

# **Diligence and Valuation Report**

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Fair share value bracket – DCF \$2.36 - \$2.96
Share price 28 September 2015: \$0.17<sup>i</sup>

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Company: Ticker:

Headquarters:

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## **Market Data**

52-Week Range:	\$0.14- \$0.40 <sup>ii</sup>
Average Daily Volume (3M Avg.):	529,577 <sup>iii</sup>
Market Cap (28 Sep. 2015) :	\$42.0MM

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

	'15E	'16E	'17E	'18E	'19E	'20E	'21E
High NI (MM)	(18.3)	13.3	66.8	126.5	182.5	134.5	144.8
High EPS	(0.10)	0.07	0.35	0.67	0.97	0.71	0.77
Low NI (MM)	(18.3)	7.4	45.0	89.7	134.2	153.8	113.2
Low	(0.10)	0.04	0.24	0.48	0.71	0.82	0.60

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® - approved for treatment of refractory or recurring external genital warts in the US and for patients who are refractory to recombinant interferon in Argentina; 2) Ampligen® - 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® LDO (Low Dose Oral), for treating Influenza. Ampligen® has also been designated as an Orphan drug for treatment of Ebola virus. Hemispherx owns and operates a Good Manufacturing Practice manufacturing facility in New Jersey.

**1H2015:** The Company's revenue decreased by 26% Y-o-Y to reach \$83,000 in 1H2015, due to decrease in the dosage being prescribed to patients utilizing Ampligen<sup>®</sup> through the cost recovery program. Net loss during the period remained relatively flat at \$8.3MM primarily due to 22% decrease in general and administrative costs and moderate 10% increase in R&D expenses. Cash and cash equivalent stood at \$15.7MM as of June 30, 2015.

# Innovative product pipeline; Alferon N Injection<sup>®</sup> - Nearing Commercialization

Arrowhead is updating coverage on Hemispherx Biopharma Inc. with a fair value bracket of \$2.36 in the low bracket and \$2.96 in the high bracket scenario using the Discounted Cash Flow (DCF) Valuation Method.

Key Highlights: (1) Alferon N Injection® 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® for CFS;(4) Ampligen® received Orphan drug designation for treatment of Ebola in Europe; (5) The Company has applied to obtain Orphan drug designation for Alferon for the treatment of Middle Eastern Respiratory Syndrome (6) The Company has invested \$8MM to upgrade the Alferon® manufacturing facility and the management expects this facility to be approved in by mid-2016; (7) The Company has formed a strategic partnership with Armada Healthcare for the distribution & marketing of Alferon® through its strong network independent specialty pharmacies of Collaborated with Emerge Health for commercialization of Ampligen® and Alferon® in Australia and New Zealand and with myTomorrows for Early Access Program (EAP) in Europe and Turkey for Ampligen.

**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 \$2.36 to \$2.96 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 mid-2016 for treatment of refractory/recurring HPV genital warts and from 2018 for treatment of Vulvar Vestibulitis. We have also factored-in the revenue from Ampligen's EAP from 2016 in our estimates.



