Hemispherx Biopharma

AMEX: HEB

Restart of Alferon production should drive revenues and earnings in the medium-term

Hemispherx Biopharma, Inc., a specialty pharmaceutical company, is engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of: viral/immune based chronic disorders, Flu, and Ebola. It has two products, Alferon and Ampligen. Alferon N Injection, the key near term driver, is an injectable formulation of natural alpha interferon for the treatment of refractory genital warts.

Investment Thesis

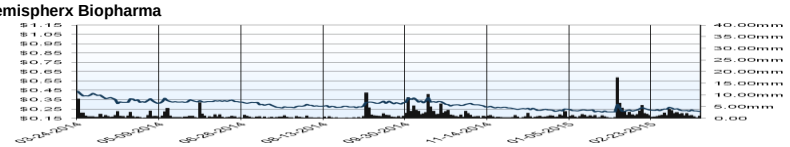
1) Alferon N Injection is a commercially ready FDA-approved product for treating refractory/recurring HPV genital warts. It has advantages over recombinant interferon: greater potency, fewer side effects and far lower incidence of neutralizing antibodies. We forecast potential revenue of about $70-100M in 2016 and the start of sustainable corporate profitability.
2) Alferon has a broader approval for patients refractory to recombinant interferon for all indications in Argentina including: genital warts, Hepatitis C, and, MS.
3) Alferon production is likely to be approved for commercialization by the FDA because: HEB uses the same process approved earlier although now on a larger scale as HEB invested in high capacity, sophisticated equipment. The upgraded facility can produce Alferon at greater volumes with more consistent quality.
4) Long Term Revenue Potential: There are additional off label uses for Alferon in the U.S which may result in material revenues several years down the road. In addition, Ampligen holds promise for the treatment of Chronic Fatigue Syndrome, if and when approved by the FDA.
5) New biomarker on the horizon for chronic fatigue syndrome which could potentially change the outcome for Ampligen.
6) Recent positive opinion re:Orphan Approval in Europe for Ebola.

HEB's stock has significant upside:

We initiate coverage with a Strong Buy/Speculative Risk rating. We value the stock at $1.45/share in 12 months, based on a discounted cash flow analysis related to U.S. and Argentina sales of the Alferon N injection product, focused on treatment of HPV-related Genital Warts.

Risks: 1) It is uncertain when the company's upgraded facility will be approved for production by the FDA 2) Failure to execute Internationally may stunt growth expectations 3) The company will likely require additional funding to commercialize Alferon N Injection and 4) Such financing may be dilutive to existing shareholders.

Hemispherx Biopharma



Rating	**Strong Buy**
Risk Rating	**Speculative**
Current Price (Mar 31, 2015)	**$0.23**
12-month Price Target	**$1.45**
Implied dividend yield	**0%**
Projected total return	**+530%**
Shares outstanding (M)	215.1
Market capitalization (M)	$49.5
Long term debt (MRQ)	$0.0
Cash (MRQ)	$16.1
Enterprise value	$32.3
EV/REV (2016)	2.9x
Rev Estimate (2016)	$92.3
Float as % of shares out.	98.5%
Short interest as % of Float	0.1%
Insider ownership	1.5%
Institutional ownership	6.3%
Tangible book value p/s	$0.14
Cash/share	$0.08

Revenue (M)				
Dec	2014A	2015E	2016E	2017E
Q1	NM	NM	NM	NM
Q2	NM	NM	NM	NM
Q3	NM	NM	NM	NM
Q4	NM	NM	NM	NM
FY	$0.2	$0.2	$87.3	$197.5

EBITDA (M)				
	2014A	2015E	2016E	2017E
Q1	NM	NM	NM	NM
Q2	NM	NM	NM	NM
Q3	NM	NM	NM	NM
Q4	NM	NM	NM	NM
FY	($18.0)	($14.3)	$30.7	$77.9

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II. Company Description

Hemispherx Biopharma, Inc., a specialty pharmaceutical company close to re-commercialization of Alferon N Injection, an FDA approved drug for condyloma acuminata (genital warts), HEB has upgraded its manufacturing facility and is now seeking approval of an amended Biologics License Application. The company's upgraded manufacturing facility employs a state-of-the-art bioreactor (at a cost of about $8 million) and other equipment to produce Alferon N Injection on a larger scale as compared to the previously used manual-based process, with equal or better quality. The new equipment for producing Alferon N Injection (which was approved in 1989 by the FDA) provides better quality control, increased capacity, and lower cost of goods sold. The current challenge Hemispherx faces is the approval of Alferon's upgraded production process. The FDA requires approval of changed manufacturing processes for existing biological products.

Research and Development

The company's research and development projects are targeting treatment therapies for Chronic Fatigue Syndrome (CFS), various cancers (as a vaccine adjuvant), and other viral diseases, such as prevention and treatment of seasonal and pandemic influenza. In 2012, the Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT) approved the sale and distribution of Alferon N Injection (under the brand name Naturaferon) in Argentina with broader approval than has been given in the U.S. In addition, Alferon LDO [Low Dose Oral Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon.

Patents and Non-Patent Exclusivity Rights

As of December 31, 2014, HEB had 25 patents worldwide with 27 additional pending patent applications comprising its intellectual property. In 2014, HEB filed for three new patents that are currently pending. One patent pending is for use of Ampligen as a vaccine adjuvant for use with seasonal influenza vaccine to induce an enhanced immune response. The second is for use of Ampligen as a method of diagnosing and stabilizing CFS symptoms in patients. The third is for use of Alferon N Injection® as a possible treatment for Oseltamivir Resistant Avian Origin Influenza A (H7N9 virus).

In May, 2014 a new composition of matter patent was issued to inventors Carter, et al, and assigned to Hemispherx Biopharma for "Double Stranded Ribonucleic Acid with Rugged Physiochemical Structure and Highly Specific Biological Activity." Rugged dsRNA tend to have high specificity of binding to Toll-Like Receptors (TLR3), and this brings a significant range of therapeutic opportunities. This newly discovered form of dsRNA has increased bioactivity and binding affinity to the TLR3 receptor. The issuance of this patent helps insure that Hemispherx will retain patent protection for novel formulations of and various uses of Ampligen until 2029.

Product Candidates Under Development

Hemispherx Biopharma Inc. has developed over nearly three decades a vast body of knowledge relating to a potentially new class of pharmaceutical products (nucleic acid compounds) that are designed to activate otherwise dormant cellular defenses against viruses and tumors. Hemispherx pursues commercialization of these products and has a strong and broad-based patent base.

Indication	Product Candidate	Status
Influenza Adjuvant	Ampligen®	Phase I/II Recruiting
Chronic Fatigue Syndrome	Ampligen®	Phase III Recruiting
Asymptomatic HIV	Alferon LDO®	Phase II Terminated
HIV Failing HAART	Ampligen®	Phase II Terminated
HIV HAART Adjuvant	Ampligen®	Phase II Completed
Chronic Fatigue Syndrome	Ampligen®	Phase III Completed
Severe Acute Respiratory Syndrome	Ampligen®	Phase I/II Study Ongoing
Ovarian Cancer	Alferon LDO®	Phase II Completed
Colorectal Cancer	Chemokine-Modulatory Regimen	Phase I/II Recruiting
Colorectal Cancer	Ampligen®	Phase I/II Study Ongoing

Source: ClinicalTrials.gov

II. Investment Thesis

1. Alferon N Injection

Alferon N has a competitive advantage for treating refractory HPV genital warts patients compared with recombinant interferons because Alferon N Injection uses the only natural interferon which has the benefits of greater potency than recombinant interferons, has fewer side effects, generates far lower incidence of neutralizing antibodies and restores the positive effect first seen with recombinant interferons. This advantage gives Alferon N ability to price in the $1,200 to $2,000 range, with $1,700+ being a high likelihood given that Merck's product Intron A costs $1,666 per equivalent treatment (5 million International Units or IUs). Alferon is an FDA-approved product with commercialization depending on upgraded manufacturing approval by the FDA (same process larger quantities) within a year.

