be exercised. There were 2,800,000 warrants with an expiration date of March 1, 2018 and an exercise price on $0.45. These warrants were exercised in January and February 2018. We realized proceeds of $1,260,000 from these exercises.

We are unable to estimate the amount, timing or nature of future sales of outstanding common stock or instruments convertible into or exercisable for our common stock. Sales of substantial amounts of our common stock in the public market, including additional sale of securities pursuant to our equity distribution agreements with Maxim Group LLC or otherwise under the universal shelf registration statement or upon exercise of outstanding options and warrants, could cause the market price for our common stock to decrease. Furthermore, a decline in the price of our common stock would likely impede our ability to raise capital through the issuance of additional shares of common stock or other equity securities. Please see Item 7- “Management’s Discussion and Analysis of Financial Condition and Result of Operations; Liquidity and Capital Resources” in PART II.

The trading price of our common stock has decreased significantly and, as a result, the NYSE American has informed us that we are not in compliance with the standards for continued listing on the NYSE American. If we are unable to raise the trading price, the market for our common stock most likely will be adversely affected.

The price per share of our common stock has closed at or below $0.20 since February 26, 2019 and most recently closed on March 26, 2019 at $0.16, with a 30 day average of $0.19. On March 26, 2016, we received written notice

from the NYSE American LLC (the "NYSE American") that we are not in compliance with the continued listing standards set forth in Section 1003(f)(v) of the NYSE American Company Guide because our common stock has been selling for a low price per share for a substantial period of time. The NYSE American has determined that the continued listing of our common stock is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time. We have until September 26, 2019 to demonstrate compliance. Please see PART II, Item 9B – "Other Information" for a discussion of our plans to regain compliance. No assurance can be given that our plans will prove successful.

If we are unable to sufficiently raise the trading price of our common stock, we risk delisting on the NYSE American. Should our stock be so delisted, stockholders' ability to sell their shares in the open market most likely will be adversely affected even if the shares are then quoted for trading on an interdealer quotation system such as the OTCBB or OTC Markets.

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. On November 14, 2017, at the direction of the Board, we amended and restated the Rights Agreement between the Company and, American Stock Transfer & Trust Company, LLC, its current Rights Agent. Pursuant to the original Rights Agreement, our Board of Directors declared a dividend distribution of one Right for each outstanding share of Common Stock to stockholders of record at the close of business on November 29, 2002. Each Right 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 at a Purchase Price of $21.00 per Unit, subject to adjustment.

Special Note Regarding Forward Looking Statements

Certain statements in this Report contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. These statements are based on our management's current beliefs, expectations and assumptions about future events, conditions and results and on information currently available to us. Discussions containing these forward-looking statements may be found, among other places, in this "Risk Factors" section; Item 1. "Business", Part I; Item 3. "Legal Proceedings" and Part II; Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations".

All statements, other than statements of historical fact, included or incorporated herein regarding our strategy, future operations, financial position, future revenues, projected costs, plans, prospects and objectives are forward-looking statements. Words such as "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," "think," "may," "could," "wi "should," "continue," "potential," "likely," "opportunity" and similar expressions or variations of such words are intended to identify forward-looking statements but are not the exclusive means of identifying forward-looking statements.

Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: our ability to adequately fund our projects as we will need additional funding to proceed with our objectives, the potential therapeutic effect of our products, the possibility of obtaining regulatory approval, our ability to find senior co-development partners with the capital and expertise needed to commercialize our products and to enter into arrangements with them on commercially reasonable terms, our ability to manufacture and sell any products, our ability to enter into arrangements with third party vendors, market acceptance of our products, our ability to earn a profit from sales or licenses of any drugs, our ability to discover new drugs in the future, changing market conditions, changes in laws and regulations affecting our industry, and issues related to our New Brunswick, New Jersey facility. In February 2013, we received a Complete Response Letter from the Food and Drug Administration, or FDA, for our Ampligen New Drug Application, or 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. 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.

In August 2016, we received approval of our NDA from Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica, or ANMAT, for commercial sale of rintatolimod (U.S. tradename: Ampligen®) in the Argentine Republic for the treatment of severe CFS. The product will be marketed by GP Pharm, our commercial partner in Latin America. We believe, but cannot assure, that this approval provides a platform for potential sales in certain countries within the European Union under regulations that support cross-border pharmaceutical sales of licensed

drugs. In Europe, approval in a country with a stringent regulatory process in place, such as Argentina, should add further validation for the product as the Early Access Program, or EAP, as discussed below and underway in Europe in pancreatic cancer. ANMAT approval is only an initial, but important, step in the overall successful commercialization of our product. There are a number of actions that must occur before we could be able to commence commercial sales in Argentina. Commercialization in Argentina will require, among other things, an appropriate reimbursement level, appropriate marketing strategies, completion of manufacturing preparations for launch. Approval of rintatolimod for severe CFS in the Argentine Republic does not in any way suggest that the Ampligen NDA in the United States or any comparable application filed in the European Union or elsewhere will obtain commercial approval.

In May 2016, we entered into a five-year agreement with myTomorrows, a Netherlands based company, for the commencement and management of an EAP in Europe and Turkey related to CFS. Pursuant to the agreement, myTomorrows, as our exclusive service provider and distributor in this territory, is performing EAP activities. In January 2017, the EAP was extended to pancreatic cancer patients beginning in the Netherlands. In February 2018, we signed an amendment to extend the territory to cover Canada to treat pancreatic cancer patients, pending government approval. In March 2018, we signed an amendment to which myTomorrows will be our exclusive service provider for special access activities in Canada for the supply of Ampligen for the treatment of CFS. No assurance can be given that we can sufficiently supply product should we experience an unexpected demand for Ampligen in our clinical studies, the commercial launch in Argentina or pursuant to the EAPs. No assurance can be given that Ampligen will prove effective in the treatment of pancreatic cancer.