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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<sup>®</sup>, 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 that 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 immunosurveillance network. Disease severity in CFS correlates with NK activity: severe CFS cases have more NK deficiency. The Company intends to discuss these data with the FDA for use as a possible biomarker of CFS which may influence FDA's decision regarding the approval of Ampligen®.
- (4) In May 2015, Ampligen® received Orphan drug designation by the European Medicines Agency (EMA) for Ampligen to treat patients with Ebola Virus Disease (EVD) as they demonstrated broad anti-viral effects and can be produced at the Company's GMP facility in New Jersey. The Company collaborated with the US Army Research Institute of Infectious Diseases (USAMRIID) and in-vitro tests showed that Ampligen® successfully protects 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 EVD viral protein designated VP35 and could thus restore a patient's endogenous immune competency against the virus. Also, researchers at Howard University demonstrated that Ampligen® strongly inhibited the Ebola minigenome in the human embryonic kidney cell system.
- (5) The Company has also applied with EMA to obtain Orphan drug designation for Alferon® for the treatment of patients affected by Middle Eastern Respiratory Syndrome (MERS), with the final result expected by October 2015.
- (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 bio-reactor manufacturing. The management team expects the facility to be approved by mid-2016. The approval will be granted when the production of three sequential lots of finished product is completed and the data shows 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 made and approved using the older manufacturing process. The new bio-reactor can produce up to 600 liters of active ingredient (1,200 vials) at one time compared to 6 liters (12 vials) flask used earlier.
- (7) The Company has formed a strategic partnership with Armada Healthcare for the distribution and market Alferon® through a network of over 800 organizations which will in the aggregate encompass about 25,000 independent specialty pharmacy sites, serving physicians locally with sales and service. Hemispherx has partnered with GP Pharma for commercialization of Alferon® and Ampligen® in Argentina and elsewhere in Latin America. For Ampligen® in the U.S., Hemispherx will seek alliance with a qualified partner. Through its partner, Hemispherx commenced efforts in 2012 to gain approval of Ampligen® for CFS in Argentina. This effort is in its final stages. Recently, the Company has collaborated with Emerge Health and myTomorrows to commence EAP in Australia and New Zealand, and Europe and Turkey, respectively.
- (8) Hemispherx has 22 patents worldwide with 26 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®, an experimental compound, Ampligen®, and a new experimental drug delivery platform (a liquid natural interferon for oral administration), Alferon® LDO.

Ampligen® includes application as a treatment for CFS, Ebola and as an influenza vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® 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® has been developed to treat refractory and recurring genital warts, the Alferon® LDO formulation is currently under development for treating Influenza.

Hemispherx owns and operates a 44,000 sq. ft. FDA approved facility in New Brunswick, NJ for the production of Alferon® and Ampligen®. Approximately \$8MM 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® production in the upgraded facility and new Alferon® 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® 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, preclinical and clinical data with respect to the development of natural interferon and nucleic acids to enhance the natural antiviral defense system of the human body and to aid the development of therapeutic products for the treatment of certain chronic diseases.

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

Exhibit 1: Product Candidates Under Development vi					
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 Study Completed			
Ovarian Cancer	Ampligen <sup>®</sup>	Phase I/II Study Ongoing			
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 vii

## 2.1.1 Alferon N Injection®

**Product Specification:** Alferon N Injection<sup>®</sup> 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<sup>®</sup> 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:

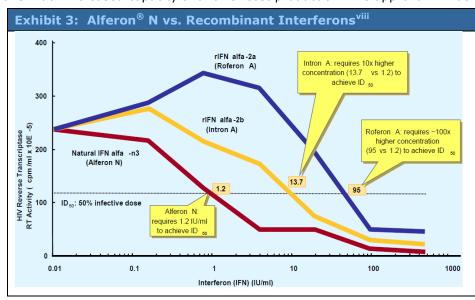
- 10 to 100 times more active in preclinical studies of HIV and SARS compared to Roferon and Intron
- In-vitro inhibition of MERS
- Negligible incidence of neutralizing antibodies (NAB's) i.e. less than 0.2%
- Multiple non-allelic genes may protect against neutralization of activity from initially induced NAB's administered against recombinant interferons
- Exhibit 3 depicts demonstrates that, Alferon<sup>®</sup> 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 44,000 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 possibly 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 typically prepare and distribute 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 $^{\otimes}$  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 defense against viruses and tumors. Ampligen<sup>®</sup> 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:** In September 2014, the Company had 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 Ampligen<sup>®</sup> as 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 Defense 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. Ampligen® was granted Orphan Drug Designation in May 2015 by EMA for the treatment of Ebola as they have exhibited broad antiviral effects.

## 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. The Company also envisions Alferon<sup>®</sup> LDO as a possible preventative against MERS.