Our expectation is that the upgraded manufacturing process for Alferon N is approved, and factoring in the penetration of patients with refractory genital warts, we expect meaningful revenue in later years (see assumptions section).

Market Size

To estimate the size of the U.S. market the company used a conservative number of potential patients, 180,000, and multiplied by the possible range of prices per treatment. As shown in the table below, varying the price per treatment from $1,400 to $4,000 yields a range in the size of the market from about $250 million on the low side to $720 million as the upper end of the range.

AWP/vial	Price/Treatment	Patients	Market Size ($)
$700	$1,400	180,000	~$250,000,000
$1,000	$2,000	180,000	~$360,000,000
$1,200	$2,400	180,000	~$400,000,000
$2,000	$4,000	180,000	~$720,000,000

Source: Company Reports

Alferon's upgraded manufacturing process is likely to be approved by the FDA because: HEB uses the same process that was approved and used earlier although now on a larger scale and HEB invested in high capacity, sophisticated equipment, which should allow good quality control. The company must produce three sequential lots of finished product and data showing at least three months stability with concomitant laboratory tests demonstrating that product made in the upgraded facility is analytically the same as the product approved and made using the original low-volume manufacturing methods.

HEB's marketing distribution alliance with Armada

HEB's marketing/distribution alliance with Armada, a network of specialty pharmacies, will be key to the sales of Alferon N Injection® Armada works through a network of approximately 400 specialty pharmacies which service their local areas with sales support, education, and product. These types of pharmacies are from which most of the modern high value biotechnology therapeutic products are dispensed. Hemispherx will support them with technical, clinical, and educational support. Armada will 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 seeking additional alliances which may be co-promotion in nature, to educate physicians treating patients (women and men) with HPV genital warts. Hemispherx will also seek relationships directly with relevant physician group practice networks.

2. Argentina- Broader approval for Alferon

In early 2013, Alferon was approved in Argentina under the brand name "Naturaferon" for the treatment of patients who have failed or become intolerant to recombinant interferon. The indication is much broader relative to the U.S as it includes patients with genital warts, hepatitis C, multiple sclerosis, certain cancers and other diseases which should not be treated with recombinant interferon, including pegylated alpha interferon.

Alferon is partnered in Argentina/Latin America with GP Pharma for the commercialization of Alferon. GP Pharm believes the approval should result in expanded insurance coverage. GP Pharm also seeks to expand the approval of Alferon in other countries in Latin America. Latin American represents about 14% of the worldwide market for the $6BN worldwide interferon market. The near term commercialization of Alferon in Argentina is contingent on approval of Alferon's manufacturing facility in New Brunswick by the FDA. In the long run, Alferon N Injection® might be manufactured in Argentina.

3. Long Term Revenue Potential

Aside from patients using Alferon for its on label uses, there are additional off label uses which may result in material revenues several years down the road. In addition, Ampligen holds promise for the treatment of Chronic Fatigue Syndrome, if and when it is approved by the FDA.

CFS is a debilitating disease with huge economic burden. CFS is an illness defined by disabling physical/mental fatigue and symptoms that cannot be explained by conventional medical and psychiatric diagnoses. CFS affects between 400,000 and 800,000 people in the U.S. with about 14% suffering the severe form of the disease. CFS has an average duration of 5 years but symptoms can persist as long as 20 years.

When Ampligen will be approved is uncertain, but, if approved, commercialization would occur fairly quickly and the ramp-up of sales is expected to be rapid with peak US sales at years 5 to 7 post-launch. Separately, and without any additional clinical trials, Hemispherx seeks to gain the approval of Ampligen for CFS in Argentina. If approved, Hemispherx and its local partner will work to expand the approval to other Latin American countries. Hemispherx is also working to generate “named patient sales” in relevant non-US countries.

Preliminary pharmacoeconomic analysis of Ampligen for CFS indicate a price for a 26 week course of treatment of between $50,000 and $100,000. Assuming 600,000 people affected, 14% of those is 85,000 people with 5% penetration at $75k/treatment equals $320M of revenue

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. Researchers at Cornell discovered a deficiency in the production of alpha-interferon in women with VVS. There is significant correlation between HPV and VVS, hence the possibility to extend the approved indication for Alferon N to include HPV-related VVS with a Phase IV study.

The population of women in the U.S. between the ages of 16 and 45 is an estimated 60 million and if only 1% seek treatment and 10% of those are treated with Alferon that would yield 9,000 patients. With a price per 12 week course of treatment for Vulvar Vestibulitis of about $15,000, the potential revenue would be approximately $135M.

III. Products and Competition

Alferon N Injection

Alferon N Injection® is the registered trademark for the company’s injectable formulation of natural alpha interferon, which is approved by the FDA for the treatment of certain categories of Human Papiloma Virus (HPV) genital warts. Alferon is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or recurring external genital warts in patients 18 years of age or older. The benefits of using a natural alpha interferon are increased potency and efficacy compared to recombinant interferon probably due to the multispecies interferon like what humans make naturally in response to viruses and less severe side effects because Alferon N Injection is “natural”, not “foreign”

Competitive Therapies to Alferon N

There are a number of methods for treating genital warts including:

- Cryotherapy, a method of freezing off the warts with liquid nitrogen.
- Laser therapy (using an intense coherent light to destroy the warts).

- Surgery (cutting off warts).
- Condylox (also called Podophyllin), a typical cream with a high recurrence rate.
- Imiquimod, a topical cream is widely used but has a high recurrence rate and needs to be washed off 6-10 hours after being administered.
- Intron A recombinant interferon which is less potent than natural interferon and has more severe side effects.

Ampligen

Ampligen is an experimental drug undergoing clinical development for the treatment of CFS. The company's drug technology utilizes specifically-configured RNA. Its double-stranded RNA drug product, trademarked Ampligen®, is an experimental, not yet approved drug, that would be administered intravenously. Ampligen has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I) poly(C12U).

In 2012, the company filed a new drug application for Ampligen with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT's Orphan Drug regulations.

In March of this year, the company entered into an agreement with with Emerge Health, Pty in Australia to, among other things, seek approval of Ampligen for CFS in Australia and New Zealand.

IV. Understanding the Science

Human Papilloma Virus (HPV) the Most Common Sexually Transmitted Infection (STI) often results in Genital Warts.

The U.S. Centers for Disease Control and Prevention (CDC) published an analysis in February 2013 of sexually transmitted infections (STI's) in the United States. Of the roughly 20 million new sexually transmitted infections Human Papilloma Virus (HPV) is by far the most common, accounting for about 70% of new STIs each year. The other most common STIs, are chlamydia, trichomoniasis, gonorrhea, herpes simplex virus2 (HSV–2), syphilis, human immunodeficiency virus (HIV) and hepatitis B, virus (HBV), in descending order.

The CDC estimates that HPV accounts for the majority of newly acquired STIs. HPV has the largest incidence of STIs with 79.1 million out of an estimated 110.2 million. HPV accounts for the majority of prevalent STIs in the United States. While there is no treatment for the virus itself there are treatments for the serious diseases that HPV can cause and vaccines are available to prevent some types of HPV infection.