Currently, two Ampligen clinical trials are underway with a number of subjects enrolled at university cancer centers testing whether tumor microenvironments can be reprogrammed to increase the effectiveness of cancer immunotherapy, including checkpoint blockade. One is at Roswell Park Comprehensive Cancer Center and the other is at the University of Pittsburgh Medical Center. Two additional studies have been approved for enrollment and subjects are being screened for enrollment recruited at Roswell Park Comprehensive Cancer Center and the University of Pittsburgh Medical Center using Ampligen in conjunction with pembrolizumab. No assurance can be given as to the results of these underway trials. Four additional cancer trials in collaboration with University Medical/Cancer Research Centers using Ampligen plus checkpoint blockade are in various pre-enrollment stages. No assurance can be given as to whether some or all of the planned additional oncology clinical trials will occur and they are subject to many factors including lack of regulatory approval(s), lack of study drug, or a change in priorities at the sponsoring Universities or Cancer Centers. Even if these additional clinical trials are initiated, we cannot assure that these clinical studies or the two studies underway will be successful or yield any useful data.

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

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

The production of new Alferon Active Pharmaceutical Ingredient, or API, inventory will begin once the validation phase is complete. While the facility has already been approved by the FDA under the Biological License Application, or BLA, for Alferon, this status will need to be reaffirmed by a successful Pre-Approval Inspection by the FDA prior to commercial sale of newly produced inventory product. If and when the Company obtains a reaffirmation of FDA BLA status and has begun production of new Alferon API, it will need FDA approval as to the quality and stability of the final product before commercial sales can resume. We will need additional funds to finance the revalidation process in our facility to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection. If we are unable to gain the necessary FDA approvals related to the manufacturing process and/or final product of new Alferon inventory, our operations most likely will be materially and/or adversely affected. In light of these contingencies, there can be no assurances that the approved Alferon N Injection product will be returned to production on a timely basis, if at all, or that if and when it is again made commercially available, it will return to prior sales levels. In addition, we are currently readying the New Brunswick facility to start manufacturing polymers

used for the production of Ampligen to satisfy our future needs. While we anticipate that we will be able to commence manufacturing polymers at the New Brunswick facility, we may need additional funding to continue manufacturing. There cannot be any guarantee that we will obtain adequate funds to sustain manufacturing at the New Brunswick facility or that the facility will be able to manufacture sufficient lots for the commercial launch of Ampligen.

We believe, and are investigating, Ampligen's potential role in enhancing the activity of influenza vaccines. While certain studies involving rodents, non-human primates (monkeys) and healthy human subjects indicate that Ampligen may enhance the activity of influenza vaccines by conferring increased cross-reactivity or cross-protection, further studies will be required and no assurance can be given that Ampligen will assist in the development of a universal vaccine for influenza or other viruses.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

This Report also refer to estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

ITEM 1B. Unresolved Staff Comments.

None.

ITEM 2. Properties.

Our principal executive office is located at 2117 SW Highway 484, Ocala FL 34473 and our finance and human resource office is located at 600 Main Street, Suite 2, Riverton, NJ 08077. We currently lease our principal executive office for $3,329 per month and our accounting and human resource office for about $1,100 per month.

In May 2017, we entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by our assets and property located at 783 Jersey Ave., New Brunswick, New Jersey. As of March 16, 2018, this note was paid off in full. See Note 14 - Note Payable below for a more complete description of the terms of the note payable.

On March 16, 2018, we sold our property located at 783 Jersey Ave., New Brunswick, NJ. This property houses our development and production facilities. The purchase price was $4,080,000 and purchaser received 3,225,806 warrants to purchase common stock. We believe that the sale and lease-back of this building will not have a material impact on our business operations. Simultaneously with the closing of the sale, the purchaser leased the facility back to us. The lease runs for 10 years, with two five year extensions. The initial annual base rent is $408,000 and will continue for the first and second year. In the third and fourth it will escalate at the rate of 2.5% per year. For all subsequent years it will escalate at the rate of 3% per year. We also will be responsible for additional rent consisting of taxes and certain insurance expenses of the purchaser. The lease contains a repurchase option pursuant to which we can repurchase the facility within the initial 10 year lease period. The purchase price would be based on a multiple of the sale price of $4,080,000. The multiple would be 1.05 plus .0025N where N represents the number of months between lease commencement and closing of repurchase.

In February 2018, the Company sold the unencumbered, unutilized, and wholly owned property located at 5 Jules Lane, New Brunswick, New Jersey to Acellories, NJ LLC, a New Jersey limited liability company, pursuant to a sale agreement dated September, 11, 2017. The sale price was $1,050,000.

ITEM 3. Legal Proceedings.

Hemispherx commenced an action against BioLife in December of 2017 for Breach of Contract. The amount of damages we are seeking in this matter are yet to be determined. Damages are not covered by insurance. BioLife, the

defendant, has filed its Answer, Affirmative Defenses and a Counterclaim in the amount of $96,676.39 representing the Invoices withheld after BioLife indicated that they were not intending to fulfill the balance of the contract. Hemispherx has denied the allegations of the counterclaim. We recently attempted mediation and were, to date, unable to resolve the matter. A discovery schedule has been issued by the Court and we are now in the initial stages of discovery. Although it cannot be determined, we believe there is little chance for an unfavorable outcome in this matter.

Hemispherx recently engaged in mediation with its insurance carrier Travelers over a Business Interruption Loss due to a flood in our New Brunswick manufacturing facility in January of 2016. The carrier to date has covered us for repairs to the facility but there still remains the unresolved issue of the amount of the claim for our Business Interruption Loss for which we have coverage under the policy. The Business Interruption Loss damages sustained after calculations by an independent Forensic Accountant (which was paid for by Travelers under the policy) exceed $4.5 million, which is the limit allowed under the policy. We have to date been unable to settle through mediation. Therefore, Hemispherx filed and served a complaint in Philadelphia Court of Common Pleas against Travelers at the end of March 2019 seeking the policy limits and additional damages.

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.

Our common stock is listed and traded on the NYSE American under the symbol HEB.

As of March 21, 2019, there were approximately 166 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.

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.

ITEM 6. Selected Financial Data.

Not Applicable.

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 two years ended December 31, 2018. This information should be read in conjunction with our consolidated financial statements and related notes thereto beginning on F-1 of this Form 10-K. Please also see "Special Note Regarding Forward Looking Statements" in ITEM 1A. Risk Factors.

Fair Value

We have issued warrants (the "Warrants") in August 2016, February 2017, June 2017, August 2017, and August 2018 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.