## 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. Thomas K. Equels, Esq. has been appointed as President for Hemispherx Biopharma in August 2015. Prior to this, he was the Executive Vice Chairman, CFO, Secretary and General Counsel of the Company. He has been a Director on the Company's Board of Directors since 2008. He has worked as a legal counsel for over 25 years and has represented national and state governments, and companies in the banking, insurance, aviation, pharmaceutical, construction and development industries. He has also served as international counsel for the Republic of Panama and also as litigation counsel for the People's Republic of China's Chinese National Petroleum Corp. He has extensive international experience and has worked in Europe, South America, Asia and Africa.
- **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<sup>®</sup> 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 mid-2016.
      - 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 estimated \$700MM US market for HPV genital warts. Furthermore, Alferon® has received a marketing approval in Argentina for any patients who became refractory to recombinant alpha interferon. The Company is collaborating with Emerge Health to sell it under EAP in Australia and New Zealand and is working towards a similar agreement with myTomorrows for Europe and Turkey. Emerge will apply for required regulatory approvals while myTomorrows will help provide data, which could be in support for regulatory approval in European Union (EU).
    - **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<sup>®</sup> is identified as one of the few medications that protects against SARS virus infection in cell culture. The Company has also applied for obtaining Orphan Drug Designation for the treatment of patients with MERS and the final decision is expected by October 2015.

#### ii. Ampligen®:

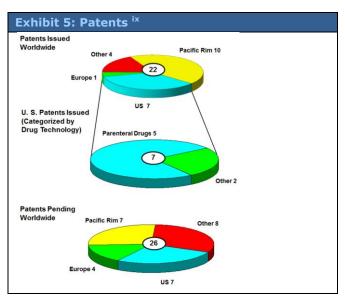
- **Patent Protection:** In May, 2014, Hemispherx was issued US patent 8,722,874 titled "Double-Stranded Ribonucleic Acids with Rugged Physiochemical structure and highly specific biologic Activity" by the United States Patent Office. This patent right will protect the Company's right to Ampligen® until 2029.
- **Orphan Drug Status:** The US FDA has granted 'Orphan drug' status to Ampligen<sup>®</sup> 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. The EU has also granted 'Orphan drug' status to Ampligen® for Ebola.



- **Potential Applications:** Hemispherx is conducting clinical trials in multiple indications because the Company believes that the use of Ampligen<sup>®</sup> 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.
  - 3. In conjunction with check point inhibitors for cancer Phase I/II clinical trials.

## - Favorable 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**<sup>®</sup>: 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.
- **Orphan drug designation for Ebola**: The Company's one of the two core products, Ampligen<sup>®</sup>, has received Orphan drug designation for treatment of EVD in EU due to the presence of certain unique structural feature such as:
  - i. Versatile Mechanism of Action: The work mechanisms of the drug has been categorized 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 Ampligen<sup>®</sup> to be highly effective in vitro against dangerous viruses. Ampligen<sup>®</sup> is found to be active in vitro against the Respiratory Syncytial Virus (RSV) that is structured in a form very similar to Ebola virus.
- **Manufacturing Facility:** Hemispherx exclusively owns a 44,000 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<sup>®</sup> and Ampligen<sup>®</sup>.



Extensive Patent Portfolio: As of June 30, 2015, Hemispherx has 22 patents worldwide with 26 additional pending patent applications 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 inmate 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 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<sup>®</sup>, approved resulting in an accumulated deficit of approximately of \$286MM as of June 30, 2015. 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 \$15.7MM as of June 30, 2015. 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. The Company's marketing strategy for Ampligen® used for CFS includes licensing/comarketing agreements, with an intent to use the resources and capacities of the strategic partners. For international marketing in Latin America, it has partnered with GP Pharma, which 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 is collaborating 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®. Emerge will also pursue with regulatory authorities in these countries to get the drug approved for general use. Until then, Emerge is working to provide Ampligen® under the regulations covering EAPs. Additionally, the Company has also recently collaborated with myTomorrows, which will commence EAP in



Europe and Turkey in 2016 and also provide the data which could help gain regulatory approvals in those countries.