HPV is so common that at least 50% of sexually active men and women get it at some point in their lives. While the vast majority (90%) of HPV infections will go away on their own within two years and cause no harm, some of these infections will take hold and potentially lead to serious diseases including genital warts and cervical cancer. Although they do not usually result in death, genital warts are painful and frequently cause significant emotional stress.

Of the estimated 14 million people per year who are infected with the HPV virus and develop genital warts, how they are treated depends on the protocol in place from whom they seek treatment.

After these treatment options have been tried, many patients are left with recurring, refractory genital warts. The number of these patients is estimated at somewhere between 180,000 up to 2-to-3 times that number annually. To calculate the potential market in the US for which Alferon N Injection is approved, we will conservatively use the low end of that range, 180,000 patients.

Vulvar Vestibulitis is also a Major Problem

Vulvar Vestibulitis Syndrome, which produces a highly localized burning type of pain in women's vulvar region, is the most common type of vulvodynia affecting about 10% to 20% of pre-menopausal women seeking gynecological care. One of the causes is thought to be human papilloma virus infection as It appears to be HPV-related. There have been studies where Alferon was administered and the patients showed great recovery, but these were not controlled studies.

Further clinical trials will need to be run to see if Alferon can be approved for treatment. As the safety of Alferon has already been established in both clinical testing and extensive usage, Hemispherx may be able to go to a phase 3 pivotal study to gain FDA approval.

This seems a likely project once Alferon is back in production and on the market and generating revenue. If the company started to organize the study in 2017 and get test sites lined up, such testing might start in late 2017. The study would probably run into 2018. To summarize the results and submit them to the FDA would probably extend a year so that it would be 2019-2020 before it would be FDA approved. The overall time horizon to perform such a study and gain approval would probably be 3 to 5 years.

Alferon

Alferon N Injection®

Alferon N Injection® is the registered trademark for Hemispherx's injectable formulation of natural alpha interferon, which was approved by the FDA in 1989 for the treatment of certain categories of genital warts. Alferon® is the only natural-source, multi-species alpha interferon currently approved for sale in the U.S. for the intralesional (within lesions) treatment of refractory (resistant to other treatment) or

recurring external genital warts in patients 18 years of age or older. Certain types of human papilloma viruses (HPV) cause genital warts, a sexually transmitted disease.

Interferons are a group of proteins produced and secreted by cells to combat diseases. Researchers have identified four major classes of human interferon: alpha, beta, gamma and omega. Alferon N Injection® contains a multi-species form of alpha interferon. When the injectable alpha interferon-based products were first marketed, they experienced rapid growth and various alpha interferon injectable products are approved for many major medical uses worldwide.

Advantages

The potential advantages of natural alpha interferon over recombinant (synthetic) interferon produced and marketed by other pharmaceutical firms may be based upon their respective molecular compositions. Natural alpha interferon is composed of a family of proteins containing many molecular species of interferon. In contrast, commercial recombinant alpha interferon products each contain only a single species the most prevalent but not the most potent one. Researchers have reported that the various species of interferons may have differing antiviral activity depending upon the type of virus. Natural alpha interferon presents a broad complement of species, which the company believes may account for its higher potency in laboratory studies.

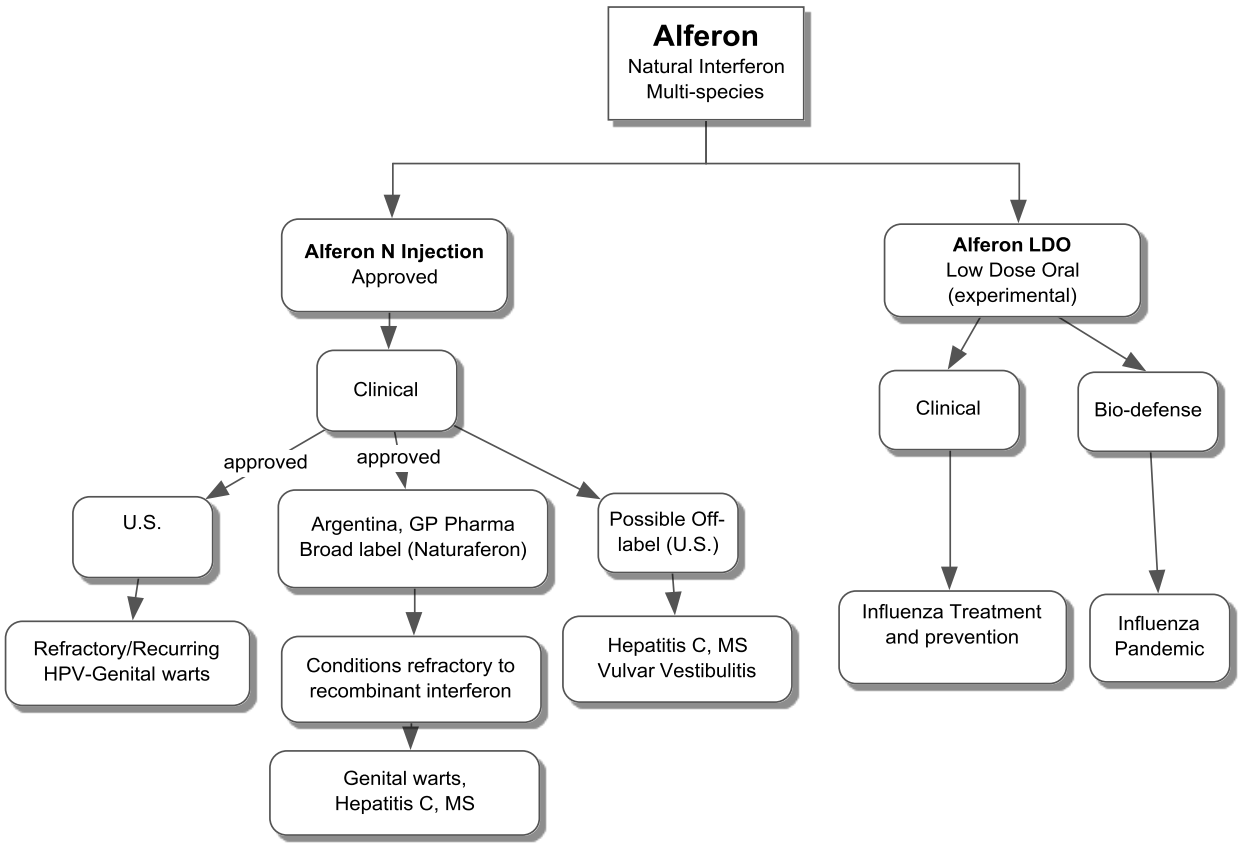
Natural alpha interferon is also glycosylated (partially covered with sugar molecules). Such glycosylation is not present on the currently U.S. marketed recombinant alpha interferons. The company believes that the absence of glycosylation may be, in part, responsible for the production of interferon-neutralizing antibodies seen in patients treated with recombinant alpha interferon. Although cell culture-derived interferon is also composed of multiple glycosylated alpha interferon species, the types and relative quantity of these species are different from HEB's natural alpha interferon.

Alferon N Injection® [Interferon alfa-n3 (human leukocyte derived)] is a highly purified, natural-source, glycosylated, multi-species alpha interferon product. There have been essentially no antibodies observed against natural interferon to date and the product has a relatively low side-effect profile. The recombinant DNA derived alpha interferon formulations have been reported to have decreased effectiveness after one year, probably due to neutralizing antibody formation. Neutralizing antibody formation has not been reported with the use of Alferon N Injection®.