On September 28, 2018, We entered into a $3,170,000 10% Secured Convertible Promissory Note (the “Note”) with Iliad Research and Trading, L.P. (the “Holder”), which was issued to the Holder in conjunction with 500,000 shares of Common Stock (the “Origination Shares”). We collected $3,000,000 in cash from the Holder during September 2018 and the remainder $170,000 was retained by the Holder for the Holder’s legal fees of $20,000 for the issuance of the Note and the Original Issue Discount of $150,000. We incurred $210,000 in third-party fees directly attributed to the issuance of the Note.

We determined the Note should be recorded at fair value with subsequent changes in fair value recorded in earnings. This conclusion is based on the redemption conversion feature, which allows the Holder to trigger the redemption of the Note for cash or conversion of the Note for common shares prior to its maturity date at a price of the lesser of $0.30 per share or the Market Price as defined within the Note. The choice of cash redemption or conversion of the Note for common shares is at our option. This feature may require that we issue a variable number of common shares to settle the Note which was determined to have a predominantly fixed monetary value at inception. In connection with the Note, we recorded a loss in the Company’s Consolidated Statements of Comprehensive Income (Loss) equal to $582,000 for the year ended December 31, 2018.

On March 13, 2019, the Convertible Note was extended from September 28, 2019 to September 28, 2020. In addition, the conversion and redemption rates were revised to a rate to be mutually agreed to us and the Lender. See note 20-Subsequent Events.

RESULTS OF OPERATIONS

Year ended December 31, 2018 versus year ended December 31, 2017

Our net loss was approximately $9,813,000 and $8,259,000 for the years ended December 31, 2018 and 2017, respectively, representing an increase in loss of approximately $1,554,000 or 19% when compared to the same period

in 2017. This increase in loss for the year ended December 31, 2018 was primarily due to the following:

1) a decrease in revenues of $70,000 or 16%;

2) an increase in interest and finance costs of $363,000;

3) the quarterly revaluation of certain redeemable warrants resulted in a non-cash gain of $1,165,000 in the year ended December 31, 2018 compared to a gain of $2,417,000 in the year ended December 31, 2017, a decrease of $1,252,000;

4) the fair value adjustment for the convertible note resulted in a loss of $582,000 in the year ended December 31, 2018, which did not occur in 2017;

5) an increase in research and development expense of $680,000 or 17%; offset by

6) a decrease in production costs of $299,000;

7) a decrease in general and administrative expenses of $371,000

8) a gain resulting from a settlement of litigation with a vendor of $474,000;

9) a gain from the sale of the underutilized building in New Brunswick of $223,000; and

10) a decrease in legal fees due to a favorable settlement of legal fees of $342,000.

Net loss per share was $(0.22) and $(0.29) for the years ended December 31, 2018 and 2017, respectively. The weighted average number of shares of our common stock outstanding as of December 31, 2018 was 44,189,217 as compared to 28,676,076 as of December 31, 2017.

Revenues

Revenues from our Ampligen® Cost Recovery Program were $367,000 and $437,000 for the years ended December 31, 2018 and 2017, respectively. The decrease in revenues of $70,000, a decrease of 16%, between periods was primarily due to the unavailability of Ampligen for our EAP through our agreement with MyTomorrows designed to enable access of Ampligen to pancreatic cancer patients in the Netherlands.

For the years ended December 31, 2018 and 2017, we had no Alferon N Injection® Finished Good product to commercially sell and all revenue was generated from the EAP and our FDA approved open-label treatment protocol, ("AMP 511"), that allows patient access to Ampligen® for treatment in an open-label safety study.

Production Costs

Production costs were approximately $884,000 and $1,183,000, respectively, for the years ended December 31, 2018 and 2017, representing a decrease of $299,000 in production costs in the current period. These costs primarily represent stability testing and pre-production expenses related to Alferon®. The reduction in costs was due to a write-off of $210,000 for expired Alferon fill and finish costs in the prior year and a decrease in other Alferon production costs of $89,000.

Research and Development Costs

Overall Research and Development ("R&D") costs for the year ended December 31, 2018 were approximately $4,778,000 as compared to $4,098,000 for the same period a year ago, reflecting an increase of approximately $680,000 or 17%. The primary reason for the increase in research and development costs was due to an increase of $653,000 for the completion of the manufacture of 8,484 vials and 7,907 vials in June and September 2018, respectively, an increase of $776,000 for the production of polymers offset by a reduction of U.S. clinical costs of $677,000 as a result of reduction in amounts due to clinical investigators resulting from renegotiated terms with the investigators.

General and Administrative Expenses

General and Administrative ("G&A") expenses for the years ended December 31, 2018 and 2017, were approximately $6,201,000 and $6,572,000, respectively, reflecting a decrease of approximately $371,000 or 6%. The decrease in G&A expenses during the current period was mainly due to a favorable settlement of legal fees of $342,000.

Interest Expense and Finance Costs

Interest and finance costs for the year ended December 31, 2018 was $502,000 compared to $139,000 in the prior year, an increase of $363,000 or 261%. The increase is mainly due to a note/mortgage payable incurred in May 2017 which was paid off in March 2018 with the resulting write off of the balance of the unamortized mortgage settlement costs in addition to the interest expense on the mortgage; plus the interest settlement costs on the Finance Obligation from the sale leaseback of the main New Brunswick building and finance costs and interest related to the convertible note from September 2018. None of these were incurred in the years ended December 31, 2017.

Interest and Other Income

Interest and other income for the years ended December 31, 2018 and 2017 was approximately $46,000 and $88,000, respectively, representing a decrease of approximately $42,000 or 48%.The primary cause for the decrease in investment income during the current period was primarily due to lower balances available to invest in the current period as compared to the prior period.

Redeemable Warrants

The quarterly revaluation of certain redeemable warrants resulted in a non-cash adjustment to the redeemable warrants liability for the year ended December 31, 2018 amounted to a gain of approximately $1,165,000, compared to a gain of $2,417,000 for the year ended December 31, 2017, which represents a decrease of $1,252,000 or 52% (see "Financial Statements: Note 18: Fair Value" for the various factors considered in the valuation of redeemable warrants).

Sale of New Jersey Tax Net Operating Loss

In December 2017, the Company effectively sold $8,000,000 New Jersey state net operating loss for approximately $622,000 and sold research credits for $169,000. In December 2018, the Company effectively sold $10,000,000 New Jersey state net operating loss for approximately $859,000. The money was received in January 2019.