- **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, 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®. The Company's arrangements with Emerge Health will also include EAP for Alferon in its territories, while it is working towards an agreement with myTomorrows in Europe and Turkey for the same.

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

Exhibit (	Exhibit 6: Collaborations						
Sr. No.	Institution	Indication	Hemispherx Product				
1.	University of Pittsburgh	Colorectal cancer	Ampligen <sup>®</sup>				
2.	University of Washington	Breast cancer	Ampligen <sup>®</sup>				
3.	Institute of Antiviral Research, Utah State University	MERS-CoV	Ampligen <sup>®</sup> & Alferon <sup>®</sup>				
4.	University of Georgia	PD-1 Checkpoint Inhibitors: Cancer	Ampligen <sup>®</sup>				
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 <sup>®</sup> Alferon <sup>®</sup>				
6.	Center of Biodefense and Emerging Disease, University of Texas Medical Branch	MERS-CoV (Middle East Respiratory Syndrome)	Ampligen <sup>®</sup> Alferon <sup>®</sup>				
7.	University of Alabama at Birmingham, Clinical Research Group	Seasonal/Pandemic Flu	Ampligen <sup>®</sup> with FluMist <sup>®</sup>				
8.	Swiss Department of Defense	H7N9/Ebola	Ampligen <sup>®</sup> & Alferon <sup>®</sup>				
9.	Rocky Mountain Labs (NIH)	MERS	Alferon <sup>®</sup>				
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 *					
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			
Total Shares Outstanding	100%	215,095,559			

Exhibit 8: Top 10 Funds Shareholders xi			
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 InstlPls	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	
Total Shares Outstanding	100%	215,095,559	

# 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 xii

# 3.1 Alferon N Injection® - Sales (Number of patients) - Refractory or Recurring External Genital Warts

Arrowhead is estimating Hemispherx to start generating revenue from its Alferon N Injection® from 2016 onwards for it 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, which will take a year to set-up. Following this, the Company 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 80-90% of their annual production volume by 2021.

Exhibit 9: Alferon N Injection® - Number of patients treated – Refractory or Recurring External Genital Warts						
In '000	2016E	2017E	2018E	2019E	2020E	2021E
Low estimate	9	36	56	76	78	80
High estimate	10	41	63	86	88	90

# 3.2 Alferon N Injection<sup>®</sup> - Revenue per patient during the course of treatment - Refractory or Recurring External Genital Warts

It is estimated that the product will generate revenue in the range of \$2,666 per patient during the course of treatment.

Exhibit 10: Alferon N Injection® - Revenue per patient during the course of treatment - Refractory or Recurring External Genital Warts			
In US\$/course			
Estimated revenue during the course of treatment	2,666		

# 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<sup>®</sup>. The Company is likely to spend \$2MM in 2017 and another \$2MM in 2018 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			



# 3.4 Ampligen® - Sales (\$ '000) - Chronic Fatigue Syndrome (CFS)

Arrowhead estimates that Hemispherx will start generating revenue from Ampligen® drug from 2016 onwards for CFS indication through EAP. According to Centers for Disease Control and Prevention (CDC), there are approximately two million seriously affected CFS patients in the US and European region. We expect the EAP of Ampligen to launch in 2016. We estimate the Company to treat approximately 25-50 patients in 2016, which will increase gradually to 500-800 patients in 2021<sup>xiii</sup>. We expect cost of Ampligen® during the treatment to be \$575 per 200mg vial. The normal course of treatment would last for 24 weeks and patients would receive four vials per week. Based on our assumptions we expect the company's total revenue generated from Ampligen® to be as follows:

Exhibit 12: Ampligen <sup>®</sup> - Sales (in \$ '000) - Chronic Fatigue Syndrome (CFS)						
In '000	2016E	2017E	2018E	2019E	2020E	2021E
Low estimate	1,380	2,760	5,520	11,040	22,080	27,600
High estimate	2,760	5,520	11,040	22,080	33,120	44,160



