

## Diligence and Valuation Report

Arrowhead Code:	69-03-03
Coverage initiated:	06 November 2014
This document:	13 April 2015
Fair share value bracket – DCF	\$1.61 - \$2.77
Share price 12 April 2015:	\$0.23 <sup>i</sup>

### Analyst Team

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### Market Data

52-Week Range:	\$0.21– \$0.40 <sup>ii</sup>
Average Daily Volume (3M Avg.):	1,857,816 <sup>iii</sup>
Market Cap (12 Apr. 2015) :	\$49.5 MM

### Financial Forecast (in USD) (FY Ending – Dec.)

	'15E	'16E	'17E	'18E	'19E	'20E	'21E
High NI (MM)	(4.7)	45.1	77.6	143.7	151.9	106.8	110.2
High EPS	(0.02)	0.24	0.41	0.76	0.81	0.57	0.59
Low NI (MM)	(4.7)	23.5	41.2	81.5	88.0	94.4	65.5
Low EPS	(0.02)	0.13	0.22	0.43	0.47	0.50	0.35

**Company Overview:** Based in Philadelphia, Pennsylvania, Hemispherx Biopharma Inc. (hereinafter referred to as “Hemispherx” or “the Company”) is a specialty pharmaceutical company primarily engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company has two flagship products, 1) Alferon N Injection<sup>®</sup> - approved for a category of STD infections; 2) Ampligen<sup>®</sup> - an experimental Ribonucleic Acid developed to treat viral diseases and disorders of the immune system, specifically Chronic Fatigue Syndrome (CFS). The Company is also developing an oral formulation of Alferon N, Alferon<sup>®</sup> LDO (Low Dose Oral), for treating Influenza. The Company has formed collaborations with many research laboratories to examine if Ampligen<sup>®</sup> and/or Alferon<sup>®</sup> exhibits antiviral activity against the Ebola virus & testing Ampligen<sup>®</sup> in humans in conjunction with a nasal flu vaccine. The Company owns and exclusively operates a Good Manufacturing Practice manufacturing facility in New Jersey.

**FY2014:** Revenue increased by 31.3% Y-o-Y to reach \$197,000 in FY2014, due to increase in the number of patients using Ampligen<sup>®</sup> through the Ampligen<sup>®</sup> cost recovery program. Net loss during the year increased further to \$17.5MM primarily due to 15.4% increase in general and administrative costs and 7.5% increase in R&D expenses. Cash and cash equivalent stood at \$16.1MM as of December 31, 2014.



Company:	Hemispherx Biopharma Inc.
Ticker:	NYSE MKT:HEB
Headquarters:	Philadelphia, Pennsylvania
Chairman, CEO, President, CSO:	Dr. William A. Carter, M.D.
CFO:	Mr. Thomas K. Equels, Esq.
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### Innovative product pipeline; Alferon N Injection<sup>®</sup> - Nearing Commercialization

Arrowhead is updating coverage on Hemispherx Biopharma Inc. with a fair value bracket of \$1.61 in the low bracket and \$2.77 in the high bracket scenario using the Discounted Cash Flow (DCF) Valuation Method.

**Key Highlights:** (1) Alferon N Injection<sup>®</sup> presents a huge growth potential for the Company due to growing number of patients in US suffering from genital warts, a common clinical manifestation of HPV infection; (2) Alferon N Injection<sup>®</sup> is the only natural interferon approved by FDA for marketing in the US, giving the Company a competitive edge; (3) The Company is conducting work, based on published studies, on the potential use of natural killer cell levels and activity to act as a biomarker for CFS, which if positive could facilitate approval of Ampligen<sup>®</sup> for CFS; (4) Alferon<sup>®</sup> & Ampligen<sup>®</sup> are identified as potential candidates for treatment of Ebola; (5) The Company's European subsidiary received positive opinion on application for Orphan designation by European Medicines Agency for Ampligen<sup>®</sup> to treat Ebola; (6) The Company has invested \$8MM to upgrade the Alferon manufacturing facility and the management expects this facility to be approved in approximately one year from now; (7) The Company has formed a strategic partnership with Armada Healthcare for the distribution & marketing of Alferon<sup>®</sup> through its strong network of independent specialty pharmacies & collaborated with Emerge Health for commercialization of Ampligen<sup>®</sup>.

**Key risks:** Key risks include cash flow uncertainty; unsuccessful product development; uncertainty related to regulatory approval; and inadequate financial resources and risk of delayed commercialization.

**Valuation and Assumptions<sup>iv</sup>:** Given the due diligence and valuation estimates, Arrowhead believes that Hemispherx' fair share value lies in the \$1.61 to \$2.77 bracket calculated using the DCF method. It has been assumed that the Alferon N Injection<sup>®</sup> is estimated to start contributing to the revenue from 2016 for treatment of refractory/recurring HPV genital warts and from 2018 for treatment of Vulvar Vestibulitis. Although promising, it is not tangible at this point to project any revenue or expense for Ampligen<sup>®</sup> for CFS and hence has not been included in the valuation.

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## 1. Summary and Outlook

We are initiating coverage of Hemispherx, a biopharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of viral and immune-based disorders.

### Key Highlights:

(1) Alferon N Injection® presents a huge growth potential for the Company due to growing number of patients in the US suffering from genital warts, a common clinical manifestation of HPV infection. Although, they are benign, they are known to cause immense psychosocial distress and physical discomfort which includes pain, bleeding, and itching. Since, genital warts are highly infectious, around 65% of people whose sexual partner has genital warts develop warts as well. Further, recurrence of warts is very common and results in high medical costs for repeated treatment. The Company also expects to generate additional revenue from indication for HPV related disease, Vulvar Vestibulitis.

(2) The Company has a unique product, Alferon N Injection® as it is the only natural interferon approved by FDA for marketing in the US. It is a multi-species, highly purified, natural alpha interferon that is produced from human white blood cells. The Company enjoys a favorable competitive position as compared to the alternative treatments available. Recombinant alpha interferon products are single species, are not glycosylated, and studies show that their use can generate neutralizing antibodies which can cause the recombinant interferon to no longer provide clinical benefit. Alferon has also been shown to be 10-100 times more potent than recombinant interferon.

(3) The Company has shown that Ampligen® increases natural killer cell (NK) activity using immune cells obtained from CFS subjects. Concentrations of Ampligen® achieving NK augmentation in-vitro are also readily achieved in-vivo in various clinical studies of Ampligen®. Ongoing clinical studies of Ampligen® are now being repositioned to focus on CFS patient subsets with NK deficiencies and corresponding Quality-Of-Life (QOL) deficiencies. CFS is characterized by a low level of natural killer (NK) cell immune function. NK cell function is a critical attribute of the body's immuno-surveillance network. Disease severity in CFS correlates with NK activity: severe CFS cases have more NK deficiency.

(4) Alferon® and Ampligen® are considered good candidates for treatment of Ebola as they have demonstrated broad anti-viral effects and can be produced at the Company's GMP facility in New Jersey. The Company is collaborating with the US Army Research Institute of Infectious Diseases (USAMRIID) and in-vitro tests by USAMRIID have shown that Ampligen® successfully protects human cells against the Ebola virus. The Department of Life and Environmental Sciences, University of Cagliari, Italy has conducted experiments showing that Ampligen® can successfully bind to the lethal Ebola Viral Disease (EVD) viral protein designated VP35 and could thus restore a patient's endogenous immune competency against the virus. More recently researchers at Howard University demonstrated that Ampligen® strongly inhibited the Ebola minigenome in the human embryonic kidney cell system.

(5) The Company's European subsidiary received positive opinion on application for Orphan designation from the European Medicines Agency for Ampligen® to treat Ebola.

(6) The Company has invested \$8MM to upgrade the Alferon manufacturing facility replacing time consumptive, costly, and volume-limiting small-scale manufacturing with large-scale, state-of-the-art bio-reactor manufacturing. The management team expects the facility to be approved in approximately one year from now. The approval will be granted when the production of 3 sequential lots of finished product is completed and the data shows at least 3 months of stability with concomitant laboratory tests exhibiting that the product manufactured in the upgraded facility is analytically the same as the product made and approved using the older manufacturing process.

(7) The Company has formed a strategic partnership with Armada Healthcare for the distribution and market Alferon® through its strong network of independent specialty pharmacies. With respect to Alferon®, in Argentina and elsewhere in Latin America, Hemispherx has partnered with a leading company, GP Pharma, for the commercialization of Alferon®. For Ampligen® for CFS, Hemispherx will seek a commercial alliance with a qualified organization in the US. Outside the US, Hemispherx' commercialization partner, GP Pharma, would commercialize Ampligen® for the CFS indication in Argentina and would expand that to other Latin American countries. Hemispherx commenced efforts in 2012 to gain approval of Ampligen® for CFS in Argentina. Recently, the Company has collaborated with Emerge Health for the commercialization of Ampligen® for CFS in Australia and New Zealand.

(8) Hemispherx has 25 patents worldwide with 43 additional pending patent applications comprising its core intellectual property estate.

(9) The Company has a strong management which includes professionals having diverse experience across clinical trials, regulatory affairs, legal matters, manufacturing & operations, finance, distribution & logistics, quality control, medicine, etc.

**Key risks:** Key risks include cash flow uncertainty; unsuccessful product development; uncertainty related to regulatory approval; and inadequate financial resources and risk of delayed commercialization.

## 2. Business Overview <sup>v</sup>

Incorporated in the early 1970's, Hemispherx is a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania. The Company is engaged in the manufacture and clinical development of new drug entities for treatment of viral and immune-based disorders. The Company has three domestic subsidiaries, BioPro Corp., BioAegean Corp., and Core BioTech Corp technologies, and a foreign subsidiary, Hemispherx Biopharma Europe N.V. /S.A. established in Belgium in 1998.