Disadvantages

Natural interferon is believed to be more expensive to make than the recombinant. In addition, the process is believed to be more difficult and to take longer.

Alferon - Potential Uses and Markets



Source: Company Reports

Overview of Alferon - Potential Uses and Target Markets

On the left side of the diagram Alferon N Injection is shown with its potential clinical uses and markets. Below that, on the extreme left is the US market for which Alferon N Injection has been approved for refractory/recurring HPV genital warts. The commercialization of this product in the US will depend on the timing of FDA's approving the upgraded manufacturing process facility in New Brunswick, New Jersey, which is expected by late 2015/early 2016.

Outside the US, is the market in Argentina where GP Pharma is the partner and Alferon N Injection has been given a broader label. There it is approved for patients that have been shown to be refractory to recombinant interferon, which would include not only treatments for HPV genital warts but also for chronic Hepatitis C and multiple sclerosis (MS).

Also under the clinical category would be possible off-label uses of the drug in the U.S. These would include Hepatitis C, MS and Vulvar Vestibulitis. Off-label clinical use could occur when physicians have patients that have stopped responding to a recombinant interferon and might benefit from the natural form of alpha interferon, Alferon N Injection. Treatment protocols for refractory HCV and MS patients would

typically require far greater volume of Alferon N Injection than would the treatment of a patient's genital warts. Vulvar Vestibulitis needs a pivotal clinical study for FDA approval.

On the right-hand side of the diagram is Alferon LDO. (Low Dose Oral) which is still experimental at this time. However the possibilities on the clinical side would include influenza treatment and prevention.

Also for Alferon LDO is the possible Bio Defense use of the drug for treatment and prevention of epidemic or pandemic influenza. Studies with monkeys conducted at Erasmus University in the Netherlands showed a very strong systemic effect when administered to H5N1 influenza virus infected monkeys. For Bio Defense purposes an oral drug has the potential to reach a broader portion of the at-risk population.

Statistics

Anogenital warts (AGWs) are a common, highly infectious disease caused by the HPV, whose high recurrence rates contribute to direct medical costs, productivity loss and increased psychosocial impact. A study "Systematic review of the incidence and prevalence of genital warts" published in 2013 reviewed the published medical literature on the incidence and prevalence of AGWs between 2001 and 2012. This type of study was necessary because of the lack of a systematic review of the epidemiology of AGWs in the literature.

The reported incidence of recurrent AGWs was as high as 110 per 100,000 among females and 163 per 100,000 among males or about 0.13% for both sexes combined.

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

Alferon® LDO (Low Dose Oral) – Trials Delayed

Alferon® LDO (Low Dose Oral) Interferon Alfa-n3 (Human Leukocyte Derived)] is an experimental low-dose, oral liquid formulation of Natural Alpha Interferon and like Alferon N Injection®, should not cause antibody formation, which is a problem with recombinant interferon. It is an experimental immunotherapeutic believed to work by stimulating an immune cascade response in the cells of the mouth and throat, enabling it to bolster systemic immune response through the 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. Oral administration of Alferon® LDO, with its anticipated affordability, low toxicity, minimal production of neutralizing antibodies, and broad range of potential bioactivity, could be a breakthrough treatment or prevention for viral diseases.

Hemispherx currently has an FDA authorized protocol to conduct a Phase II, double-blind, adaptive-design, randomized, placebo-controlled, dose-ranging study of Alferon® LDO for the prophylaxis and treatment of seasonal for pandemic influenza of more than 200 subjects. pandemic influenza of more than 200 subjects. Hemispherx's Phase II study has been delayed as HEB has redirected many of its resources to complete the upgrades in its New Brunswick facility.

Alferon N Injection - Shown Clinically Effective in Extensive studies::
In a double-blind, placebo-controlled, randomized clinical study of Alferon N Injection to treat HPV-related genital warts, the vast majority of the patients, 96%, responded to some degree to treatment with Alferon.

- 54% of patients saw all warts disappear and there was no recurrence in 76% of the complete responders at follow-up.
- 26%of the patients had a partial response with better than or equal to 50% of wart resolution.
- 16% of patients has a minor response to treatment, with less than 50% wart resolution.

Key Results:

- Alferon contains multiple species of interferon
- Provides a spectrum of multiple alpha interferon subtypes.
- The biological activity of the species varies substantially based on an HIV monocyte assay
- The least active species (Peak 1-2) contains interferon α2b
- No human antibodies to interferon alfa-n3 were detected in clinical trials.

Alferon Has been shown to be Well-Tolerated
No surgery or caustics and resultant ulceration or scarring.

- No specific post-treatment care necessary.
- The most common adverse effects (mild to moderate, transient flu-like symptoms) were comparable to placebo after weeks of therapy.
- The majority of patients considered Alferon N Injection preferable to conventional therapy.

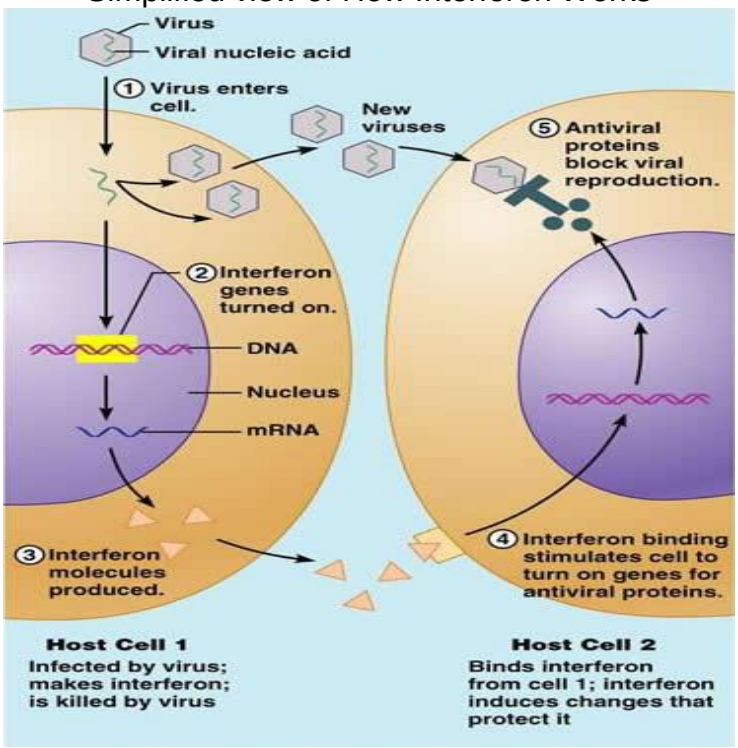
For further proof of concept, there was a comparative safety study with recombinant interferon (Intron A from Merck/Schering Plough) in 30 normal male volunteers. In addition, a multicenter, randomized, double-blind, placebo controlled efficacy and safety trial. Other studies include: open label clinical trial of efficacy, three confirmatory open clinical trials, and a comparison of clinical trials of Alferon N and Intron A to treat HPV genital warts. All yielded results similar or better than the results obtained above in the double-blind, placebo-controlled, randomized clinical study summarized above.