#### 4. News xiv

- Hemispherx Biopharma announces patient assistance program for CFS open label study: Hemispherx Biopharma, Inc., announced on September 17, 2015 the approval by the Board of Directors for a Patient Assistance Program for the open-label AMP-511 study of Ampligen® in CFS patients. Recently the company announced the first increase in the cost of the drug in 17 years. The Patient Assistance Program will allow the patients currently on the open-label treatment protocol to continue to receive the drug, through March 2016, at the cost-recovery rate in effect when they entered the study.
- Hemispherx Biopharma Extends its Strategic Alliance with Armada Health Care for Alferon N Injection®: On August 17, 2015 Hemispherx Biopharma, Inc. announced that as the Company works toward the re-launch of Alferon N, it has extended its agreement with Armada Health Care, LLC for two years (through August 14 2017) for the sales/marketing of Alferon N Injection®. Under this Agreement, the Company will manufacture and supply Alferon N Injection® to physicians and patients through Armada's national network of specialty pharmacies. Armada has agreed to provide ongoing sales and marketing to support the product's relaunch.
- Hemispherx Biopharma Announces Financial Results for the Six Months Ended June 30, 2015: On August 11, 2015, announced its financial results for the six months ended June 30, 2015. The net loss narrowed to \$8.3MM or \$(0.04) per share as compared to a net loss of \$8.8MM or (\$0.05) per share for the same six month period in 2014. Cash, cash equivalents and marketable securities were approximately \$15.7MM at June 30, 2015 as compared to \$16.1 as of December 31, 2014.
- Hemispherx expands its collaboration with Emerge Health for the commercialization of Alferon® in Australia and New Zealand: Hemispherx Biopharma, Inc. reported on August 11, 2015 that it has executed an agreement with Emerge Health Pty Ltd. to seek approval of Alferon N Injection® in Australia and New Zealand and to commence distribution of Alferon in both countries on a named patient basis, where deemed appropriate. Hemispherx and Emerge will collaborate on seeking regulatory approval from Australia's Therapeutic Goods Administration and New Zealand's Medicines and Medical Devices Safety Authority.
- Hemispherx Enters into an Agreement with myTomorrows for an EAP for Rintatolimod in Europe: On August 10, 2015 Hemispherx Biopharma, Inc. announced that it has executed an agreement with Impatients, N.V., a Netherlands based company doing business as myTomorrows, for the commencement and management of an EAP in all of Europe and Turkey. myTomorrows, as Hemispherx' exclusive service provider in Europe and Turkey, will perform EAP activities in Europe and Turkey to include the supply of rintatolimod for the treatment of CFS to patients with an unmet medical need.
- Hemispherx Biopharma Europe Submits application for Orphan Medicine Designation to the EMA for Alferon N Injection® for treatment of MERS: On July 15, 2015, Hemispherx Biopharma, Inc. announced that they have submitted an application for orphan drug designation to the EMA for Alferon N Injection®, an experimental therapeutic, to treat MERS. The EMA has determined the application to be valid, and the Committee for Orphan Medicinal Products (COMP) has initiated the official review process. It is anticipated that the COMP will give an opinion on the application within the next 90 days.
- Hemispherx Biopharma Europe receives Orphan Medicine Designation by the EMA for Ampligen to treat patients with EVD: On May 11, 2015, Hemispherx Biopharma, Inc. announced that it received a formal notification from the European Commission approving its Orphan Medicinal Product Application for Ampligen<sup>®</sup>, an experimental therapeutic, to treat EVD. Benefits for achieving orphan drug designation, including eligibility for grants from EU and Member State programs as well as initiatives supporting research and development encompassing clinical protocol design assistance. Designated orphan medicines are assessed for marketing authorization centrally in the EU with reductions/waivers in the fees and costs of the overall regulatory process. Authorized orphan medications, once commercially approved, receive benefits including ten years of complete protection from market competition with similar medicines. Sponsors may also have access via orphan designation to conditional approval, which is also conducted under the centralized procedure.
- 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<sup>®</sup>, to treat EVD. Orphan designation by the 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 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**<sup>®</sup> **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<sup>®</sup>.
- 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<sup>®</sup>, 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® N and Ampligen®, 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.