The Company's pharmaceutical product portfolio includes FDA approved natural interferon product, Alferon N Injection<sup>®</sup>, an experimental compound, Ampligen<sup>®</sup>, and a new experimental drug delivery platform (a liquid natural interferon for oral administration), Alferon<sup>®</sup> LDO.

Ampligen<sup>®</sup> includes application as a treatment for CFS and as an influenza vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection<sup>®</sup> is the company's registered trademark for its injectable formulation of Natural Alpha Interferon, and is approved by the FDA for a category of STD infection. While, Alferon N Injection<sup>®</sup> has been developed to treat refractory and recurring genital warts, the Alferon<sup>®</sup> LDO formulation is currently under development for treating Influenza.

Further, the Company continues to seek collaborations with multiple research laboratories to further study Ampligen's<sup>®</sup> and/or Alferon's<sup>®</sup> antiviral activity against the Ebola virus.

Hemispherx owns and operates a 43,000 sq. ft. FDA approved facility in New Brunswick, NJ for the production of Alferon<sup>®</sup> and Ampligen<sup>®</sup>. Approximately \$7.5MM has been spent on the project to upgrade the Alferon manufacturing facility replacing time consumptive, costly, and volume-limiting small-scale manufacturing with large-scale, state-of-the-art bio-reactor manufacturing. The Company is currently completing the validation phase of Alferon<sup>®</sup> production in the upgraded facility and new Alferon<sup>®</sup> commercial inventory will be produced when the upgraded facility using the large scale bio-reactor manufacturing process is approved by the FDA. Commercial sales of Alferon<sup>®</sup> will resume when new batches of commercial filled and finished are produced and released by the FDA.

Founded in the early 1970s, the Company was initially involved in doing contract research for the National Institutes of Health (NIH). Over the years, the Company has successfully established a strong foundation of laboratory, pre-clinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defence system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases.

The Company has expertise across new class of pharmaceutical products (nucleic acid compounds) that are designed to activate otherwise dormant cellular defences against viruses and tumors.

Exhibit 1: Product Candidates Under Development <sup>vi</sup>		
Indication	Product Candidate	Status
CFS/ME	Ampligen <sup>®</sup>	Phase III Double Blind Study Completed
CFS/ME	Ampligen <sup>®</sup>	Phase III Treatment Protocol Ongoing
Influenza Vaccine Adjuvant	Ampligen <sup>®</sup>	Phase I/II Study Ongoing
Influenza Treatment	Alferon <sup>®</sup> LDO	Phase II Study In Preparation
Influenza Prevention	Alferon <sup>®</sup> LDO	Phase II Study In Preparation
Thermal Injury	Ampligen <sup>®</sup>	Phase I/II Study In Preparation
Breast Cancer	Ampligen <sup>®</sup>	Phase I/II Study Ongoing
Ovarian Cancer	Ampligen <sup>®</sup>	Phase I/II Study In Preparation
Peritoneal Cancer	Ampligen <sup>®</sup>	Phase I/II Study In Preparation
Colorectal Cancer	Ampligen <sup>®</sup>	Phase I/II Study Ongoing

**2.1 Product Offerings** <sup>vii</sup>

**2.1.1 Alferon N Injection**®

**Product Specification:** Alferon N Injection® is an alpha interferon, which was approved by the FDA in 1989 for refractory recurring external genital HPV warts in patients 18 years of age or old. Alferon® is the only highly purified, natural source, multispecies alpha interferon product currently approved in the US; it is also approved for sale in Argentina. The following are the key attributes of Alferon:

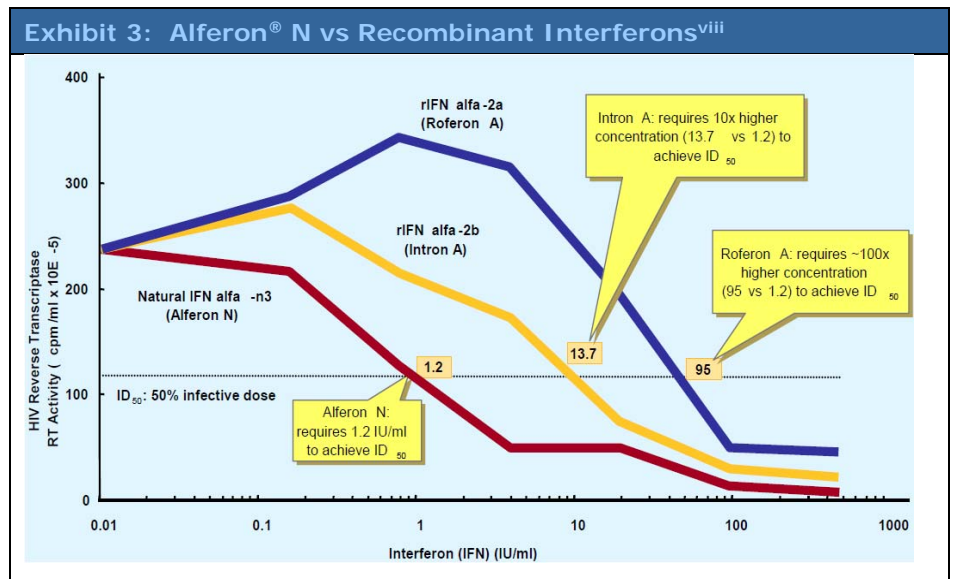
- 10 to 100 times more active in preclinical studies of HIV and SARS compared to Roferon and Intron
- In-vitro inhibition of MERS
- Negligible incidence of neutralizing antibodies (NAB's) i.e. less than 0.2%
- Multiple non-allelic genes may protect against neutralization of activity from initially induced NAB's administered against recombinant interferons
- Exhibit 3 depicts demonstrates that, Alferon® N is 10 to 100 fold More Effective than Equal Concentrations of Recombinant Interferons (Intron A or Roferon A) producing the same HIV antiviral activity with significantly lower doses.



**Manufacturing Facility:** Hemispherx has a 43,000 sq. ft. GMP compliant manufacturing facility in, New Brunswick, New Jersey. In 2010, the Company's management and board decided to suspend the production of Alferon and to completely "gut" and then upgrade the Alferon portion of its manufacturing facility. The installation and validation phase is now complete and will allow to have much increased capacity and lower cost production. The approval will be granted when the production of three sequential lots of finished product is completed and the data is showing at least three months of stability with concomitant laboratory tests exhibiting that the product manufactured in the upgraded facility is analytically the same as the product approved and used using the older manufacturing process. The Company anticipates that Alferon will be back on the market in about one year from now. The Company plans to re-enter that market at a higher price than in the past.

**Focus Area:** The Company is working actively on programs to expand Alferon's reach geographically and simultaneously into new therapeutic indications.

**Collaborations:** Hemispherx' has signed an agreement with Armada Healthcare for distribution and marketing of Alferon through its strong network of independent specialty pharmacies. These pharmacies are typically which distributes modern high value biotechnology therapeutic products. Armada will also provide both pre-prescription educational material to its member pharmacies and will manage the follow up with patients to make sure they are complying with their treatment protocol. Hemispherx is also looking for alliances to educate physicians treating patients (women and men) with HPV genital warts. Hemispherx will also seek relationships directly with relevant physician group practice networks which manage women's and men's health care. In Argentina and Latin America, the Company has formed an alliance with GP Pharma, for the commercialization of Alferon, the approval of Ampligen® for CFS and its sales in those countries.





### 2.1.2 Ampligen®

Ampligen® (poly I: poly C12U) is a synthetic specifically configured double-stranded RNA containing regularly occurring regions of mismatching. Ampligen® is an experimental nucleic acid which has the potential for treating viral diseases and disorders of the immune system such as HPV, HIV, CFS, Hepatitis and Influenza. Currently, the product is in the clinical development stage and more than 100,000 doses have been delivered to over 1,200 patients.

Ampligen® has received an Orphan Drug Product Designation (FDA), Treatment IND (e.g., treatment investigational new drugs, or “Emergency” or “Compassionate” use authorization) with Cost Recovery Authorization (FDA) and “promising” clinical outcome recognition based on the evaluation of certain summary clinical reports (AHRQ or Agency for Healthcare Research and Quality).

Ampligen® is the first drug in the class of large (macromolecular) RNA molecules to apply for NDA review and is expected to have a broad-spectrum of anti-viral and anti-cancer properties.

Nucleic acid compounds represent a potential new class of pharmaceutical products as they are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, 1) DNA and 2) 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 define 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 defence against viruses and tumors. Ampligen® utilizes the specifically-configured RNA.

Ampligen® has been assigned the generic name, rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly (I) poly (C12U).

**Ebola:** Alferon® and Ampligen® are considered as potential candidates for the treatment of Ebola as they have exhibited broad antiviral effects. In September 2014, the Company collaborated with the United States Army Medical Research Institute of Infectious Diseases, a unit of the Department of Defense responsible for medical biological defense research, to conduct research studies Alferon® and Ampligen® as potential drug for Ebola treatment. Further, the Company expanded the collaborative research agreement with Swiss Department of Defense, Civil Protection and Sports to include both the drugs in the study against Ebola.

In October, 2014 the Company formed a strategic relationship with Squire Patton Boggs to serve as the Company's global governmental relations team in association to find additional ways for testing both the drugs. Additionally, Squire would work with foreign officials in Africa, Europe and the United States, to pursue opportunities to provide Ampligen® and Alferon® to populations suffering from the Ebola crisis. Hemispherx additionally, has collaborated with various other institutions including NIH's Rocky Mount Labs, the Swiss National Defence Spiez Lab, and the University of Texas at Galveston. In November, the Company received a study report from Professor Tramontano in the Department of Life and Environmental Sciences, University of Cagliari, Italy. According to their study, the biochemical study demonstrated that Ampligen® can successfully bind to the lethal EVD viral protein designated VP35. Recently, in December 2014, researchers from Howard University, Washington DC submitted their research report demonstrating Ampligen® has the potential to inhibit the Ebola minigenome in the human embryonic kidney cell system.