Convertible Note Payable

The quarterly valuation of the convertible note payable resulted in a non-cash loss of $582,000 in 2018 which did not occur in 2017.

Other Transactions

During the year ended December 31, 2018 there was a gain of $474,000 resulting from the settlement of litigation with Nitto Avecia Pharma Services, Inc. (“NAPS”).

There was also a gain of $223,000 resulting from the sale of the second building in New Brunswick, New Jersey.

Liquidity and Capital Resources

In 2018, we sold an under-utilized warehouse at 5 Jules Lane for $1,050,000 and we sold our manufacturing facility for $4,080,000 while simultaneously entering into a favorable long term lease with an option to repurchase the facility. In 2018, we also realized $1,260,000 through the exercising of outstanding warrants.

In March 2019, we completed a rights offering to our stockholders and certain option and warrant holders, pursuant to which we issued Preferred stock convertible into an aggregate of 26,560,000 shares of common stock and warrants exercisable for up to an additional 26,560,000 shares of common stock. We netted approximately $4.69 million from the sale of securities in the rights offering.

In December 2017, we reactivated the Equity Distribution Agreement ("EDA") and, through strategic management, have raised $1,039,000. On March 24, 2018, we sold common stock netting us an additional $475,000. On April 24, 2018 we sold common stock netting us an additional $2,344,000.

Cash used in operating activities for the year ended December 31, 2018 was approximately $10,640,000 compared to approximately $7,941,000 for the same period in 2017, an increase of $2,699,000 or 34%.The primary reasons for this increase in cash used in operations in 2018 was the receipt of $791,000 in funds in 2017 from the sale of our New Jersey state net operating loss carryforwards. In 2018, we did not receive the funds from the sale of our New Jersey net operating loss carryforwards until January 2019. In 2018, we also expended about $1,500,000 toward the manufacturing of additional polymers for Ampligen for commercial launch in Argentina in May or June on 2019.

Cash provided by investing activities for the year ended December 31, 2018 was approximately $92,000 compared to cash provided by investing activities of approximately $2,730,000 for the same period in 2017, representing a decrease of $2,638,000. The primary reason for the decrease was the sale of marketable securities of approximately $831,000 during the current period compared to $2,799,000 the year ended December 31, 2017.

Cash provided by financing activities for the year ended December 31, 2018 was approximately $9,435,000 compared to approximately $4,215,000 for the same period in 2017, an increase of $5,220,000. The primary reasons for this increase was that we received net proceeds of $3,377,000 from the sale leaseback of our manufacturing facility and $5,070,000 in 2018 from the sale of shares compared to $2,417,000 from the sale of shares in 2017.

As of December 31, 2018, we had approximately $1,825,000 in cash, cash equivalents and marketable securities, inclusive of approximately $1,526,000 in Marketable Securities, representing a decrease of approximately $282,000 from December 31, 2017.

If we are unable to commercialize and sell Ampligen and/or recommence material sales of Alferon N Injection, our operations, financial position and liquidity may be adversely impacted, and additional financing may be required. In this regard, due to the high cost estimates to bring the facility back online, we will need additional funds to finance the revalidation process in our facility and to initiate commercial manufacturing, thereby readying ourselves for an FDA Pre-Approval Inspection and to commercialize our products. However, there is no assurance that such financing will be available.

In an effort to conserve cash, effective with the semi-monthly period ended April 30, 2017, all of the members of the Company's Board of Directors agreed to accept 100% of their directors' fees in the form of options to purchase Company Common Stock. This program was terminated as of August 31, 2017. As of September 1, 2017, the directors agreed to defer 100% of their fees until cash is available. On February 13, 2018, 226,023 options were issued to each of the two independent directors with an exercise price of $0.37 for a period of 10 years with a vesting period of 3 years. In addition, commencing with the semi-monthly period ended June 15, 2017, certain officers of the Company, and certain other employees of the Company, agreed to accept 20% of their salary in options to purchase Company Common Stock. This program was also terminated as of August 31, 2017. In this regard, options to purchase 214,866 shares of Company common stock were issued with exercise prices ranging from $0.36 to $0.67, a holding period of 10 years and vesting over three years.

As part of the cash conservation program adopted on August 28, 2017, starting with the month of September 2017, the directors agreed to defer 100% of their fees until cash is available. In consideration of this deferral, 226,023 options were issued to each of the two independent directors in February 2018 with an exercise price of $0.37; 152,053 options were issued to each of the two independent directors in May 2018 with an exercise price of $0.30, and 98,098 options were issued in July 2018 with an exercise price of $0.31. All of the foregoing options and the options discussed below are exercisable for a period of 10 years with a vesting period of three years. This program was suspended as of July 15, 2018 and all remaining deferred fees were paid in July 2018.This Program was reactivated as of August 16, 2018 with the understanding that options would not be issued on the deferred amounts until the 2018 Equity Incentive Plan was approved by the stockholders. The 2018 Equity Incentive Plan was approved by the stockholders and the securities issuable thereunder were registered with the SEC and, on October 17, 2018, 172,786 options were issued to each of the two independent directors with an exercise price on $0.22 for a period of ten years with a vesting period of one year. On January 28, 2019, 207,343 options were issued to each of the two independent directors with an exercise price of $0.22 for a period of ten years with a vesting period of one year. Also on January 28, 2019, 50,000 options were issued to each of the two independent directors with an exercise price of $0.22 for a period of ten years with a vesting period of one year for chairing the committees in 2018.

Also as part of the cash conservation program adopted on August 28, 2017, starting with the month of September 2017, certain officers agreed to defer 40% of their salaries until cash is available. In consideration of this deferral, 884,459 options were issued to these officers in February 2018 with an exercise price of $0.37; 599,168 options were issued to these officers in May 2018 with an exercise price of $0.30, and 389,249 options were issued to these officers in July 2018 with an exercise price of $0.31. This program was suspended as of July 15, 2018 and all remaining deferred salaries were paid on July 2018. This Program was reactivated as of August 16, 2018 for 50% of their salaries with the understanding that options would not be issued on the deferred amounts until the 2018 Equity Incentive Plan was approved by the shareholders and the plan registered with the SEC. The 2018 Equity Incentive Plan has been approved by the shareholders and registered with the SEC and on October 17, 2018, 808,712 options were issued to these officers with an exercise price on $0.22 for a period of ten years with a vesting period of one year. On January 28, 2019, 1,213,069 options were issued to these officers with an exercise price of $0.22 for a period of ten years with a vesting period of one year.