# 5. Management and Governance xv

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 13: Ma	Exhibit 13: Management Team					
Name	Age	Position	Past Experience			
Dr. William A. Carter	75	Chairman of the Board, CEO, Chief Scientific Officer	<ul> <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®</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> <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> <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® 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® NDA</li> <li>At present, he is managing a capital improvement budget to enhance the Company's Alferon® facility in accordance with current Good Manufacturing Practice ("cGMP")</li> </ul>			



			• In the past, he had served World Fashion Concepts in New York and oversaw operations at several locations throughout the United States and overseas
Mr. Adam Pascale	67	Chief Accounting Officer	<ul> <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> <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> <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>



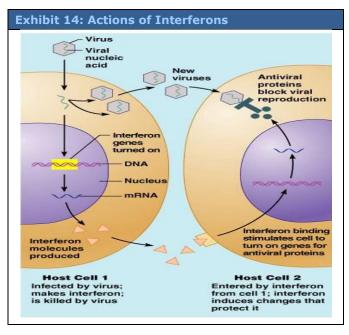
### 6. Technologies and Markets

## 6.1 Interferon<sup>xvi</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. \*\*Viii\*\* 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. \*\*Viii\*\*

### 6.2 General Action of Interferons xix



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.\*

## 6.4 Functions of Alpha and Beta xxi

- 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



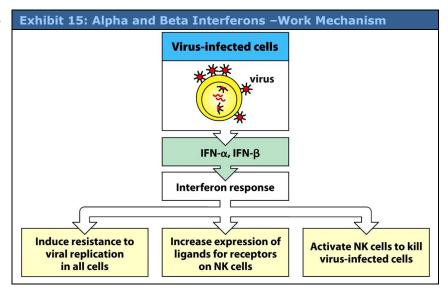
#### 6.5 Alpha and Beta Work Mechanism

- Alpha and beta bind to heterodimeric receptor on cell surface
- Alpha receptor is made up of at least 2 polypeptide chains named as IFNa-R1 and IFNa-R2
- IFNa-R1 is involved in signal transduction
- IFNa-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 transductors and activators of transcription proteins, which translocate to the nucleous as a trimeric complex, ISGF-3.
- ISGF-3 activates transcription of interferon stimulated genes, with many biological effects

## 6.6 Alpha Interferon xxii

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\*\*xiii

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.

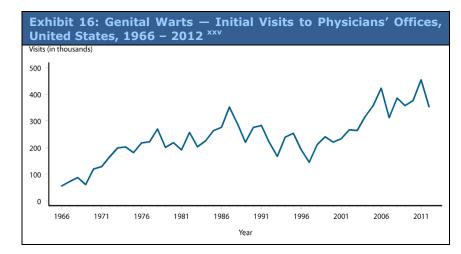
Hemispherx produces the only commercially available natural-source, multispecies Alpha Interferon in the US. Hemispherx' Natural Alpha Interferon consists of a specific blend of proteins containing many different molecular species of alpha interferon; recombinant interferons contain only a single protein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

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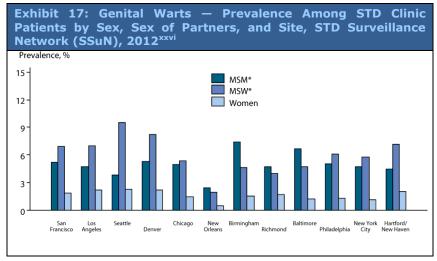
## 6.8 Anogenital Warts market xxiv

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.



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.



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.  $(\sim.12\%)$ . 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 gynecological 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) \*\*xvii\*\* estimates that in US between 1MM to 4MM Americans are affected by the disease.