### 2.1.3 Alferon® LDO (Low Dose Oral)

Alferon® LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon. It is expected that this formulation will not cause any antibody formation. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the entire body by absorption through the oral mucosa. Oral interferon could be economically feasible for patients and logistically manageable globally for development programs for prevention and, or treatment of pandemic influenza, seasonal influenza and other emerging viruses. This product is expected to be affordable with low toxicity, no production of antibodies, and broad range of potential bioactivity that could treat viral diseases. Hemispherx currently has an FDA authorized protocol to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal and pandemic influenza of more than 200 subjects.

Exhibit 4: Ampligen®



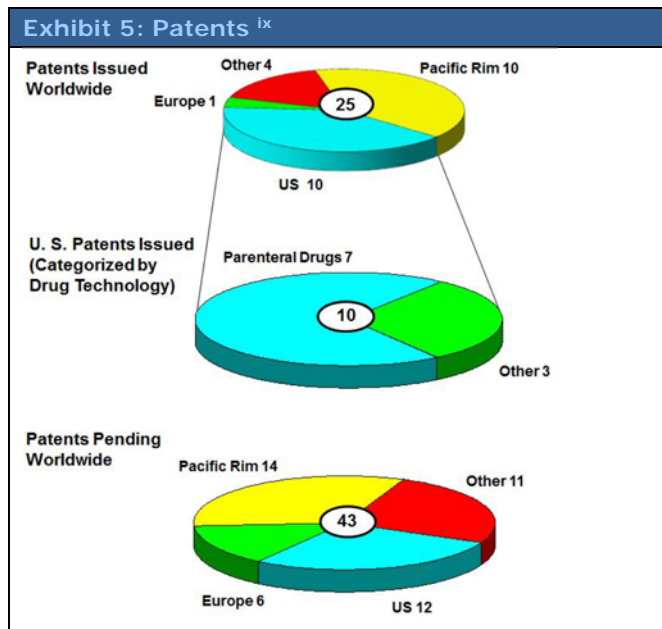
## 2.5 Company Premiums

The Company is well placed to create global value by leveraging the following points,

- **Seasoned Management Team:** Hemispherx's management team includes professionals having decades of diverse experience in the fields of clinical trials, regulatory affairs, legal matters, manufacturing & operations, finance, distribution & logistics, quality control, medicine, etc. William Carter, M.D., is inventor or co-inventor of several patents that were exclusively licensed to Hemispherx Biopharma, and also received the first FDA approval to initiate clinical trials on a beta interferon product manufactured in the US under his supervision; Mr. Wayne Springate, managed the consolidation phase of the Company's Rockville facility to New Brunswick location, and relocation of manufacturing polymers from South Africa to production facility in New Brunswick. He was also responsible for successful Preapproval Inspection by the FDA pertaining to the filing of Ampligen® NDA at New Brunswick manufacturing facility.
- **Strong Product Pipeline:** Aligned with Hemispherx's mission to develop therapeutic products for the treatment of viral and immune based chronic disorders, the Company has developed various applications of its two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®.
  - i. **Alferon®:**
    - **FDA Approved Application:** Alferon N Injection® is the only natural Interferon approved by the FDA.
    - **Manufacturing Facility:** Recently, the Company invested over \$8MM primarily to upgrade the Alferon® manufacturing facility indicating completion of capital improvement process and the validation phase. These upgrades are expected to improve the production capacity and manufacturing process of the facility. The Company has commenced manufacturing with the new process, and anticipates the upgraded facility to be approved and re-launched in approximately one year from now.
      - o **Marketing Regions:** Alferon® is identified as the only natural interferon with marketing approval in the US. The approved indication is to treat refractory HPV genital warts which represents an enormous growth opportunity for the Company's Alferon® to tap the \$250-\$400MM market for HPV genital warts. Furthermore, Alferon® has received a marketing approval in Argentina for any patients who became refractory to recombinant alpha interferon. Going forward, the Company plans to tap Europe and Australia to market the product.
    - **High Ranking in Sensitivity Testing against MERS/SARS Coronaviruses:** According to the study funded by the Genome Institute of Singapore at height of SARS crisis, Alferon® is identified as one of the few medications that protects against SARS virus infection in cell culture.
  - ii. **Ampligen®:**
    - **Patent Protection:** In May 2014, Hemispherx was issued US patent 8,722,874 titled "Double-Stranded Ribonucleic Acids with Rugged Physiochemical structure and highly specific biologic Activity" by the United States Patent Office. This patent right will protect the Company's right to Ampligen® until 2029.
    - **Orphan Drug Status:** The US FDA has granted 'Orphan drug' status to Ampligen® for CFS, HIV/AIDS, and renal cell carcinoma and malignant melanoma. This status has protected the Company against competition for a period of seven years following FDA approval.
    - **Potential Applications:** Hemispherx is conducting clinical trials in multiple indications because the Company believes that the use of Ampligen® has the potential to increase the positive therapeutic responses in life threatening diseases. The current clinical program comprises
      1. Nasal vaccine enhancer - Phase I/ II clinical trials;
      2. CFS/ME - Phase III clinical trial discussion in progress with regulators with respect to FDA approval.  
PD-1 cancer - Phase I/II clinical trials.
- **Favourable Competitive Profile:**
  - i. **Alferon®:** According to an article published in the journal of Interferon and Cytokine Research on "Recombinant and Natural Human Interferons: Analysis of the Incidence and Clinical Impact of Neutralizing Antibodies", it is inferred that a significant number of patients being treated with recombinant interferon become refractory to the recombinant interferon, primarily because the patient develops neutralizing antibodies, and then interferon no longer provides the therapeutic benefit. However, when these patients are administered with Alferon®, a natural interferon, the clinical benefit is restored. Natural interferon does not produce neutralizing antibodies because

they are of a human source. With this reference it is important to note that Alferon® is the only approved natural interferon in the US, which could allow this product to gain a larger market share.

- ii. **Ampligen®:** There is no approved treatment for CFS anywhere in the world. Most of the Company's competitors have tried in the past, and failed to achieve satisfactory results. The Company considers most of those players as its potential strategic allies than as a potential competitor.
- **Potential Candidate for Ebola:** The Company's core product Alferon® and Ampligen® are identified as good candidates for the treatment of Ebola attributed to the presence of certain unique structural feature such as:
  - i. **Versatile Mechanism of Action:** The work mechanisms of both drugs have been categorised as multifaceted by working through cellular "molecular cascades" (i.e. multiple mediators which protect cells from viral pathogenesis) rather than target viral targets whose specificity is vulnerable to mutational change.
  - ii. **Effective against Highly Dangerous Viruses:** Singapore investigators and independent US health researchers from their research have shown Alferon® and Ampligen® both to be highly effective in vitro against dangerous viruses. Alferon® has proved to be effective in vitro potency as compared to recombinant alpha interferons. Ampligen® is also found to be active in vitro against the Respiratory Syncytial Virus (RSV) that is structured in a form very similar to Ebola virus.
  - iii. **Ampligen® Gained Positive Opinion on Application for Orphan Designation:** In March 2015, the Company's European subsidiary, Hemispherx Biopharma Europe N.V/S.A, received a positive opinion on its Orphan Medicinal Product Application for Ampligen®, to treat patients with Ebola Virus Disease (EVD) from the Committee on Medical Products.
- **Manufacturing Facility:** Hemispherx exclusively owns a 43,000 sq. ft. facility in New Brunswick, New Jersey, which meets all necessary GMP standards. This facility is endowed with all necessary arrangement required to produce large quantities of Alferon® and Ampligen®.
- **Extensive Patent Portfolio:** As of March 31, 2014, Hemispherx has 25 patents worldwide with 43 additional pending patent application comprising its core intellectual property estate. In 2013, Hemispherx was granted four new patents, three patents were issued for the use of Alferon® LDO to treat bacterial or protozoan infections in Australia, New Zealand, & Singapore; and one in Singapore for the use of Ampligen® to initiate innate immunity and to treat or prevent viral infections and tumors.





## 2.6 Company Risks

- **Unsuccessful Product Development:** Currently, Hemispherx does not have any products in the commercial stage. The development of Ampligen® and Alferon LDO® are subject to a significant number of risks. Unsuccessful product development could primarily be a result of adverse side effects of the products or complexity in the manufacturing processes of the drugs.
- **Uncertainty related to regulatory approval:** Currently, Alferon N Injection® is the Company's only product that is approved for the intralesional treatment of refractory or recurring external genital warts. All other products including Ampligen® are exposed to several regulations imposed by governmental authorities in the US and other countries, the Health Protection Branch (HPB) of Canada, the Agency for the European Medicines Agency (EMA) in Europe and the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT) in Argentina. Uncertainty is further enhanced by the time consuming nature of obtaining these approvals and demands expenditure of substantial resources.
- **Cash Flow Uncertainty:** The Company has suffered major losses in the pursuit of obtaining their experimental drug, Ampligen®, approved resulting in an accumulated deficit of approximately of \$260,319,000 as of December 31, 2013. Since the Company has been unable to generate substantial revenues from its products, uncertainty related to future profits and cash flows remains a concern. Furthermore, the regulatory approvals required and complex product development procedures prevents the Company from providing any kind of assurance related to generation of revenues and cash flows in the future.
- **Inadequate financial resources/Delay in Commercialization:** Inadequate financial resources to perform time consuming research, preclinical development, clinical trials and other procedures required to commercialize and market products remains a significant risk. Cash and cash equivalent stood at \$17.4MM as of September 30, 2014. However, inability to commercialize and sell Ampligen® or Alferon® LDO and/or recommence material sales of Alferon N Injection® would put significant pressure on the Company's operational, financial and liquidity position.
- **Reduction in the Incidence of Ebola Cases:** According to the World Health Organization (WHO), incidence of Ebola is falling in Guinea, Liberia and Sierra Leone. Following the news, Chimerix Inc., a company engaged in discovering, developing, and commercializing broad-spectrum antivirals, called off clinical trials of its antiviral brincidofovir to protect against Ebola. Nevertheless, Ebola is a deadly disease and has a history of recurrence, and with Chimerix's withdrawal of brincidofovir, Hemispherx has the opportunity to tap a much larger market.