Also as part of the cash conservation program adopted on August 28, 2017, all employees agreed to be paid 50% of their salaries in the form of unrestricted common stock of the Company. Starting with the month of September 2017,

the salaries of all the employees of the Company were paid 50% in the form of unrestricted common stock of the Company. The total number of shares issued as of June 30, 2018 to the employees under this program was 2,116,881 shares at stock prices ranging from $0.31 to $0.55 per share. This program was suspended by the Board of Directors on June 30, 2018.

On March 24, 2018, the Company sold 1,250,000 shares of common stock under its S-3 shelf registration. The Company realized net proceeds of $475,000 from this stock offering and paid $25,000 in placement agent fees.

On April 20, 2018, the Company entered into Securities Purchase Agreements (the “Purchase Agreements”) with certain investors (the “Investors”) for the sale by the Company of an aggregate of 6,600,000 shares (the “Common Shares”) of the Company’s common stock, par value $0.001 per share (the “Common Stock”), at a purchase price of $0.39 per share. Concurrently with the sale of the Common Shares, pursuant to the Purchase Agreements the Company also sold 6,600,000 warrants, 50% of which are Class A Warrants and 50% of which are Class B Warrants (collectively, the “Warrants”). The Company received gross proceeds from the sale of the Warrants solely to the extent such Warrants are exercised for cash. Both classes of Warrants will not be exercisable until six months after issuance and will have an exercise price of $0.39 per share, subject to adjustments as provided under the terms of the Warrants. The Class A Warrants and Class B Warrants will expire, respectively, two and five years after the date on which they are first exercisable. The closing of the sales of these securities under the Purchase Agreements took place on April 24, 2018. The Company received net proceeds from the transactions of $2,343,820 after deducting certain fees due to the placement agent and the Company’s transaction expenses.

On November 27, 2017, we reactivated the EDA. During the year ended December 31, 2018, we sold an aggregate of 2,176,392 shares under the EDA for proceeds of $827,000 net of $25,000 in commissions. Pursuant to a prospectus supplement dated February 7, 2018, we were able to sell up to 6,549,157 of our common stock (inclusive of shares already sold under the prospectus supplement) under the EDA. From January 1, 2019 through March 25, 2019 we sold an aggregate of 115,606 shares under the EDA for proceeds of $26,000 net of $1,000 in commissions. The actual number of shares that we can sell and the proceeds to be received therefrom are dependent upon the market price of our common stock.

In February 2017, we entered into Securities Purchase Agreements (each, a "Purchase Agreement") with certain investors for the sale by us of 1,818,185 shares of our common stock at a purchase price of $0.55 per share. Concurrently with the sale of the common stock, pursuant to the Purchase Agreement, we also sold warrants to purchase 1,363,639 shares of common stock for aggregate net proceeds of approximately $875,000. We also issued placement agent warrants for the purchase of an aggregate of 90,910 shares of our common stock.

In May 2017, we entered into a mortgage and note payable agreement with a bridge funding company to obtain a two-year funding line of up to $4,000,000 secured by our assets and property located at 783 Jersey Ave., New Brunswick, New Jersey. We paid interest on this note at a fixed rate of 12% per annum. We were permitted to prepay the line without penalty commencing after six months. The balance on this note was $1,835,000 as of December 31, 2017; however, it was paid off on March 16, 2018 in conjunction with the sale of 783 Jersey Ave.

On March 16, 2018, we sold our property located at 783 Jersey Ave, New Brunswick, NJ for $4,080,000 and the purchasers received 3,225,806 warrants to purchase common stock. Simultaneously therewith, we leased the facility back. See PART I, Item 2 - "Properties."

In February 2018, the Company sold the unencumbered, unutilized, and wholly owned property located at 5 Jules Lane, New Brunswick, New Jersey to Acellories, NJ LLC, a New Jersey limited liability company, pursuant to a sale agreement dated September, 11, 2017. The sale price was $1,050,000.

On June 1, 2017, pursuant to an offer (the "Exchange Transaction") to the holders of warrants issued to investors in September 2016 (the "2016 Warrants"), the exercise price of the 2016 warrants was changed to $0.50. As a result the warrant holders exercised 2016 Warrants and purchased 2,370,000 shares of Company common stock. The Company realized net proceeds of $1,055,000 from this exercise. As part of the Exchange Transaction, the Company issued 2,370,000 series A warrants with an exercise price of $0.60 per share, an initial exercise date of December 1, 2017 and expiring March 6, 2022, and 7,584,000 series B warrants with an exercise price of $0.60, an initial exercise date of December 1, 2017 per share and expiring March 1, 2018. These warrants were exercised in January and February 2018 for proceeds of $1,260,000. In addition, in July 2017, the warrant holders exercised the remaining 130,000 2016 Warrants and purchased 130,000 shares of common stock. The Company realized net proceeds of $65,000 from this exercise. In conjunction with the foregoing the Company issued 130,000 series A warrants with an exercise price of

$0.60 per share and an initial exercise date of January 10, 2018 and expiring March 6, 2022, and 416,000 series B warrants with an exercise price of $0.60 and an initial exercise date of January 10, 2018.

On August 23, 2017, the Holders of the series A warrants and series B warrants exchanged all of their series A warrants and series B warrants for new warrants (respectively, the “Series A Exchange Warrants” and the “Series B Exchange Warrants” and, collectively, the “Exchange Warrants”) identical to the series A warrants and series B warrants except as follows: the exercise price of both Exchange Warrants is $0.45 per share, subject to adjustment therein, and the number of Series B Exchange Warrants issued was proportionately reduced so that all Exchange Warrants in the Exchange Transaction do not exceed 19.9% of the number of the Company’s issued and outstanding shares of Common Stock as of May 31, 2017, the date of the Exchange Transaction offer letters. The issuance of the Exchange Warrants by the Company and the shares of Common Stock issuable upon exercise of the Exchange Warrants is exempt from registration pursuant to Sections 3(a)(9) and 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”).There were 2,800,000 warrants with an expiration date of March 1, 2018 and an exercise price on $0.45. These warrants were exercised in January and February 2018. The Company realized proceeds of $1,260,000 from these exercises.