CFS is serious, debilitating conditions that have negative economic consequences at both the individual and the societal level. The direct and indirect economic costs of ME/CFS to society have been estimated at \$17BN to \$24BN\*\*viii annually. High medical costs combined with reduced earning capacity often have devastating effects on patients' financial status. Also, cancer, heart disease, and suicide are the most common causes of death among those diagnosed with CFS, and people with CFS die from these causes at younger ages than others in the general population.

## **Immune System Connection**\*xix

CFS is characterized 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.



### 7. Valuation

The Fair Market Value for all of Hemispherx's shares stands between \$581MM and \$731MM as of September 28, 2015. The Fair Market Value for one of Hemispherx's publicly traded regular shares stands between \$2.36 and \$2.96 as of September 28, 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>xxx</sup>
Beta	0.81 <sup>xxxi</sup>
Market Return	9.4% <sup>xxxii</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 $^{\circledR}$ and Ampligen $^{\circledR}$	Revenue per course of treatment and revenue per vial
Refer to <i>Key Variabl</i> i	es Analysis section

Year Ending - December	2015E	2016E	2017E	2018E	2019E	2020E	2021E
FCFF (High)							
Net cash from operating activities	(19,456)	18,135	83,000	136,689	184,467	121,012	128,609
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	(19,552)	16,972	81,696	135,229	182,832	119,181	126,558
Discount factor	0.88	0.77	0.68	0.60	0.53	0.46	0.41
Present Value of FCFF	(17,200)	13,134	55,619	80,989	96,327	55,239	51,602
FCFF (Low)							
Net cash from operating activities	(19,456)	12,913	63,383	102,500	140,047	143,284	100,442
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	(19,552)	11,749	62,080	101,041	138,413	141,453	98,391
Discount factor	0.88	0.77	0.68	0.60	0.53	0.46	0.41
Present Value of FCFF	(17,200)	9,092	42,264	60,514	72,924	65,561	40,117

Arrowhead Fair Value Bracket	High	Low	
Terminal Value (TV)	965,477	750,601	
Present Value of TV	393,656	306,044	
Present value of FCF	335,709	273,272	
Present Value of FCF + TV	729,365	579,317	
Net Debt	(2,134)	(2,134)	xxxiii
Equity Value Bracket	731,499	581,451	
Shares on issue ('000)	246,887	246,887	xxxiv
Fair Share Value Bracket (\$)	2.96	2.36	
Current Market price (\$)	0.17	0.17	xxxv
Current Market Cap. (\$) MM	42	42	
Target Market Cap. Bracket (\$) MM	731	581	



#### **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<sup>®</sup>.

**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 (Number of patients) - Refractory or Recurring External Genital Warts

Exhibit 18: Alferon N Injection® - Sales (Number of patients) – Refractory or Recurring External Genital Warts								
In '000	2016E	2017E	2017E 2018E		2020E	2021E		
Low estimate	9	36	56	76	78	80		
High estimate	10	41	63	86	88	90		

# Alferon N Injection® - Revenue per patient during the course of treatment- Refractory or Recurring External Genital Warts

	injection <sup>®</sup> - Revenue per Refractory or Recurring S
In US\$/course	
Estimated revenue during the course of treatment	2,666

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

Exhibit 20: Alferon N Injection® - Revenue per course of treatment - Vulvar Vestibulitis  In US\$/course  Low estimate 10,800		
In US\$/course		
Low estimate	10,800	
High estimate	13,500	

# Ampligen® - Sales (Number of patients treated) - CFS

Exhibit 21: Ampligen® - Sales (Number of patients treated) - CFS									
In	2016E	2017E	2018E	2019E	2020E	2021E			
Low estimate	25	50	100	200	400	500			
High estimate	50	100	200	400	600	800			

### Ampligen® - Revenue per month per patient during the course of treatment - CFS

Exhibit 22: Ampligen® during the course of to	
In US\$/month	
Estimated price per month	9,200

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 highbracket 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 27 of this report.