## 2.7 Corporate Strategy

**Forming Strategic Partnerships:** Hemispherx has adopted approaches such as strategic alliances, licenses, and third party distribution agreements to commercialize its products. Among these approaches, the Company's focus is on building strategic alliances. Some of the commercialization approaches adopted by the Company with respect to Alferon® and Ampligen® are as follows:

**i. Ampligen®:** Commercial strategies for Ampligen® used for various indications are as follows:

- **Ampligen® For CFS:** Presently, the Company is seeking approval for commercialization of Ampligen® for CFS in the US and abroad. However, the Company's marketing strategy for Ampligen® used for CFS, includes licensing/co-marketing agreements, with an intent to use the resources and capacities of the strategic partners. Aligned with its objective, the Company seeks a commercial alliance with a qualified organizations. For international marketing, it has partnered with GP Pharma, who would be responsible for gaining regulatory approval in Argentina and also for commercializing Ampligen® for CFS in Argentina. The Company has also granted GP Pharma with rights to sell the therapeutic to other Latin America countries, which is subjected to GP Pharma achieving certain performance milestones.

The Company has collaborated with Emerge Health, an innovative pharmaceutical company, with an intention to sell, market, and distribute Ampligen® in Australia and New Zealand to treat CFS patients. Given that CFS prevalence rate is increasing in Australia and New Zealand, along with the fact that there are no therapeutic indications approved specifically for the treatment of disorder worldwide, it is estimated that around 50,000 to 150,000 CFS patients will be left untreated. On gaining regulatory approval from Australia's Therapeutic Goods Administration and New Zealand's Medicines and Medical Devices Safety Authority, Emerge would be able to provide Ampligen®.

- **Ampligen® For Cancer:** In case of Ampligen® for various cancer indications, explicitly for those targeted with checkpoint inhibitor products such as PD-1 inhibitors, the Company intends to collaborate with renowned cancer research experts to include Ampligen® in the combinatorial approaches.
  - **Ampligen® for Flu:** In 2011, the Company received FDA authorization to initiate a clinical trial of intranasal Ampligen® to be used in conjunction with commercially approved seasonal influenza vaccine. With respect to commercialization of Ampligen® used in conjunction with FluMist®, the Company intends to partner with companies having a nasal flu vaccine
- ii. **Alferon®:** As a part of the commercial strategy for Alferon® in the US, Hemispherx has partnered with Armada Healthcare, LLC, in 2011, for the distribution and market support of Alferon® through its strong network of independent specialty pharmacies, where modern high value biotechnology therapeutic products are dispensed. Furthermore, Armada will provide pre-prescription educational material to its member pharmacies and will also manage the follow up with patients to ascertain the treatment protocols are properly followed. Further, with respect to Alferon®, Hemispherx has partnered with GP Pharma in Argentina and Latin America to commercialize Alferon®.

Following is the list of institutions with whom Hemispherx has partnered with in association with Ampligen® and Alferon® on various indications:

Exhibit 6: Collaborations			
Sr. No.	Institution	Indication	Hemispherx Product
1.	University of Pittsburgh	Colorectal cancer	Ampligen®
2.	University of Washington	Breast cancer	Ampligen®
3.	Institute of Antiviral Research, Utah State University	MERS-CoV	Ampligen® & Alferon®
4.	University of Georgia	PD-1 Checkpoint Inhibitors: Cancer	Ampligen®
5.	US Department of Homeland Security Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD), Kansas State University, College of Veterinary Medicine	H7N9 (In-Vitro) Flu	Ampligen® Alferon®
6.	Center of Biodefense and Emerging Disease, University of Texas Medical Branch	MERS-CoV (Middle East Respiratory Syndrome)	Ampligen® Alferon®
7.	University of Alabama at Birmingham, Clinical Research Group	Seasonal/Pandemic Flu	Ampligen® with FluMist®
8.	Swiss Department of Defence	H7N9/Ebola	Ampligen® & Alferon®
9.	Rocky Mountain Labs (NIH)	MERS	Alferon®
10.	Viral Clinics Biosciences, Netherlands	H5N1 Flu	Alferon® LDO

## 2.8 Shareholding Pattern

The total basic shares outstanding are 215MM as on March 01, 2015.

Exhibit 7: Top 10 Institutional Shareholders <sup>x</sup>		
Shareholders	% of Total	No. of Shares
Vanguard Group, Inc.	2.39%	5,148,046
BlackRock Fund Advisors	2.37%	5,099,017
Geode Capital Management, LLC	0.42%	897,977
Knight Capital Americas LLC	0.15%	330,323
Renaissance Technologies Corp	0.12%	254,400
Northern Trust Investments, N.A.	0.11%	236,866
Morgan Stanley & Co Inc.	0.11%	232,842
Dimensional Fund Advisors, Inc.	0.05%	104,750
State Street Corp	0.04%	81,000
Wedbush Morgan Securities Inc.	0.03%	75,000
Other Shareholders	94.21%	202,635,338
<b>Total Shares Outstanding</b>	<b>100%</b>	<b>215,095,559</b>

Exhibit 8: Top 10 Funds Shareholders <sup>xi</sup>		
Shareholders	% of Total	No. of Shares
Vanguard Total Stock Mkt Idx	1.30%	2,804,855
Vanguard Extended Market Idx Inv	0.96%	2,061,987
Fidelity Spartan® Extended Mkt Index Inv	0.36%	767,203
Fidelity Spartan® Total Market Idx Inv	0.06%	130,774
Vanguard Balanced Index Inv	0.05%	110,190
Vanguard Instl Ttl Stk Mkt Idx InstIPs	0.05%	96,879
The Vanguard Total Stock Market Index	0.04%	92,360
Mellon Capital EB DL NSL Mkt Completion	0.02%	52,679
Wilshire Micro-Cap ETF	0.02%	37,501
Master Extended Market Index Series	0.00%	9,683
Other Shareholders	97.13%	208,931,448
<b>Total Shares Outstanding</b>	<b>100%</b>	<b>215,095,559</b>

## 2.9 Listing and Contact Details

Hemispherx Biopharma is listed on NYSE MKT (Ticker: HEB)

### Company Contacts

Address: One Penn Center, 1617 JFK Blvd., Suite 500 Philadelphia, PA 19103  
Contact No: 215-988-0080; Fax: 215-988-1739; Email Id: info@hemispherx.net

### Manufacturing Facility & Development Center

Address: 783 Jersey Avenue, New Brunswick, NJ 08901  
Contact No: 732-249-3250; Fax: 732-249-6895

### 3. Key Variable Analysis <sup>xii</sup>

#### 3.1 Alferon N Injection® - Sales (Volume) – Refractory or Recurring External Genital Warts

Arrowhead is estimating Hemispherx to start generating revenue from its Alferon N Injection® from 2016 onwards for its refractory and recurring genital warts indication. The Company has a 600 L bioreactor, which can produce around 50,000 vials per year operating in a single shift. On average, two vials are required per patient over a multi-week course of treatment. Once the Company starts 2 shifts, they can produce 100,000 vials per year. However, the Company is planning to invest in a second 600 L bioreactor and is expecting to generate around 200,000 vials per year once both the reactors start production in 2 shifts. Arrowhead expects the company to sell around 85-90% of their production volume.

Exhibit 9: Alferon N Injection® - Sales (Volume) – Refractory or Recurring External Genital Warts						
In '000	2016E	2017E	2018E	2019E	2020E	2021E
Low estimate	64	106	170	170	170	170
High estimate	68	113	180	180	180	180

#### 3.2 Alferon N Injection® - Price – Refractory or Recurring External Genital Warts

It is estimated that the product will have a Wholesale Acquisition Cost (WAC) in the range of \$630 - \$1,080 per vial.

Exhibit 10: Alferon N Injection® - Wholesale Acquisition cost – Refractory or Recurring External Genital Warts	
In US\$/vial	
Low estimate	630
High estimate	1,080

#### 3.3 Alferon N Injection® - Price – Vulvar Vestibulitis

It is assumed that out of the 60 million women population (16-45 years) in US, 15% of them are suffering from Vulvar Vestibulitis. Out of these around 1% of the women are likely to opt for a treatment which generates the potential target market for Alferon N Injection®. The Company is likely to spend \$2MM in 2016 and another \$2MM in 2017 for this program. Based on this assumption, Arrowhead believes that this program can start contributing to the revenue from 2018 onwards. It is estimated that the revenue per course of treatment is assumed to be in the range of \$10,080 - \$13,500.