How Interferon Works

Interferon Stimulates Host Cells to Resist Viral Invasion
Interferons have comprehensive and multifaceted antiviral actions. Although interferons inhibit many steps of viral replication, the major antiviral actions appear to affect the translation of the viral genome into virus specified proteins.
Interferon antiviral actions inhibit viral messenger RNA (mRNA) synthesis, viral assembly, viral packaging, and release of virions by:

- reducing the translation of viral proteins by interfering with the normal host cell translation mechanism
- enzymatically degrading viral RNA, thus diminishing its usability as a template for assembly of viral proteins
- inhibiting viral transcription
- modifying glycosylation patterns of viral proteins which could influence virus packaging, release, or virulence
- altering the cell membrane (e.g. increasing cell fluidity) which may influence virion maturation and release

Simplified view of How Interferon Works



Source: Midlandstech

When a virus enters the cell the viral nucleic acid uses the cells reproductive mechanisms to creates new viruses. When the viral nucleic acid interacts with the cell's DNA, it creates mRNA

- The infected cell's interferon genes are turned on and DNA produces interferon molecules.
- Interferon binding stimulates the cells to turn on their genes for antiviral proteins.
- The antiviral proteins block viral reproduction

Interferon has profound immunomodulatory actions, some of which would be expected to affect virus multiplication and spread. The immunostimulatory actions of interferon involve the enhancement of various components of the immune response and activation of cytotoxic cells via the direct action of Interferon on a number of Interferon-responsive cells in the immune system.

By binding to specific Interferon receptors on the membranes of these cells, Interferon induces a number of intracellular events which ultimately result in:

- enhancing the expression of cell surface antigens, resulting in increased recognition and killing of infected cells by cytotoxic leukocytes
- enhancing induction of antibodies to improve cell lysis mediated by complement and by antibody-dependent, cell-mediated cytotoxic leukocytes
- activating macrophages, regulating natural killer(NK) cells, cytotoxic T-lymphocytes, and complement for enhanced cytotoxicity of target cells
- triggering the secondary release of other potent cytokines, such as the interleukins, which themselves have profound immunostimulatory effects throughout the immune system.

Interferon is Antiproliferative
Interferon inhibits viral assembly and replication by destroying RNA templates
IFNs exert powerful effects on target cell growth by:

- slowing target cell growth by increasing the length of their multiplication cycle
- depleting essential metabolites
- increasing cell lysis through cytotoxic mechanism
- inhibiting the expression of certain oncogenes

Additional Indications

Alferon has been tested for efficacy for the following indications: MERS-CoV, Avian Influenza A H7N9,

Institution	***Indication***
Institute for Antiviral Research, Utah State University	MERS-Co-V
U.S. Dept. of Homeland Security Center of Excellence for Emerging and Zoonotic Animal Diseases (CEEZAD) & Kansas State University, College of Veterinary Medicine	Avian Influenza A H7N9 (In-Vitro)
Center of Biodefense and Emerging Disease, University of Texas Medical Branch	MERS-CoV
Swiss Dept. of Defense	Avian Influenza A H7N9
Rocky Mountain Labs (NIH)	MERS

Ampligen

Ampligen® is an experimental drug currently undergoing clinical development for the treatment of Chronic Fatigue Syndrome. Ampligen® represents the first drug in the class of large (macromolecular) RNA (nucleic acid) molecules for which the developer applied for an NDA review. Based on the results of published, peer-reviewed pre-clinical studies and clinical trials, management believes that Ampligen® may have broad-spectrum anti-viral and anti-cancer properties.

Management further believes that nucleic acid compounds represent a potential new class of pharmaceutical products as they are designed to act at the molecular level for treatment of human diseases. There are two forms of nucleic acids, DNA and RNA. DNA is a group of naturally occurring molecules found in chromosomes, the cell's genetic machinery. RNA is a group of naturally occurring informational molecules produced by DNA which orchestrate a cell's behavior which, in turn, regulates the action of groups of cells, including the cells which make up 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.

The company’s drug technology utilizes specifically-configured RNA. Its double-stranded RNA drug product, trademarked Ampligen®, is an experimental drug, that would be administered intravenously. Ampligen® has been assigned the generic name rintatolimod by the United States Adopted Names Council (USANC) and has the chemical designation poly(I) poly(C12U).

In March 2015, Hemispherx announced that it had gained a positive opinion from the Committee on Medical Products (COMP) regarding its Orphan Medicinal Product Application for Ampligen, its experimental therapeutic, to treat Ebola Virus Disease (EVD). Hemispherx submitted *in vitro* and *in vivo* data in appropriate preclinical models relevant to the EVD indication to the European Union (EU) Committee for Orphan Medicinal Products. In the comprehensive application, efficacy data and clinical safety information were included. There is no assurance that in the final decision Ampligen will be designated as an Orphan Medical Product for treatment of Ebola.

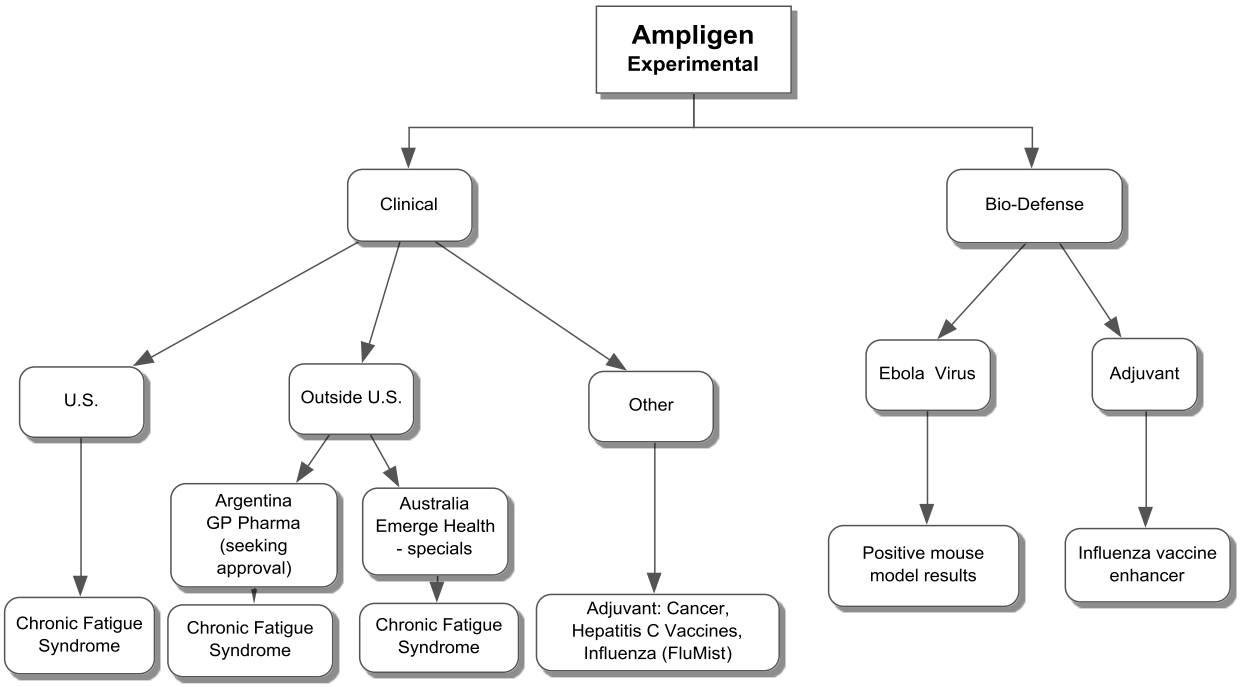
In early 2013, the FDA in its Complete Response Letter (CRL) declined to approve the NDA for the treatment of Chronic Fatigue Syndrome with Ampligen®. Over its developmental history, Ampligen® has received various designations, including Orphan Drug Product Designation (FDA), Treatment IND (e.g., treatment 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 Agency for Healthcare Research and Quality (AHRQ).