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

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

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

The Company has elected to apply the Full Retrospective Application to implement the new revenue recognition standard ASC 606. The Company, based on the nature of its Ampligen® sales under its cost recovery programs, determined that there were no material differences between the new accounting standard and legacy GAAP and that difficulties will not arise for any "open" contract issues with its customers during the transition period. The Company also determined that the adoption of this standard will have little or no impact to the Company's opening balance of retained earnings.

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 and net realizable value 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 consider 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.

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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. 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 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

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, consider 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.

Convertible Note Payable

In September 2018, we entered into a $3,170,000 10% Secured Convertible Promissory Note with Iliad Research and Trading, L.P. (the "Note"). We determined the Note should be recorded at fair value with subsequent changes in fair value recorded in earnings. This conclusion is based on the redemption conversion feature, which allows the Holder to trigger the redemption of the Note for cash or conversion of the Note for common shares prior to its maturity date at a price of the lesser of $0.30 per share or the Market Price as defined within the Note. The choice of cash redemption or conversion of the Note for common shares is at our option. This feature may require that we issue a variable number of common shares to settle the Note which was determined to have a predominantly fixed monetary value at inception. In connection with the Note, we recorded a loss in our Consolidated Statements of Comprehensive Income (Loss) equal to $582,000 for the year ended December 31, 2018. For more detail about the Note, please see the disclosure in "Fair Value" above.

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. 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.

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

Not Applicable.

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ITEM 8. Financial Statements and Supplementary Data.

The consolidated balance sheets as of December 31, 2018 and 2017, and our consolidated statements of comprehensive loss, changes in stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2018, together with the reports of Morrison, Brown, Argiz & Farra, LLC, our current independent registered public accountants, and RSM US LLP, our prior independent registered public accountants, are 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.

On April 2, 2018, we released RSM US LLP ("RSM") as our independent registered public accounting firm. The decision to rotate the independent registered public accounting firms was approved by the Audit Committee of our Board of Directors (the "Audit Committee"). The Audit Committee determined to transition to another accounting firm for best practices as RSM had been the Company's auditors for 12 years. In this regard, on April 4, 2018, the Audit Committee entered into an agreement with Morrison, Brown, Argiz & Farra, LLC ("MBAF") to serve as our independent registered public accounting firm. We did not consult with MBAF regarding any of the matters or events set forth in Item 304(a)(2)(ii) of Regulation S-K.

During the fiscal years ended December 31, 2017 and 2018, there were (i) no disagreements between us and RSM on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreement, if not resolved to the satisfaction of RSM, would have caused RSM to make reference thereto in their reports on the financial statements for the year ended December 31, 2017, and (ii) no "reportable events" as that term is defined in Item 304(a)(1)(v) of Regulation S-K, except as follows. As noted in our quarterly reports on Form 10-Q for the second and third quarters of 2017, we, in carrying out an evaluation of the effectiveness of our disclosure controls and procedures, determined that, at the end of these quarters, there was a material weakness. The material weakness related to the completeness and accuracy of the recording of the exercise of certain redeemable warrants. The Audit Committee discussed this material weakness with RSM during the second and third quarters of 2017. We authorized RSM to respond fully to the inquiries of MBAF regarding the previously reported material weakness. We believe that we have corrected this issue and no such material weakness was found during the fourth quarter of 2017.

The reports of RSM for the fiscal years ended December 31, 2017 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principles.

We provided RSM and MBAF with a copy of the Current Report on Form 8-K related to the change in accounting firms prior to its filing with the Commission and RSM furnish us with a letter addressed to the SEC stating that it agreed with the above statements.

ITEM 9A. Controls and Procedures.

Effectiveness of Control Procedures

As of December 31, 2018, 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, 2018 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, 2018. 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, 2018. 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, 2018, based on the criteria set forth in "Internal Control—Integrated Framework" issued by the COSO.

ITEM 9B. Other Information.

The price per share of our common stock has closed at or below $0.20 since February 26, 2019 and most recently closed on March 26, 2019 at $0.16, with a 30-day average of $0.19. On March 26, 2016, we received written notice (the "Notice") from the NYSE American LLC (the "NYSE American") that we are not in compliance with the continued listing standards set forth in Section 1003(f)(v) of the NYSE American Company Guide because our common stock has been selling for a low price per share for a substantial period of time. The NYSE American has determined that the continued listing of our common stock is predicated on us effecting a reverse stock split of our common stock or otherwise demonstrating sustained price improvement within a reasonable period of time. We have until September 26, 2019 to demonstrate compliance.

Prior to our receipt of the Notice, and based upon our significant advances in oncology, we were contemplating seeking stockholder approval at our next annual meeting for a reverse stock split to raise the market price of our common stock to a range where it could allow a broader variety of institutions to invest in the common stock. Currently many funds are prohibited from buying stocks with a price below a certain threshold price. Should we have success in the current clinical trials, potentially increasing the trading volume and liquidity of the common stock confers major benefits. We believe that such a reverse stock split could help increase analyst and broker interest in the common stock, as their policies can discourage them from following or recommending companies with lower stock prices. Because of the trading volatility often associated with lower-priced stock, many brokerage houses and institutional investors have adopted internal policies and practices that either prohibit or discourage them from investing in such stocks or recommending them to their customers. Some of those policies and practices may also function to make the processing of trades in lower-priced stocks economically unattractive to brokers.

The Company now plans on holding a special meeting of its stockholders to approve a reverse stock split which it anticipates holding in late May or early June 2019.

As discussed above in PART I. Item 1 – "Business", there are a number of existing and planned business activities that, we believe, should increase stockholder value and the market price of our common stock. However, we cannot assure that ongoing activities will continue to be positive or that such activities will increase stockholder value or the market price of our common stock. Nor can we assure that stockholders will approve the reverse split.

There is no immediate impact on the listing of our common stock, which will continue to trade on the NYSE American, subject to our compliance with other listing standards.