Exhibit 11: Alferon N Injection® - Revenue per course of treatment – Vulvar Vestibulitis	
In US\$/course	
Low estimate	10,800
High estimate	13,500

#### 4. News <sup>xiii</sup>

- **Hemispherx gained positive opinion on Application for Orphan designation by the European Medicines Agency for Ampligen® to treat patients with Ebola Virus Disease:** On March 24, 2015, Hemispherx announced that its European subsidiary, Hemispherx Biopharma Europe N.V/S.A, received a positive opinion from Committee on Medical Products (COMP) for its Orphan Medicinal Product Application for Ampligen®, to treat EVD. Orphan designation by the European Medicines Agency (EMA) promotes the clinical development of drugs that target rare life-threatening conditions and which are expected to provide significant therapeutic advantage over any existing treatments and includes some tropical diseases primarily found in developing nations as is the case for EVD.
- **Hemispherx to present data on the activity of Ampligen® against the Ebola Virus:** On March 23, 2015, Hemispherx announced that it will present its findings of new studies of Ampligen® (rintatolimod) that are performed in various models of Ebola virus infection. The studies will be presented during the 7<sup>th</sup> International Symposium on Filoviruses – Ebola: West Africa and Recent Developments in Washington, DC, on March 25-28, 2015. Dr. David Strayer, Medical Director, Hemispherx will present the paper entitled “Anti-EBOV Activity/Increased Survival with Rintatolimod, a Specifically Configured dsRNA, to Target Ebola VP35-Induced Disarming of Innate Immune Responses.”
- **Hemispherx inked a license agreement with Emerge Health Pty Ltd:** On March 09, 2015, Hemispherx announced that it had signed an agreement with Emerge Health Pty Ltd. (“Emerge”), with an intention to gain exclusive license to sell, market, and distribute Ampligen® in Australia and New Zealand to treat CFS. As per the agreement, Emerge will seek orphan drug designation and approval of Ampligen® to treat CFS from Australia’s Therapeutic Goods Administration (TGA) and New Zealand’s Medicines and Medical Devices Safety Authority (Medsafe). Further, Emerge will conduct regulatory-compliant programs to educate physicians about Ampligen for CFS. Hemispherx will support these efforts and will supply Ampligen® at a predetermined transfer price.
- **Completion of the Newly Upgraded Alferon® Facility:** On March 02, 2015, Hemispherx announced the completion of \$8MM of upgrades for its manufacturing site located in New Brunswick, New Jersey. The upgraded facility is expected to improve the production capacity and will also provide a more cost effective manufacturing process for the production of Alferon N Injection®.
- **National Academy of Sciences plans to rename Chronic Fatigue Syndrome as a “Systemic Exertion Intolerance Disease” (SEID):** On February 23, 2015, Hemispherx announced that the Institute of Medicine of the National Academy of Sciences plans to rename the disorder CFS as Systemic Exertion Intolerance Disease (SEID), which in the Institute’s words means ‘to more accurately capture the central characteristics of the disease’. According to the Company, it is the only pharmaceutical company to have used quantitatively measured exercise tolerance in order to understand patient response when it’s experimental therapeutic, Ampligen®, is compared to placebo.
- **Hemispherx and USAMRIID to present new discoveries concerning the efficacy of Ampligen® against the Ebola:** On February 12, 2015, Hemispherx announced that the Company and U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) together will be presenting their findings of new studies of Ampligen® (rintatolimod). The findings will be presented during the 7<sup>th</sup> Annual International Symposium on Filoviruses (Ebola West Africa and Recent Developments in Washington, DC) on March 25-28, 2015.
- **Ampligen® Produced 100% Survival Rate in Ebola Virus Rodent Study:** On February 2, 2015, Hemispherx announced the results of the tests conducted by scientists at the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) on the efficacy of Ampligen® in a mouse model of Ebola virus (EBOV) infection. Ampligen® (rintatolimod), was administered on Ebola-infected mice with varying dosage schedules infused every alternate day. The most effective dose, resulted in 100% survival (~human dose of approximately 400 mg) which has been used clinically approximately 50,000 times and has been generally well-tolerated when administered twice weekly. When higher doses of Ampligen® were used in the Ebola-infected mice, the survival rate dropped to 90%. The Ebola-infected mice treated with placebo had a 100% median death rate by Day 5 and all were dead by Day 7 post-infection.
- **Scientists indicated Hemispherx’s Experimental Biotherapeutics might escape mutational impediments:** On January 26, 2015, Hemispherx announced that scientists at USAMRIID, Harvard University, and Massachusetts Institute of Technology (MIT) studied genetic changes in the Ebola virus (EBOV) circulating in West Africa and inferred that genomic drift of the EBOV over time may be sufficient to block the action of otherwise potential



therapies that target EBOV genetic sequences. But, Alferon<sup>®</sup> N and Ampligen<sup>®</sup>, have mechanisms of action which are multifaceted by working through cellular “molecular cascades” rather than by targeting viral protein or genetic sequences whose specificity is vulnerable to mutational change.

- **Ampligen<sup>®</sup> indicated improved function of NK cells obtained from CFS patients:** On January 12, 2015, Hemispherx announced that it had conducted new in-vitro studies on NK cells obtained from CFS patients in conjunction with a comprehensive review of the medical literature to analyse the relative incidence of NK cell functional deficiencies in CFS disease. Studies indicated that low NK cell cytotoxicity (NKCC) has been consistently reported in CFS patients compared to normal controls. Ampligen<sup>®</sup> (rintatolimod), was found to increase in vitro NK activity utilizing cells from CFS patient donors.
- **Ampligen<sup>®</sup> demonstrated analogous actions to emerging immune checkpoints inhibitors:** On December 16, 2014, Hemispherx announced further progress on developing Ampligen<sup>®</sup> (rintatolimod) as a potential therapeutic complement to a new molecular class of anti-tumor drugs termed immune checkpoint inhibitors or PD-1 inhibitor. With respect to this study, remarkable success to date clinically reported by Bristol Meyers Squibb (BMS), Merck, Genentech and Novartis on a variety of human tumors including malignant melanoma and metastatic renal cancer with PD inhibitors. It was also announced that full regulatory approval of commercialization for PD-1 inhibitors has already been received.
- **Howard University Research report demonstrated inhibition of Ebola by Ampligen<sup>®</sup>:** On December 9, 2014, Hemispherx announced that it received research report from Howard University demonstrating Ampligen<sup>®</sup> strongly inhibited the Ebola minigenome in the human embryonic kidney cell system.
- **Hemispherx reported positive publication of Ampligen<sup>®</sup> in blocking Ebola viral disease protein:** On November 17, 2014, Hemispherx announced that it had received a new research report from Professor Tramontano in the Department of Life and Environmental Sciences, University of Cagliari, Italy. The research report concluded that Ampligen<sup>®</sup> can successfully bind to the lethal Ebola Viral Disease (EVD) viral protein designated VP35. The experiment conducted on Ampligen successfully established it as a potential preventive or an early onset therapeutic for Ebola, due to the fact that the inhibitory concentration of 4 µg/ ml at 50% viral protection is similar to the VP35 binding result showing Ampligen<sup>®</sup> binds to VP35 and displaces the viral dsRNA with a 50% inhibition at 1.1 µg/ml.
- **Hemispherx collaborated with United States Army Medical Research Institute of Infectious Disease (USAMRIID) on Alferon<sup>®</sup> and Ampligen<sup>®</sup> against Ebola virus:** On November 3, 2014, Hemispherx announced that USAMRIID scientists have in-vitro data reporting that Alferon<sup>®</sup>, the only multi-species, natural alpha interferon (IFN) commercially approved in the US, successfully protected human cells against the Ebola virus. Additionally, low Concentrations of Ampligen<sup>®</sup> also was reported to successfully protect human cells against the Ebola virus. The scientists plan to continue to collect the data and to begin in-vitro synergy studies using both Alferon<sup>®</sup> and Ampligen<sup>®</sup>.

**5. Management and Governance** <sup>xiv</sup>

Hemispherx's management team is comprised of qualified professionals and experts with years of industry experience in the fields of clinical trials, regulatory affairs, legal matters, manufacturing & operations, finance, distribution & logistics, quality control, medicine, etc.

Exhibit 12: Management Team			
Name	Age	Position	Past Experience
Dr. William A. Carter	75	Chairman of the Board, CEO, Chief Scientific Officer	<ul style="list-style-type: none"> <li>• He holds M.D. from Duke University, and underwent Post-doctoral training at the National Institutes of Health and Johns Hopkins University</li> <li>• He is working with Hemispherx since 1978, and ever since has served numerous positions such as: Chief Scientific Officer since May 1989; the Chairman of Board of Directors since January 1992; CEO since July 1993; President from April 1995 to November 2006 and then again December 2011 to present; and a Director since 1987. From 1987 to 1988, he served as the Company's Chairman</li> <li>• He is the co-inventor Ampligen<sup>®</sup></li> <li>• He was a leading innovator in the development of human Interferon for a variety of treatment indications including various viral diseases and cancer</li> <li>• He has received the first FDA approval to initiate clinical trials on a beta interferon product manufactured in the US under his supervision</li> <li>• He has also served as professor of Neoplastic Diseases at Hahnemann Medical University, a position he held from 1980 to 1998, and have served as Professor and Director of Clinical Research for Hahnemann Medical University's Institute for Cancer and Blood Diseases</li> </ul>
Mr. Thomas K. Equels	61	Executive Vice Chairman, Chief Financial Officer, Secretary & General Counsel	<ul style="list-style-type: none"> <li>• He holds Juris degree with high honors from Florida State University, summa cum laude graduate of Troy University, and Masters' degree from Troy</li> <li>• He has been practising legal for over more than 30 years with focus on complex business litigation, including cases associated to corporate finance and market issues</li> <li>• He is the President and Managing Director of the Equels Law Firm based in Miami Florida that focuses on litigation</li> <li>• In the past, he has represented national and state governments as well as companies in the banking, insurance, aviation, pharmaceutical and construction industries</li> </ul>
Mr. Wayne S. Springate	42	Senior Vice President - Operations	<ul style="list-style-type: none"> <li>• Since May 1, 2011, he is serving the Company as a Senior Vice President of Operations, and assists the CEO in details of operations including the aspects of manufacturing, warehouse management, distribution, and logistics</li> <li>• He came on board when the Company acquired Alferon N Injection<sup>®</sup> and its New Brunswick, NJ manufacturing facility</li> <li>• He led the consolidation of the Company's Rockville facility to New Brunswick location as well as coordinated the relocation of manufacturing polymers from South Africa to its production facility in New Brunswick</li> <li>• Additionally, he held responsibility of preparing and having a successful Preapproval Inspection by the FDA for its New Brunswick manufacturing plant in connection with the filing of Ampligen<sup>®</sup> NDA</li> <li>• At present, he is managing a capital improvement budget to enhance the Company's Alferon<sup>®</sup> facility in accordance with current Good Manufacturing Practice ("cGMP")</li> </ul>