Clinical trials of Ampligen® already conducted by the company include studies of the potential treatment of Chronic Fatigue Syndrome, Hepatitis C, HIV and cancer patients with renal cell carcinoma and malignant melanoma. All of these potential uses will

require additional clinical trials to generate the safety and effectiveness data necessary to support regulatory approval.

In May 1997, the FDA approved an open-label treatment protocol, (Ampligen Treatment Study "AMP 511"), allowing patient access to Ampligen® for treatment in an open-label safety study under which severely debilitated Chronic Fatigue Syndrome patients have the opportunity to be on Ampligen® to treat this very serious and chronic condition. The data collected from the AMP 511 protocol through a consortium group with active clinical sites in New York City, NY, Charlotte, NC, Miami, FL, Incline Village, NV and Salt Lake City, UT, provide safety information regarding the use of Ampligen® in patients with Chronic Fatigue Syndrome. As of December 31, 2014, there were thirty-one patients participating in this open label treatment protocol with twenty taking treatment and eleven on drug holiday. The company is establishing an enlarged data base of clinical safety information which it believes will provide further documentation regarding the absence of autoimmune disease associated with Ampligen® treatment. Management believes that continued efforts to understand existing data, and to advance the development of new data and information, will ultimately support its future filings for Ampligen® and/or the design of future clinical studies.

Overview of Ampligen – Potential Uses and Target Markets



Source: Company Reports

On the left side of the above Ampligen diagram under the Clinical category for the US market, Ampligen is primarily intended to treat Chronic Fatigue Syndrome. The

company has not yet received approval for this and the timing of future clinical trials and approval are uncertain.

Outside the US there are two efforts to gain approval. In Argentina, the effort to have Ampligen approved for chronic fatigue syndrome continues and if approval is granted the drug could spread to other Latin American markets. Emerge Health, a partner in Australia that also covers New Zealand, is working with Hemispherix to apply to the regulatory body for CFS approval. In Australia there is a special program where physicians request the drug be used for certain patients on a “named patient” basis. This might generate some near term revenue. There is some hope that the product might be approved in 2017 or 2018.

There are no active programs for Ampligen as a monotherapy for any disease but there are programs using Ampligen as an adjuvant, in connection with vaccines and therapies for other diseases, including influenza and several types of cancer.

Ampligen is a TLR-3 stimulator which upregulates the immune system so that when a vaccine of one type or another is given, Ampligen has the potential to stimulate that immunogen further, not only making the vaccine more effective, but also reducing the amount of vaccine needed.

Under the Bio Defense category, Ampligen is believed to have potential for Ebola. In both *in vitro* trials and *in vivo* trials the data with Ebola-infected mice with the United States Army Medical Research Institute for Infectious Diseases (USAMRIID) showed that all the untreated infected mice died within 7 days and all the mice treated with Ampligen (dosed for bodyweight) were still alive after 21 days. The thought is this could be very significant for the treatment of Ebola patients and also against bio-weapons.

Complete Response Letter

Regarding the FDA Complete Response Letter (CRL), the FDA set forth the reasons for its action and provided recommendations to address certain of the outstanding issues. The FDA stated that the submitted data do not provide substantial evidence of efficacy of Ampligen® for the treatment of Chronic Fatigue Syndrome and that the data do not provide sufficient information to determine whether the product is safe for use in treating Chronic Fatigue Syndrome due to the limited size of the safety database and multiple discrepancies within the submitted data. In addition to the safety and effectiveness issues recommended to be addressed in at least one additional clinical trial, the CRL states that Hemispherx should conduct complete rodent carcinogenicity studies in two species prior to approval and also conduct additional animal toxicology studies providing more comprehensive evaluation of Ampligen® fragments and degradation products. The CRL also requests evaluation of variation between lots of Ampligen® tested in the development process and recommends tighter control of the Ampligen® manufacturing process.

In response to the CRL, the company continues to plan to avail itself of the opportunity for an “end-of-review” meeting with representatives of the Office of Drug Evaluation II which issued the CRL in order to clarify and seek to narrow the outstanding issues regarding the further development of Ampligen® for the treatment of Chronic Fatigue Syndrome.

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

Until the company undertakes the end-of-review conference(s) with the FDA, it will be unable to reasonably estimate the nature, costs, necessary efforts to obtain FDA clearance or anticipated completion dates of any additional clinical study or studies. Utilizing the industry norms for undertaking a Phase III clinical study, management estimates upon acceptance of the study's design that it would take approximately 18 months to three years to complete a new well-controlled Ampligen® clinical study for resubmission to the FDA. Industry norms suggest that it will require three to six months to initiate the study, one to two years to accrue and test patients, three to six months to close-out the study and file the necessary documents with the FDA. The actual duration to complete the clinical study may be different based on the length of time it takes to design the study and obtain FDA's acceptance of the design, the final design of an acceptable Phase III clinical study design, availability of suitable participants and clinical sites along with other factors that could impact the implementation of the study, analysis of results or requirements of the FDA and/or other governmental organizations.

Management anticipates that the time and cost to undertake clinical trial(s), studies and data analysis are beyond the company’s current financial resources without gaining access to additional funding.

New *In Vitro* Studies

Hemispherx reported in January 2015 that it had conducted new *in-vitro* studies of natural killer (NK) cells obtained from Chronic Fatigue Syndrome patients in conjunction

with a comprehensive review of the medical literature to determine the relative incidence of NK cell functional deficiencies in CFS disease. This review indicates that low NK cell cytotoxicity (NKCC) has been consistently reported in CFS patients compared to normal controls. In the new laboratory studies, Ampligen® was found to increase in vitro NK activity utilizing cells from CFS patient donors. The authors of the new report are all affiliated with Hemispherx.

Overseas Filing

In July 2012, HEB filed a new drug application for Ampligen® with the ANMAT (Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica), the agency responsible for the national regulation of drugs, foods and medical technology in Argentina, under the ANMAT's Orphan Drug regulations. The company believes that the approval of Ampligen® as an Orphan Drug may allow reimbursement by the Health Services Authority (SSS), the central health authority in Argentina for patients seeking treatment for Chronic Fatigue Syndrome.

V. Assumptions

To saturate the Alferon market in the U.S. Hemispherx would have to produce 360,000 vials.

With one bioreactor and one shift, Hemispherx can produce 50,000 vials per year. Assuming an average of two vials per patient, this would treat about 25,000 patients or about 13% of the projected market starting possibly in 2016. Six months or so after commercialization, the company should be able to train and implement a second shift increasing its capacity to 100,000 vials, doubling the number of patients that could be treated to about 26% of the projected U.S. market possibly in the following year.

To install and validate a second bioreactor would take another year from the decision point and roughly $1 million. When operating the second bioreactor for one shift the plant could make 150,000 vials. If a second shift were to be added for the second bioreactor, taking another six months, production could total 200,000 vials.

Using these assumptions, Hemispherx revenue potential at $2,000/vial ($1,200 reimbursement rate to patients) from 2016 to 2020 is approximately $90M, $200M, $300M, $390M, and $430M, respectively.