# 8. Appendix

# **Hemispherx's Balance Sheet Forecast - High Estimates**

Exhibit 23: Consolidated Balance Sheet \$ '000	High Brack	High Bracket estimates									
Year Ending December 31	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	
Total current assets	44,728	18,552	16,507	12,287	31,358	128,249	283,878	489,100	624,268	767,034	
Total Non-current assets	12,971	13,315	12,933	12,734	13,605	14,543	15,557	16,655	17,847	19,145	
TOTAL ASSETS	57,699	31,867	29,440	25,021	44,963	142,792	299,435	505,755	642,115	786,179	
Total current Liabilities	12,649	2,532	4,436	5,257	13,420	45,972	76,078	99,916	101,781	101,090	
Total Non-current Liabilities	350	37	-	3,000	1,500	-	-	-	-	-	
TOTAL LIABILITIES	12,999	2,569	4,436	8,257	14,920	45,972	76,078	99,916	101,781	101,090	
Total Shareholder's Equity	44,700	29,298	25,004	16,763	30,043	96,820	223,357	405,839	540,334	685,089	
TOTAL LIABILITIES & EQUITY	57,699	31,867	29,440	25,021	44,963	142,792	299,435	505,755	642,115	786,179	

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

Exhibit 24: Consolidated Balance Sheet \$ '000	Low Brack	Low Bracket estimates									
Year Ending December 31	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	
Total current assets	44,728	18,552	16,507	12,287	26,098	103,318	223,859	383,271	538,671	650,915	
Total Non-current assets	12,971	13,315	12,933	12,734	13,605	14,543	15,557	16,655	17,847	19,145	
TOTAL ASSETS	57,699	31,867	29,440	25,021	39,702	117,861	239,415	399,926	556,518	670,061	
Total current Liabilities	12,649	2,532	4,436	5,257	13,974	48,632	80,487	106,763	109,597	109,960	
Total Non-current Liabilities	350	37	=	3,000	1,500	-	-	-	-	=	
TOTAL LIABILITIES	12,999	2,569	4,436	8,257	15,474	48,632	80,487	106,763	109,597	109,960	
Total Shareholder's Equity	44,700	29,298	25,004	16,763	24,228	69,229	158,928	293,163	446,921	560,101	
TOTAL LIABILITIES & EQUITY	57,699	31,867	29,440	25,021	39,702	117,861	239,415	399,926	556,518	670,061	



#### 9. Analyst Certifications and Important **Disclosures**

#### **Analyst certifications**

I, Abhishek Bansal, 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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#### 10. Notes and References

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Source: Bloomberg, September 28, 2015
       52 weeks to September 28, 2015. Source: Bloomberg, September 28, 2015
       3 months to September 28, 2015. Source: Bloomberg, September 28, 2015
       Arrowhead Business and Investment Decisions Fair Value Bracket - AFVBTM. See information on valuation on pages 23-25 of this report and important disclosures on page 27 of this report.
       Source: Company Website and Company Documents
vi
       Source: Company Website
vii
       Source: Hemishperx 10Q – 30 September 2014
       Source: Company Management
       Source: Company Management
       Source: Company management
хi
       Source: Company management
xii
       Source: Arrowhead BID estimate
xiii
       Source: Company management
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       Source: Company website - Press Release section
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       8OdK0uAS7oICYCw&ved=0CDQQFjAGOAo&usg=AFQjCNHdqKhqJUOH-2SMrk41w8jYNc3y7g
       Source: Company Website
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       Source: http://www.bio.davidson.edu/Immunology/Students/spring2006/V_Alvarez/IFN-gamma.html
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        Source: Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness - Institute of Medicine of the National Academies
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       Source: Bloomberg
       Source: Bloomberg
xxxii
       Source: Bloomberg
xxxiii
       Source: Company Documents, Cash (as on December 31, 2014) and Debt (As on December 31, 2014)
xxxiv
      Shares as on September 28, 2015
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Source: Bloomberg, September 28, 2015