			<ul style="list-style-type: none"> <li>In the past, he had served World Fashion Concepts in New York and oversaw operations at several locations throughout the United States and overseas</li> </ul>
Mr. Adam Pascale	67	Chief Accounting Officer	<ul style="list-style-type: none"> <li>He holds an accounting degree from Rutgers University</li> <li>He is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants</li> <li>Before being promoted as Chief Accounting Officer, he had served Hemispherx for 18 years as the controller</li> <li>His past experience includes 24 years of public accounting and prior public company experience</li> </ul>
Dr. Ralph Christopher Cavalli	55	Vice President – Quality Control	<ul style="list-style-type: none"> <li>He holds a Ph.D. in Chemistry from Temple University in Philadelphia, PA.</li> <li>Since, April 15, 2010, he is serving the Company as Vice President – Quality Control</li> <li>Recently, he also served as the Director of Quality Control at the Company's New Brunswick, NJ manufacturing facility</li> <li>Presently, his main primary responsibility includes manufacturing Alferon® Purified Drug Concentrate and active pharmaceutical ingredients for Ampligen® and to supervise the Quality Control ("QC") Department to continue Hemispherx Good Laboratory Practices and Good Manufacturing Practices</li> <li>In the past, he served Discovery Laboratories from 1999 until 2006, as Associate Director of Analytical Services and then ultimately as Senior Director of Analytical and Technical Services, assuming the responsibility for Quality Control and Process Development, and then Cytogen Corporation from 2006 until 2009 as a Senior Director of Manufacturing Operations assuming the responsibility for the manufacture of Cytogen's three commercial products</li> </ul>
Dr. David R. Strayer	67	Chief Medical Officer, Medical Director – Regulatory Affairs	<ul style="list-style-type: none"> <li>He holds M.D. from the University of California at Los Angeles, and is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders</li> <li>In the past, he served as a Professor of Medicine at the Medical College of Pennsylvania and Hahnemann University from 1987 to 1998; and served as a principal investigator in studies funded by the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health</li> </ul>

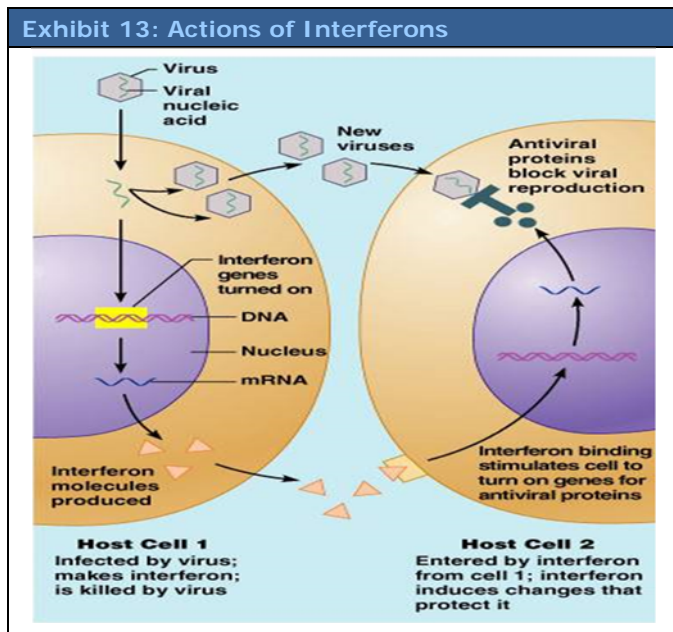
## 6. Technologies and Markets

### 6.1 Interferon<sup>xv</sup>

Interferons are a group of proteins that play a vital role in inhibiting viral infections and in stimulating the entire immune system to fight disease, in response to pathogens such as hepatitis, microbes, tumors, and antigens (foreign substances that can cause production of antibodies). It belongs to the large class of glycoproteins, categorized as cytokines, which are characterized by an amino acid chain that is 145-166 amino acids long.

British bacteriologist, Alick Isaacs and Swiss microbiologist, Jean Lindenmann discovered Interferons in 1957. According to their study, the virus infected cells secreted a special protein that caused both infected and non-infected cells to produce other proteins that prevented viruses from replicating. Interferons bind to specific receptors on cell surfaces. This binding initiates a series of events, including induction of specific proteins, which produce antiviral, anti-proliferative, and other actions controlling the immune system.<sup>xvi</sup> They named the protein 'Interferon' because it "interferes" with infection. Originally, scientists contemplated that there was only one Interferon protein, but subsequent studies concluded that there are different types of Interferon proteins.<sup>xvii</sup>

### 6.2 General Action of Interferons<sup>xviii</sup>



Interferons are small proteins released by macrophages, lymphocytes, and tissue cells infected with a virus. It is also important to note that in contrast to antibodies, Interferons are not virus specific but host specific. So, when a tissue cell is infected by a virus, it releases interferon. Interferon will further diffuse to the surrounding cells. When it binds to receptors on the surface of those adjacent cells, they began the production of a protein that prevents the synthesis of viral proteins. This prevents the spread of the virus throughout the body.

### 6.3 Types of Interferons:

There are four major classes of human interferons have been identified: alpha, beta, gamma, and omega. Thus far, alpha and beta interferons have demonstrated the greatest medical usefulness. Alpha interferons have become one of the most important classes of therapeutic products in the world with an estimated annual market of more than \$1.5B worldwide.<sup>xix</sup>

### 6.4 Functions of Alpha and Beta<sup>xx</sup>

- Alpha Interferons are produced by leukocytes
- Beta Interferons are produced by fibroblasts
- Both bind to Interferon cell receptors type 1 and both encoded on chromosome 9
- They have different binding affinities but similar biological effects
- Viral infection is the stimulus for alpha and beta expression
- Used to mobilize human 1<sup>st</sup> line of defense against invading organisms
- Largest group and are secreted by almost all cell types

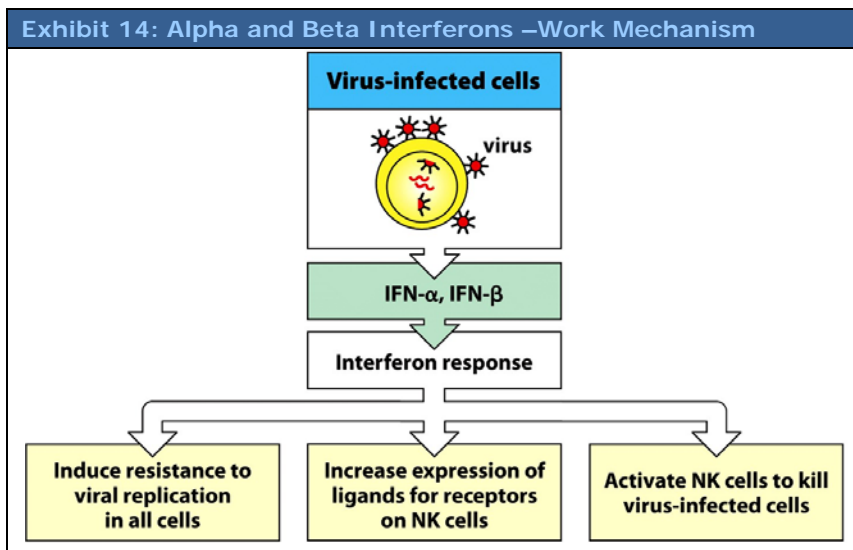
### 6.5 Alpha and Beta Work Mechanism

- Alpha and beta bind to heterodimeric receptor on cell surface
- Alpha receptor is made up of at least 2 polypeptide chains named as IFN $\alpha$ -R1 and IFN $\alpha$ -R2
- IFN $\alpha$ -R1 is involved in signal transduction
- IFN $\alpha$ -R2 is the ligand-binding chain that also plays a role in signal transduction
- Ligation induces oligomerisation and initiation of the signal transduction pathway
- This results in phosphorylation of signal transducers and activators of transcription proteins, which translocate to the nucleus as a trimeric complex, ISGF-3.
- ISGF-3 activates transcription of interferon stimulated genes, with many biological effects

### 6.6 Alpha Interferon <sup>xxi</sup>

Alpha interferon, otherwise known as interferon alpha or IFN-alpha, is a type of chemotherapy drug. It is the first of three classes of interferon and precedes the beta and gamma classes. Although, widely used to treat many forms of cancer, alpha interferon can also be used to treat several blood disorders.

As a type of chemotherapy, alpha Interferons is manufactured by using human Interferons and artificial DNA. The result is a treatment that can be used to fight complex disorders, such as forms of cancer. Unlike other treatments, alpha interferon is not a means of curing cancer or any other disease. Instead, it is used like a booster. It works in conjunction with the body's natural production to attack foreign substances. It also works to reduce the amount of antigen on a tumor cell's surface, making it easier to be destroyed by the immune system.



### 6.7 Types of Alpha Interferon - Natural and Recombinant<sup>xxii</sup>

There are two types of Alpha Interferon namely – Natural Alpha Interferon and Recombinant Alpha Interferon. At presently, most of the Alpha Interferon sold worldwide are Recombinant Interferon. The Recombinant Interferon are produced by fermentation of genetically engineered bacteria and this kind of interferon can be manufactured less expensively and in larger quantities. But this type of Alpha Interferon have demonstrated certain disadvantages which are not found in Natural Alpha Interferon.

Natural Alpha Interferon, or Interferon Alfa-n3 (the United States Adopted Name assigned under the aegis of the US Pharmacopoeia Drug Nomenclature Committee), is a natural-source, highly purified product made from human white blood cells. Researchers report that the various natural species may have differing antiviral activities depending upon the type of virus they confront. In addition, Natural Alpha Interferon proteins produced by human cells are partially glycosylated (contain sugar molecules), whereas recombinant interferon proteins are not. These differences in molecular composition may give Natural Alpha Interferon certain advantages over recombinant products, including reduced antibody formation when used in human treatments.