VI. Valuation

Figure 1: DCF

Discounted Cash Flow (DCF) Analysis

Fiscal Year Ending ($MMs)	12/31/15	12/30/16	12/30/17	12/30/18	12/30/19	12/29/20
Revenue	**$0.20**	**$87.31**	**$197.50**	**$294.35**	**$389.78**	**$433.96**
EBIT	-$14.86	$30.12	$77.25	$125.04	$171.84	$182.77
Less: Taxes	-$5.20	$10.54	$27.04	$43.77	$60.15	$63.97
Debt-Free Earnings	**-$9.66**	**$19.58**	**$50.21**	**$81.28**	**$111.70**	**$118.80**
Less: Capital Expenditures	-$2.00	-$2.00	-$2.00	-$2.00	-$2.00	-$2.00
Less: Working Capital Requirements	-$1.50	-$1.50	-$1.50	-$1.50	-$1.50	-$1.50
Add: Depreciation and Amortization	$0.60	$0.60	$0.60	$0.60	$0.60	$0.60
Total Net Investment	**-$12.56**	**$16.68**	**$47.31**	**$78.38**	**$108.80**	**$115.90**
Net Debt-Free Cash Flows:	**-$22.22**	**$36.25**	**$97.53**	**$159.66**	**$220.50**	**$234.71**
Discount Period	0.75	1.75	2.75	3.75	4.75	5.75
Discount Factor @ 35.0%	0.80	0.59	0.44	0.32	0.24	0.18
PV of Net Debt-Free Cash Flows:	**-$17.74**	**$21.44**	**$42.73**	**$51.81**	**$53.00**	**$41.79**

Terminal Value Assumptions	
Terminal Revenue (2020)	$434.0
Terminal Multiple	0.8x
Terminal Value	**$325.5**
Discount Period	$3.8
Discount Factor @ 35.0%	$3.1
PV of Terminal Value	**$105.6**
PV of FCF	**$189.3**
Total EV ($MMs)	**$295.0**

DCF - Price Target - 2015	
Total EV ($MMs)	**$295.0**
Total Debt	$0.0
Total Cash	$16.1
Total Equity Value	**$311.1**
Shares Out.	**215.1**
Price Target	**$1.45**
Current Price	$0.23
Upside	**529%**

Source: Midtown Partners Estimates, Capital IQ

We view HEB's valuation as favorable given the likelihood that the FDA will approve the manufacturing of Alferon with potential upside from: Argentina, Interferon Alfa 2b sales, and possibly Ampligen.

We derived our price target of $1.45/share based on Discounted Cash Flow (DCF) model that assumes $0.49/share for the terminal value, based on a multiple of 0.8x Revenue. Also, we take the present value of our FCF projections, $0.96/share by using a discount rate of 35%. This discount rate is based on the benchmark range of early stage companies: 40-45% and we took a haircut to account for the fact that one of the products (Alferon) is very likely to be approved for production and the other (Ampligen) is in a late stage of development. We believe a DCF valuation is appropriate given that HEB has minimal revenue at the moment and the value of the company is based on

expectations five years out. We used various assumptions that are reasonable relative to industry standards.

We estimate revenues out to 2020 with a larger emphasis on 2016 based on the commercialization of Alferon after it likely receives manufacturing approval. After which, we expect an acceleration of revenue growth in the out years. Our revenue estimates are based on the commercialization of Alferon in the US and Argentina, the most likely revenue streams in the near future (excludes Ampligen)

Income Statement (HEB) For the Fiscal Period Ending (12-31)	2015E	2016E	2017E	2018E	2019E	2020E
Ampligen (clinical treatment programs)	0.2	0.2	0.2	0.2	0.2	0.2
Interferon 2b US						
Potential cases (refractory, U.S.)	200,000.0	201,400.0	202,809.8	204,229.469	205,659.075	207,098.688
Penetration Rate	0.0%	10.5%	23.8%	34.5%	45.0%	50.0%
Cases	0	21,147.0	48,268.732	70,459.167	92,546.584	103,549.344
Total Vials at 2 per case	0	42,294.0	96,537.465	140,918.333	185,093.167	207,098.688
Price Per vial	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0	2,000.0
Revenue	0	84,588,000.0	193,074,929.6	281,836,666.668	370,186,334.784	414,197,376.809
Interferon 2b International						
Potential cases (refractory, Argentina)	100,000.0	100,900.0	101,808.1	102,724.373	103,648.892	104,581.732
Penetration Rate	0.0%	0.6%	1.0%	2.9%	4.5%	4.5%
Cases	0	605.4	1,018.081	2,979.007	4,664.2	4,706.178
Total Vials at 3 per case	0	1,816.2	3,054.243	8,937.02	13,992.6	14,118.534
Total Vials	**0**	**44,110.2**	**99,591.708**	**149,855.354**	**199,085.768**	**221,217.222**
Price Per vial	1,500.0	1,500.0	1,450.0	1,400.0	1,400.0	1,400.0
Revenue	0	2,724,300.0	4,428,652.35	12,511,828.619	19,589,640.636	19,765,947.402
Revenue	**200,000.0**	**87,312,300.2**	**197,503,582.15**	**294,348,495.487**	**389,775,975.621**	**433,963,324.411**

Source: Capital IQ Estimates, Midtown Partners Estimates

Our estimates for U.S sales are based around assumptions relating to the HPV market size, the number of refractory cases, and how many patients HEB will successfully penetrate. After which, we assume that each of those penetrated cases will use the treatment average (2 vials @ $1200-$2000/vial., i.e we use $200/vial). In order to remain conservative, we assume pricing toward the upper end of the range given Alferon's comparative advantages and calculated future potential cases based on the population growth rate in the U.S.

Our estimates for Argentina sales are based around assumptions relating to the HPV market size, the number of refractory cases, and how many patients HEB will successfully penetrate. After which, we assume that each of those penetrated cases will use the treatment average (3 vials @ $1500/vial). In order to remain conservative, we assume the penetration rates will be lower in Argentina given the price of the product and the economics of the area. The challenge for HEB will be to price this product appropriately.

Additionally, we assume gross margins of 70% based on the cost of the product and potential commission to Armada Health Care. We project overhead costs, SG&A and

R&D, to be comparable to past levels with a constant trend based on the improved productivity from the new bioreactor. Also, we expect the company to raise capital and increase the share count in future years.

Management

WILLIAM A. CARTER, M.D., 75, Chairman, Chief Executive Officer, President and Chief Scientific Officer. Dr. Carter is the co-inventor of Ampligen®. He joined Hemispherx in 1978, and has served as: (a) Chief Scientific Officer since May 1989; (b) the Chairman of the Board of Directors since January 1992; (c) Chief Executive Officer since July 1993; (d) President from April 1995 to November 2006 and then again December 2011 to present; and (e) a Director since 1987. From 1987 to 1988, Dr. Carter served as Chairman. Dr. Carter was a leading innovator in the development of human interferon for a variety of treatment indications including various viral diseases and cancer. Dr. Carter received the first FDA approval to initiate clinical trials on a beta interferon product manufactured in the U.S. under his supervision. From 1985 to October 1988, Dr. Carter served as Chief Executive Officer and Chief Scientist. He received his M.D. degree from Duke University and underwent his post-doctoral training at the National Institutes of Health and Johns Hopkins University. Dr. Carter also served as Professor of Neoplastic Diseases at Hahnemann Medical University, a position he held from 1980 to 1998. Dr. Carter served as Professor and Director of Clinical Research for Hahnemann Medical University's Institute for Cancer and Blood Diseases, and as a member of the faculty at Johns Hopkins School of Medicine and the State University of New York at Buffalo. Dr. Carter is a Board certified physician and author of more than 200 scientific articles, including the editing of various textbooks on anti-viral and immune therapy.