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:

Name	Age	Position
Thomas K. Equels, Esq	66	Chief Executive Officer, President, and Director
Peter W. Rodino III	67	Executive Director Gov't Relations, General Counsel, & Secretary
William M. Mitchell, M.D., Ph.D.	84	Chairman of the Board and Director
Stewart L. Appelrouth	65	Director
Adam Pascale	71	Chief Financial Officer
David R. Strayer, M.D.	73	Chief Scientific Officer and Medical Director
Wayne S. Springate	47	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.

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' 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: American 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 is also the Company's Chief Accounting Officer. Mr. Pascale has been employed with the Company for 23 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. Previously, as founder and president of Rodino Consulting, Mr. Rodino 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. 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, 2018, 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 2018**.**

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: American 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: American 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 American 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 Audit Committee formally met six times in 2018 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 in the "Investor Relations" tab under "Corporate Governance".

Scientific Advisory Board

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. The Scientific Advisory Board met two times in 2018.

Disclosure Controls Committee

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, Senior Vice President of Operations 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, Dr. David Strayer, our Chief Scientific Officer, Adam Pascale, our Chief Financial and Accounting Officer, and Ann Marie Coverly, Director of HR and Administration serving as the Deputy Investor Relations Coordinator. The full text of the DCC's Charter, as approved by the Board, is available on our website: www.hemispherx.net in the "Investor Relations" tab under "Corporate Governance". The DCC actively met on numerous occasions in 2018.

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 in the "Investor Relations" tab under "Corporate Governance". The Committee did not meet in 2018.

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. 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 consultant 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, or persons performing similar functions.

You may obtain a copy of this Code by visiting our web site at www.hemispherx.net (Investor Relations / Corporate Governance) or by written request to our office at 2117 SW Highway 484, Ocala, FL 34473.

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. For the purposes of discussion and analysis, the following NEOs are 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

Peter Rodino, General Counsel and Company Secretary ("CS")

Governance of Compensation Committee

The Compensation Committee consists of the following two directors, each of whom is "independent" under applicable NYSE American 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 in the "Investor Relations" tab under "Corporate Governance".

This Committee formally met two times in 2018 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 September 12, 2018 Annual Meeting of Stockholders, the Stockholders approved the annual, non-binding advisory vote on Executive Compensation.

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.

EXECUTIVE COMPENSATION

The following table provides information on the compensation during the fiscal years ended December 31, 2018 and 2017 of our Chief Executive Officer, Chief Financial Officer, and Peter Rodino, General Counsel and Company Secretary constituting the Company's Named Executive Officers, based on the year ended 2018 for each fiscal year.

Summary Compensation Table

Name & Principal Position	Year	Salary / Fees (2)(3)	Bonus	Stock Awards	Option Awards (1)	Non-Equity Incentive Plan Compensation	Change in Pension Value and NQDC	All Other Compensation	Total (3)

							Earnings ($)		
Thomas K. Equels	2018	$751,000	$18,350(3)	$ 500	$ 335,731(1)	—	—	$ 65,927 (4)	$1,171,508
CEO & President (2) (3)	2017	$712,500	$22,067(3)	—	$ 174,052 (1)	—	—	$ 78,604 (4)	$987,223
Adam Pascale	2018	$251,000	$—	$ 500	$99,979	—	—	$ 40,973 (6)	$392,452
CFO	2017	$234,500	$—	$ —	$12,501	—	—	$ 48,379 (6)	$295,380
Peter Rodino	2018	$351,000	$—	$ 500	$138,599	—	—	$ 36,684 (5)	$526,783
General Counsel and Secretary	2017	$332,500	$—	—	$17,500	—	—	$ 48,656 (5)	$398,656

Notes:

(1) All option awards were valued using the Black-Scholes method.

(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 2018 and 2017 as well as reported separately in the “Compensation of Directors” section (see below) for calendar year 2018.

(3) As stated in Thomas Equels’ employment contract, he is entitled to 5% of Ampligen® sales. In 2018 and 2017, a bonus of 5% of Ampligen® sales for 2018 and 2017 was accrued.

For 2017, salaries for Messrs. Equels, Pascale and Rodino include 40% deferred salaries of $100,000, $33,333 and $46,667, respectively, starting from September 1, 2017.

For 2018, salaries for Messrs. Equels, Pascale and Rodino include 50% deferred salaries of $140,625, $46,875 and $65,625, respectively, starting from August 1, 2018

(4) Mr. Equels’ All Other Compensation consists of:

	2018	2017
Life and Disability Insurance	$22,677	$26,837
Healthcare Insurance	25,250	33,767
Car Expenses / Allowance	18,000	18,000
401(k) Matching Funds	—	—
	$65,927	$78,604

(5) Mr. Rodino’s All Other Compensation consists of:

	2018	2017
Life and Disability Insurance	$2,542	$2,504
Healthcare Insurance	19,742	31,752
Car Expenses / Allowance	14,400	14,400
401(k) Matching Funds	—	—
	$36,684	$48,656

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

	2018	2017
Life and Disability Insurance	$2,272	$2,212
Healthcare Insurance	24,301	31,767
Car Expenses / Allowance	14,400	14,400
401(k) Matching Funds	-	-
	$40,973	$48,379

Outstanding Equity Awards at Fiscal Year End

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned 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 Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights that Have Not Vested (#)
Thomas Equels, President and Chief Executive Officer	25,000	—	—	7.92	6/11/2020	—	—	—	—
	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	—	—	—	—
	300,000	—	—	0.56	6/8/2027	—	—	—	—
	14,212	—	—	0.49	6/15/2027	—	—	—	—
	14,214	—	—	0.49	6/30/2027	—	—	—	—
	—	18,124	—	0.48	7/15/2027	—	—	—	—
	—	20,786	—	0.42	7/31/2027	—	—	—	—
	—	21,336	—	0.41	8/15/2027	—	—	—	—
	—	24,463	—	0.36	8/31/2027	—	—	—	—
	—	371,622	—	0.37	2/13/2028	—	—	—	—
	—	125,000	—	0.38	4/12/28	—	—	—	—
	—	300,000	—	0.30	5/16/28	—	—	—	—
	—	250,000	—	0.30	5/16/28	—	—	—	—
	—	161,290	—	0.31	7/18/21	—	—	—	—
	—	284,091	—	0.22	10/17/28	—	—	—	—
	—	1,000	—	0.22	10/17/28	—	—	—	—