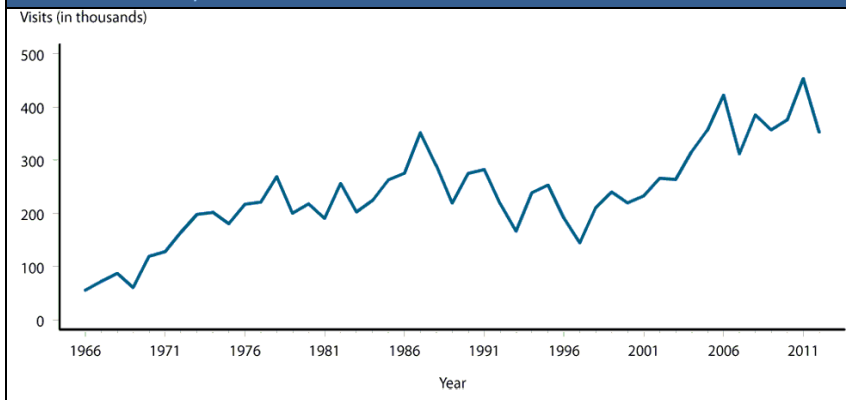
Hemispherx produces the only commercially available natural-source, multispecies Alpha Interferon in the US. Hemispherx' Natural Alpha Interferon consists of a specific blend of proteins containing many different molecular species of alpha interferon; recombinant interferons contain only a single protein species.



### 6.8 Anogenital Warts market <sup>xxiii</sup>

Anogenital warts (AGW) are small lumps that develop on the genitals and/or around the anus. They are caused by a virus called the human papillomavirus (HPV) and can be passed on by close sexual contact. Treatment options include chemicals or physical treatments such as freezing to destroy the warts. They are very common, highly infectious and are one of the most commonly diagnosed sexually transmitted infections and can be found to infect men and women both. Some of the treatments involved in treatment of warts are freezing warts using liquid nitrogen, surgical removal of warts, electro cautery, and laser. However, all these treatments are known to cause skin irritation.

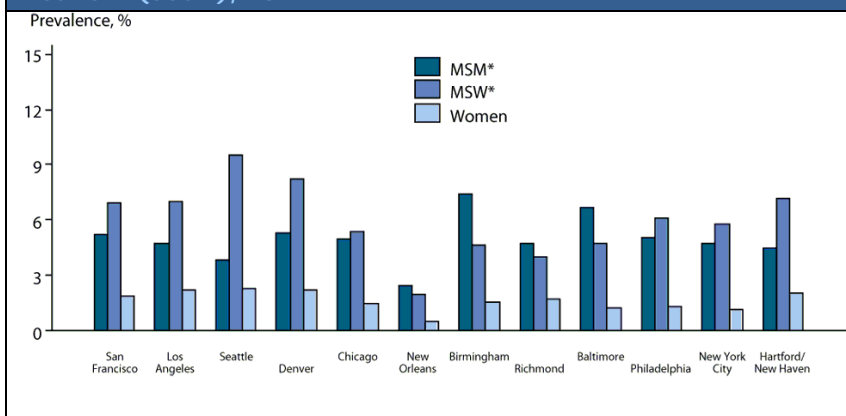
**Exhibit 15: Genital Warts — Initial Visits to Physicians’ Offices, United States, 1966 – 2012 <sup>xxiv</sup>**



Majority of HPV infections are asymptomatic and around 70% of incident infections clear within a year. Although, they are benign, they cause psychosocial distress and physical discomfort such as pain, bleeding and itching. Since the genital warts are highly infectious, approximately 65% of people whose sexual partner has genital warts will develop warts as well.

It is known that around 20–30% of genital warts regress spontaneously, however, recurrence of warts is common, resulting in high medical costs for repeated treatment.

**Exhibit 16: Genital Warts — Prevalence Among STD Clinic Patients by Sex, Sex of Partners, and Site, STD Surveillance Network (SSuN), 2012 <sup>xxv</sup>**



According to the report ‘Systematic review of the incidence and prevalence of genital warts’, the overall incidence of warts (including new and recurrent) ranges from 160 to 289 per 100,000, with a median of 194.5 per 100,000 (~.2%). New AGW incidence rates among males ranged from 103 to 168 per 100,000, with a median of 137 per 100,000 and among females from 76 to 191 per 100,000, with a median of 120.5 per 100,000 per annum. (~.12%). The reported incidence of recurrent AGWs was as high as 110 per 100,000 among females and 163 per 100,000 among males. (.13% for both sexes). Incidence peaked before 24 years of age in females and between 25 and 29 years of age among males. The overall prevalence of AGWs based on retrospective

administrative databases or medical chart reviews or prospectively collected physician reports ranged from 0.13% to 0.56%, whereas it ranged from 0.2% to 5.1% based on genital examinations.

### 6.9 Vulvar Vestibulitis

Vulvar Vestibulitis (VVS) is a chronic and persistent inflammatory condition characterized by severe pain on attempted vaginal penetration that is often associated with HPV infection. VVS has been demonstrated in up to 15% of women during routine gynaecological examinations and is the most common cause of dyspareunia (pain during intercourse) in reproductive-aged women. Researchers at the Medical College of Cornell University have discovered a deficiency in the production of alpha-interferon in women with VVS. There is significant correlation between HPV & VVS, hence the possibility to extend the approved indication for Alferon N to include HPV-related VVS with a Phase IV study.

### **6.10 Chronic Fatigue Syndrome (CFS)**

Chronic Fatigue Syndrome (CFS) is a complicated disorder which is characterized by extreme fatigue. It is the common name for a group of significantly debilitating medical conditions characterized by persistent fatigue and other specific symptoms that lasts for a minimum of six months in adults (and 3 months in children or adolescents). However, the cause of this syndrome is unknown. Some experts believe CFS might be triggered by a combination of factors. Also, there's no single test to confirm a diagnosis of CFS.

CFS has eight symptoms such as fatigue, loss of memory or concentration, sore throat, enlarged lymph nodes in the neck or armpits, unexplained muscle pain, pain that moves from one joint to another without swelling or redness, headache of a new type, pattern or severity, unrefreshing sleep, extreme exhaustion lasting more than 24 hours after physical or mental exercise. The Center for Disease Control (CDC) <sup>xxvi</sup> estimates that in US between 1MM to 4MM Americans are affected by the disease.

#### **Immune System Connection<sup>xxvii</sup>**

CFS is characterised by immune system dysfunction, mainly reduced Natural Killer cell (NK) function. Natural killer cells form a part of the innate immune system, therefore they can form antibodies without coming in contact with pathogens. These NK cells rapidly respond to viral infections and tumor cells. Reduced NK function acts an indication that the immune system is not able to fight the viruses. It has been observed that the reduced NK function has a direct correlation with the CFS disease severity; higher the NK deficiency, higher the severity of CFS disease increase.

## 7. Valuation

The Fair Market Value for all of Hemispherx's shares stands between \$346MM and \$595MM as of April 13, 2015. The Fair Market Value for one of Hemispherx's publicly traded regular shares stands between \$1.61 and \$2.77 as of April 13, 2015. The valuation approach followed is the Discounted Cash Flow method.

### 7.1 Discounted Cash Flow Method

Valuation	
WACC	
Risk-free rate	2.0% <sup>xxviii</sup>
Beta	0.81 <sup>xxix</sup>
Market Return	9.4% <sup>xxx</sup>
Additional Risk Premium	7.1%
Cost of Equity	13.81%
Cost of Debt	0.65%
Terminal Growth Rate	0.5%
WACC (Discount Rate)	13.67%

Figures are in '000 \$, unless indicated otherwise.

#### KEY VARIABLES

Sales Volume of Alferon N Injection® (Genital Warts)	Wholesale acquisition cost (For Genital Warts indication)	Revenue per course of treatment (Vulvar Vestibulitis)
Refer to <i>Key Variables Analysis</i> section		

Year Ending - December	2015E	2016E	2017E	2018E	2019E	2020E	2021E
<b>FCFF (High)</b>							
Net cash from operating activities	(5,488)	44,011	59,555	111,426	97,446	102,684	104,921
Capital Expenditure	(96)	(1,164)	(1,303)	(1,460)	(1,635)	(1,831)	(2,051)
Net Debt Addition	0	0	0	0	0	0	0
Free Cash Flow to Firm	(5,584)	42,848	58,252	109,966	95,811	100,853	102,870
Discount factor	0.88	0.77	0.68	0.60	0.53	0.46	0.41
Present Value of FCFF	(4,912)	33,159	39,658	65,859	50,479	46,744	41,944
<b>FCFF (Low)</b>							
Net cash from operating activities	(5,488)	23,769	32,481	65,227	57,532	61,664	63,127
Capital Expenditure	(96)	(1,164)	(1,303)	(1,460)	(1,635)	(1,831)	(2,051)
Net Debt Addition	0	0	0	0	0	0	0
Free Cash Flow to Firm	(5,584)	22,605	31,177	63,767	55,897	59,833	61,076
Discount factor	0.88	0.77	0.68	0.60	0.53	0.46	0.41
Present Value of FCFF	(4,912)	17,494	21,226	38,191	29,450	27,732	24,903

Arrowhead Fair Value Bracket	High	Low
Terminal Value (TV)	784,770	465,934
Present Value of TV	319,976	189,976
Present value of FCF	272,931	154,082
Present Value of FCF + TV	592,907	344,058
Net Debt	(2,134)	(2,134)
<b>Equity Value Bracket</b>	<b>595,041</b>	<b>346,192</b>
Shares on issue ('000)	215,096	215,096
<b>Fair Share Value Bracket (\$)</b>	<b>2.77</b>	<b>1.61</b>
Current Market price (\$)	0.23	0.23
Current Market Cap. (\$ MM)	49	49
<b>Target Market Cap. Bracket (\$ MM)</b>	<b>595</b>	<b>346</b>

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### Approach for DCF Valuation

**Time Horizon:** The Arrowhead fair valuation for Hemispherx is based on the Discounted Cash Flow (DCF) method. The time period chosen for the valuation is 84 months (2015E-2021E).

**Terminal Value:** Terminal Value is estimated to depend on a terminal growth rate of 0.5%.

**Prudential nature of valuation:** It should be noted that this Arrowhead Fair Value Bracket estimate is a relatively prudential estimate, as it discounts the eventuality of any of Hemispherx' other R&D projects other than Alferon N Injection®.

**Key variables:** The upper and lower bounds in the estimation correspond to the extreme positions taken by the following key variables:

#### Alferon N Injection® - Sales (Volume) – Refractory or Recurring External Genital Warts

Exhibit 17: Alferon N Injection® - Sales (Volume) – Refractory or Recurring External Genital Warts						
In '000	2016E	2017E	2018E	2019E	2020E	2021E
Low estimate	64	106	170	170	170	170
High estimate	68	113	180	180	180	180

#### Alferon N Injection® - Wholesale Acquisition Cost– Refractory or Recurring External Genital Warts

Exhibit 18: Alferon N Injection® - Wholesale Acquisition Cost (WAC) – Refractory or Recurring External Genital Warts	
In US\$/vial	
Low estimate	630
High estimate	1,080

#### Alferon N Injection® - Revenue per course of treatment – Vulvar Vestibulitis

Exhibit 19: Alferon N Injection® - Revenue per course of treatment – Vulvar Vestibulitis	
In US\$/course	
Low estimate	10,800
High estimate	13,500

Note: Refer the Key Variable Section 3, for more details.

### **Important information on Arrowhead methodology**

The principles of the valuation methodology employed by Arrowhead BID are variable to a certain extent depending on the subsectors in which the research is conducted, but all Arrowhead valuation research possesses an underlying set of common principles and a generally common quantitative process.

With Arrowhead Commercial and Technical Due Diligence, Arrowhead extensively researches the fundamentals, assets and liabilities of a company, and builds solid estimates for revenue and expenditure over a coherently determined forecast period.

Elements of past performance, such as price/earnings ratios, indicated as applicable, are present mainly for reference purposes. Still, elements of real-world past performance enter the valuation through their impact on the commercial and technical due diligence.

Elements of comparison, such as multiple analyses may be to some limited extent integrated in the valuation on a project-by-project or asset-by-asset basis. In the case of this Hemispherx report, there are no multiple analyses integrated in the valuation.

### **Arrowhead BID Fair Market Value Bracket**

The Arrowhead Fair Market Value is given as a bracket. This is based on quantitative key variable analysis, such as key price analysis for revenue and cost drivers or analysis and discounts on revenue estimates for projects, especially relevant to those projects estimated to provide revenue near the end of the chosen forecast period. Low and high estimates for key variables are produced as a tool for valuation. The high-bracket DCF valuation is derived from the high-bracket key variables while the low bracket DCF valuation is based on the low bracket key variables.

In principle, an investor who is comfortable with the high-brackets of our key variable analysis will align with the high-bracket in the Arrowhead Fair Value Bracket, and likewise in terms of low estimates. The investor will also take into account the company intangibles – as presented in the first pages of this document in the analysis on strengths and weaknesses and on other essential company information. These intangibles serve as supplementary decision factors for adding or subtracting a premium in the investor's own analysis.

The bracket should be understood as a tool provided by Arrowhead BID for the reader of this report and the reader should not solely rely on this information to make his decision on any particular security. The reader must also understand that on one hand, global capital markets contain inefficiencies, especially in terms of information, and that on the other hand, corporations and their commercial and technical positions evolve rapidly: this present edition of the Arrowhead valuation is for a short to medium-term alignment analysis (one to twelve months). The reader should refer to important disclosures on page 25 of this report.



## 8. Appendix

### Hemispherx's Balance Sheet Forecast – High Estimates

Exhibit 20: Consolidated Balance Sheet \$ '000		<i>High Bracket estimates</i>								
Year Ending December 31	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Total current assets	44,728	18,552	16,507	14,510	81,167	173,275	350,086	505,271	615,287	726,973
Total Non-current assets	12,971	13,315	12,933	12,734	13,605	14,543	15,557	16,655	17,847	19,145
<b>TOTAL ASSETS</b>	<b>57,699</b>	<b>31,867</b>	<b>29,440</b>	<b>27,244</b>	<b>94,772</b>	<b>187,817</b>	<b>365,642</b>	<b>521,926</b>	<b>633,135</b>	<b>746,118</b>
Total current Liabilities	12,649	2,532	4,436	3,913	27,799	44,776	78,902	83,297	87,736	90,527
Total Non-current Liabilities	350	37	-	3,000	1,500	-	-	-	-	-
<b>TOTAL LIABILITIES</b>	<b>12,999</b>	<b>2,569</b>	<b>4,436</b>	<b>6,913</b>	<b>29,299</b>	<b>44,776</b>	<b>78,902</b>	<b>83,297</b>	<b>87,736</b>	<b>90,527</b>
Total Shareholder's Equity	44,700	29,298	25,004	20,331	65,473	143,041	286,740	438,629	545,399	655,591
<b>TOTAL LIABILITIES &amp; EQUITY</b>	<b>57,699</b>	<b>31,867</b>	<b>29,440</b>	<b>27,244</b>	<b>94,772</b>	<b>187,817</b>	<b>365,642</b>	<b>521,926</b>	<b>633,135</b>	<b>746,118</b>

### Hemispherx's Balance Sheet Forecast – Low Estimates

Exhibit 21: Consolidated Balance Sheet \$ '000		<i>Low Bracket estimates</i>								
Year Ending December 31	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Total current assets	44,728	18,552	16,507	14,510	48,795	97,315	199,797	290,350	387,325	453,693
Total Non-current assets	12,971	13,315	12,933	12,734	13,605	14,543	15,557	16,655	17,847	19,145
<b>TOTAL ASSETS</b>	<b>57,699</b>	<b>31,867</b>	<b>29,440</b>	<b>27,244</b>	<b>62,399</b>	<b>111,858</b>	<b>215,353</b>	<b>307,004</b>	<b>405,172</b>	<b>472,838</b>
Total current Liabilities	12,649	2,532	4,436	3,913	17,031	26,830	48,785	52,469	56,189	58,382
Total Non-current Liabilities	350	37	-	3,000	1,500	-	-	-	-	-
<b>TOTAL LIABILITIES</b>	<b>12,999</b>	<b>2,569</b>	<b>4,436</b>	<b>6,913</b>	<b>18,531</b>	<b>26,830</b>	<b>48,785</b>	<b>52,469</b>	<b>56,189</b>	<b>58,382</b>
Total Shareholder's Equity	44,700	29,298	25,004	20,331	43,868	85,028	166,568	254,536	348,984	414,455
<b>TOTAL LIABILITIES &amp; EQUITY</b>	<b>57,699</b>	<b>31,867</b>	<b>29,440</b>	<b>27,244</b>	<b>62,399</b>	<b>111,858</b>	<b>215,353</b>	<b>307,004</b>	<b>405,172</b>	<b>472,838</b>

## 9. Analyst Certifications and Important Disclosures

### Analyst certifications

I, Snehal Mahajan, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security and the subject Company, based on the collection and analysis of public information and public Company disclosures.

### Important disclosures

Aside from certain reports published on a periodic basis, the large majority of reports are published by Arrowhead BID at irregular intervals as appropriate in the analyst's judgment.

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Neither Arrowhead BID nor any of its principals or employees owns any long or short positions in the Company, but in the future may from time to time engage in transactions with respect to the Company or other companies mentioned in the report.

## 10. Notes and References

- i Source: Bloomberg, April 12, 2015
- ii 52 weeks to April 12, 2015. Source: Bloomberg, April 12, 2015
- iii 3 months to April 12, 2015. Source: Bloomberg, April 12, 2015
- iv Arrowhead Business and Investment Decisions Fair Value Bracket – AFVBTM. See information on valuation on pages 21-23 of this report and important disclosures on page 25 of this report.
- v Source: Company Website and Company Documents
- vi Source: Company Website
- vii Source: Hemispherx 10Q – 30 September 2014
- viii Source: Company Management
- ix Source: Company Management
- x Source: Company management
- xi Source: Company management
- xii Source: Arrowhead BID estimate
- xiii Source: Company website – Press Release section
- xiv Source: <http://www.reuters.com/finance/stocks/companyOfficers?symbol=HEB&WTmodLOC=C4-Officers-5>
- xv Source: <http://www.google.com/url?url=http://faculty.smu.edu/jbuynak/Interferons%2520power%2520pt.ppt&rct=j&frm=1&q=&esrc=s&sa=U&ei=YQR0VP-8OdK0uAS7oICYCw&ved=0CDQQFjAGOAo&usg=AFQjCNHdqKhqJUOH-2SMrk41w8jYNc3y7g>
- xvi Source: Company Website
- xvii Source: [http://www.bio.davidson.edu/Immunology/Students/spring2006/V\\_Alvarez/IFN-gamma.html](http://www.bio.davidson.edu/Immunology/Students/spring2006/V_Alvarez/IFN-gamma.html)
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- xxi Source: <http://www.wisegeek.com/what-is-an-alpha-interferon.htm>
- xxii Source: Company Website
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- xxiv Source: <http://www.cdc.gov/std/stats12/figures/46.htm>
- xxv Source: <http://www.cdc.gov/std/stats12/figures/47.htm>
- xxvi Source: <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM368806.pdf>
- xxvii Source: <http://www.prohealth.com/me-cfs/what-is-chronic-fatigue-syndrome-me.cfm>
- xxviii Source: Bloomberg
- xxix Source: Bloomberg
- xxx Source: Bloomberg
- xxxi Source: Company Documents, Cash (as on December 31, 2014) and Debt ( As on December 31, 2014)
- xxxii Shares as on March 01, 2014
- xxxiii Source: Bloomberg, April 12, 2015