	—	426,136	—	0.22	1/28/2029	—	—	—	—
Adam	500	—	—	48.36	4/13/2022	—	—	—	—
Pascale,	4,167	—	—	3.96	7/8/2024	—	—	—	—
Chief Financial	598								
Officer	12,500	—	—	1.56	6/21/2026	—	—	—	—
	—	4,738	—	0.49	6/15/2027	—	—	—	—
	—	7,738	—	0.49	6/30/2027	—	—	—	—
	—	6,042	—	0.48	7/15/2027	—	—	—	—
	—	6,929	—	0.42	7/31/2027	—	—	—	—
	—	7,112	—	0.41	8/15/2027	—	—	—	—
	—	8,155	—	0.36	8/31/2027	—	—	—	—
	—	123,874	—	0.37	2/13/2028	—	—	—	—
	—	75,000	—	0.38	4/12/28	—	—	—	—
	—	83,334	—	0.30	5/16/21	—	—	—	—
	—	53,763	—	0.31	7/18/21	—	—	—	—
	—	94,697	—	0.22	10/17/19	—	—	—	—
	—	1,000	—	0.22	11/14/19	—	—	—	—
	—	142,046	—	0.22	1/28/2029	—	—	—	—
Peter	12,500	—	—	3.00	8/2/2023	—	—	—	—
Rodino,	12,500	—	—	1.56	6/21/2026	—	—	—	—
General Counsel and Secretary	—	6,632	—	0.49	6/15/2027	—	—	—	—
	—	6,633	—	0.49	6/30/2027	—	—	—	—
	—	8,458	—	0.48	7/15/2027	—	—	—	—
	—	9,700	—	0.42	7/31/2027	—	—	—	—
	—	9,957	—	0.41	8/15/2027	—	—	—	—
	—	11,416	—	0.36	8/31/2027	—	—	—	—
	—	173,423	—	0.37	2/13/2028	—	—	—	—
	—	100,000	—	0.38	4/12/2028	—	—	—	—
	—	116,667	—	0.30	5/16/2028	—	—	—	—
	—	75,269	—	0.31	7/18/2028	—	—	—	—
	—	132,576	—	0.22	10/17/2028	—	—	—	—
	—	1,000	—	0.22	11/14/2028	—	—	—	—
	—	198,864	—	0.22	1/28/2029	—	—	—	—

Payments on Disability

At December 31, 2018, 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 Mr. Rodino, 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 2017 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, 2018, 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 Mr. Rodino, 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 2018 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 (NEO)

At December 31, 2018, 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. Mr. Rodino 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, 2019. 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.

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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)	$768,000	$62,320	—	—	$830,320
	Termination (for cause)	—	—	—	—	—
	Death or disability	$768,000	$62,320	—	—	$830,320
	Termination by employee or retirement	$768,000	$62,320	—	—	$830,320
Adam Pascale CFO	Involuntary (no cause)	—	—	—	—	—
	Termination (for cause)	—	—	—	—	—
	Death or disability	—	—	—	—	—
	Termination by employee or retirement	—	—	—	—	—
Peter Rodino General Counsel and Secretary	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 the closing market price of our common stock on the date of grant. For the purpose of this schedule, an NYSE American closing price at March 16, 2018 of $0.30 was used with an estimated exercise price of $0.30 for Mr. Equels. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718.

Payments on Termination in Connection with a Change in Control Named Executive Officers

At December 31, 2018, 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 thereby the term of his respective agreement would automatically be extended for three additional years. Mr. Rodino 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, 2019, 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, 2018

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, 2018. The amounts assume a January 1, 2019 termination date regarding base pay and use of the opening price of $0.18 on the NYSE American 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 ($)
Thomas K. Equels	768,000 (1)	—	—	—	$62,320 (4)	—	—	—	$830,320
Adam Pascale	—	—	—	—	—	—	—	—	—
Peter Rodino	—	—	—	—	—	—	—	—	—

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 employment agreement with Mr. Equels had 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, 2018 ($0.18 per share) minus the per share exercise price of $0.30 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. For the purpose of this schedule, an NYSE American closing price at March 16, 2018 of $0.30 was used with an estimated exercise price of $0.30 for Mr. Equels. The value was obtained using the Black-Scholes-Merton pricing model for stock-based compensation in accordance with FASB ASC 718.

(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 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, 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. Appelrouth, 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.

There was no cost of living increase granted in 2017 or 2018. Directors' fees are currently being deferred and will continue to be deferred until cash is available.

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. Options shares for stock compensation were issued under the 2009 and 2018 Equity Incentive Plans.

Director Compensation – 2018

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	- (2)	-	-	-	-	-	-
W. Mitchell, Chairman of the Board (1)	$114,039	$ 500	$193,411	-	-	-	$307,950
Stewart L. Appelrouth, Director (1)	$114,039	$ 500	$193,411	-	-	-	$307,950

Notes:

(1) Independent Director of the Company. Beginning August 16, 2018, the independent directors are deferring payment of 100% of their director's fees until cash is available.

(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 2018 and 2017 (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 18, 2019, 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	3,976,414	(1)(8)	6.4	%
Peter W. Rodino III 17400 Sterling Lake Drive Fort Myers, FL 33967	1,073,968	(2)(8)	1.7	%
William M. Mitchell, M.D. Vanderbilt University Department of Pathology Medical Center North 21st and Garland Nashville, TN 37232	1,750,550	(3)(8)	2.8	%
Stewart L. Appelrouth 999 Ponce de Leon., Suite 625 Coral Cables, FL33134	1,954,652	(7)(8)	3.1	%
Wayne S. Springate 783 Jersey Ave. New Brunswick, NJ 08901	791,026	(4)(8)	1.3	%
David R. Strayer, M.D.	542,235	(5)(8)	.9	%
Adam Pascale	791,341	(6)(8)	1.3	%

All directors and executive officers as a group (6 persons)	10,880,186	17.5 %

(1) Mr. Equels is Executive Vice Chairman of our Board of Directors, Chief Executive Officer and President who owns 1,123,307 shares of common stock and beneficially owns 2,853,107 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	$		