THOMAS K. EQUELS, Esq., 61, Executive Vice Chairman, Chief Financial Officer, Secretary and General Counsel. He has been a Director since 2008. Mr. Equels is the President and Managing Director of the Equels Law Firm based in Miami Florida that focuses on litigation. For over a quarter century, Mr. Equels has represented national and state governments as well as companies in the banking, insurance, aviation, pharmaceutical and construction industries. Mr. Equels received his Juris Doctor degree with high honors from Florida State University. He is a summa cum laude graduate of Troy University and also obtained his Masters' Degree from Troy. He is a member of the Florida Bar Association and the American Bar Association.

ADAM PASCALE serves as Chief Accounting Officer. He has been the Controller at Hemispherx for eighteen years, with twenty four years of public accounting experience and prior public company experience. His degree is from Rutgers University in Accounting and he served for many years as a CPA prior to joining Hemispherx. He is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants.

DAVID R. STRAYER, M.D., Chief Financial Officer, has acted as Medical Director since 1986. He has served as Professor of Medicine at the Medical College of

Pennsylvania and Hahnemann University from 1987 to 1998. Dr. Strayer is Board Certified in Medical Oncology and Internal Medicine with research interests in the fields of cancer and immune system disorders. He has served as principal investigator in studies funded by the Leukemia Society of America, the American Cancer Society, and the National Institutes of Health. Dr. Strayer attended the School of Medicine at the University of California at Los Angeles where he received his M.D. in 1972.

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

VII. Risks

Competition

RNA based products and toll-like receptors have demonstrated great promise in pre-clinical and limited clinical applications resulting in active research and development by large pharmaceutical companies and emerging Biotech firms. As such, the company's potential competitors are among the largest pharmaceutical companies in the world, are well known to the public and the medical community, and have substantially greater financial resources, product development, and manufacturing and marketing capabilities than those of Hemispherix. These companies and their competing products may be more effective and less costly than those of Hemispherix. In addition, conventional drug therapy, surgery and other more familiar treatments will offer competition to the company's products.

No assurance of successful product development

The development of Ampligen® and other related products is subject to a number of significant risks. Ampligen® may be found to be ineffective or to have adverse side effects, fail to receive necessary regulatory clearances, be difficult to manufacture on a commercial scale, be uneconomical to market or be precluded from commercialization by proprietary rights of third parties. Hemispherix's investigational products are in various stages of clinical and pre-clinical development and require further clinical

studies and appropriate regulatory approval processes before any such products can be marketed. Management is uncertain as to when, if ever, Ampligen® or the company's other products will be generally available for commercial sale for any indication. Generally, only a small percentage of potential therapeutic products are eventually approved by the FDA for commercial sale.

Regulatory Approval

Although Alferon N Injection® is approved for marketing in the United States for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older, to date it has not been approved for other indications. Drug and related technologies are investigational and subject to regulatory approval. All of Hemispherix's drugs and associated technologies, other than Alferon N Injection®, are investigational and must receive prior regulatory approval by appropriate regulatory authorities for commercial distribution and sale and are currently legally available only through clinical trials with specified disorders. At present, Alferon N Injection® is only approved for the intralesional treatment of refractory or recurring external genital warts in patients 18 years of age or older. Use of Alferon N Injection® for other indications will require regulatory approval.

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

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

Hemispherix may continue to incur losses

Hemispherix may continue to incur substantial losses and future profitability is uncertain. The company last reported net profit from 1985 through 1987. Since 1987, with a major emphasis on new drug diagnostic and development, it has incurred substantial operating losses, as it pursued its clinical trial effort to get its experimental drug, Ampligen®, approved. As of December 31, 2014, its accumulated deficit was approximately ($277,769,000). The firm has not yet generated significant revenues from its products and may incur substantial and increased losses in the future. Management cannot predict that the firm will ever achieve significant revenues from product sales or become profitable. The company requires, and will continue to require, the commitment of substantial resources to develop its products. It cannot assure that product development efforts will be successfully completed or that required regulatory approvals will be obtained or that any products will be manufactured and marketed successfully, or be profitable.

HEB will most likely will require additional financing which may not be available

The development of company products requires the commitment of substantial resources to conduct the time consuming research, preclinical development, and clinical trials that are necessary to bring pharmaceutical products to market. There can be no assurances that the firm will be able to obtain additional funding, and if not, its ability to develop products, commercially produce inventory or continue operations may be materially adversely affected.

Income Statement (HEB) For the Fiscal Period Ending (12-31)	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue	**$0.2**	**$0.2**	**$0.2**	**$0.2**	**$87.3**	**$197.5**	**$294.3**	**$389.8**	**$434.0**
Cost Of Goods Sold	2.0	1.2	1.2	0.1	26.2	59.3	88.3	116.9	130.2
Gross Profit	**(1.8)**	**(1.1)**	**(1.1)**	**0.1**	**61.1**	**138.3**	**206.0**	**272.8**	**303.8**
Selling General & Admin Exp.	9.1	7.7	9.1	7.5	30.0	60.0	80.0	100.0	120.0
R & D Exp.	9.5	8.2	9.0	7.5	1.0	1.0	1.0	1.0	1.0
Depreciation & Amort.	-	-	-	-	-	-	-	-	-
Other Operating Expense/(Income)	-	-	-	-	-	-	-	-	-
Other Operating Exp., Total	**18.5**	**15.9**	**18.0**	**15.0**	**31.0**	**61.0**	**81.0**	**101.0**	**121.0**
Operating Income	**(20.3)**	**(17.0)**	**(17.3)**	**(14.9)**	**30.1**	**77.3**	**125.0**	**171.8**	**182.8**
Interest Expense	(0.0)	(0.0)	(0.1)	(0.0)	0.0	0.0	0.0	0.0	0.0
Interest and Invest. Income	1.2	0.8	0.6	0.6	0.0	0.0	0.0	0.0	0.0
Net Interest Exp.	**1.2**	**0.8**	**(17.5)**	**0.6**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Other Non-Operating Inc. (Exp.)	1.4	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBT Excl. Unusual Items	**(17.7)**	**(15.2)**	**(17.5)**	**(15.4)**	**30.1**	**77.3**	**125.0**	**171.8**	**182.8**
Impairment of Goodwill	-	-	-	0.0	0.0	0.0	0.0	0.0	0.0
Gain (Loss) On Sale Of Invest.	0.4	(0.8)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Asset Writedown	(0.0)	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Unusual Items	-	-	-	0.0	0.0	0.0	0.0	0.0	0.0
EBT Incl. Unusual Items	**(17.4)**	**(16.2)**	**(17.5)**	**(15.4)**	**30.1**	**77.3**	**125.0**	**171.8**	**182.8**
Income Tax Expense	-	-	-	(10.0)	19.6	50.2	81.3	111.7	118.8
Earnings from Cont. Ops.	**(17.4)**	**(16.2)**	**(17.5)**	**(5.4)**	**10.5**	**27.0**	**43.8**	**60.1**	**64.0**
Earnings of Discontinued Ops.	-	-	-	-	-	-	-	-	-
Extraord. Item & Account. Change	-	-	-	-	-	-	-	-	-
Net Income to Company	**(17.4)**	**(16.2)**	**(17.5)**	**(5.4)**	**10.5**	**27.0**	**43.8**	**60.1**	**64.0**
Basic EPS	($0.12)	($0.1)	($0.09)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29
Basic EPS Excl. Extra Items	(0.12)	(0.1)	(0.09)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29
Weighted Avg. Basic Shares Out.	141.017	167.326	188.292	190.0	218.292	218.292	218.292	218.292	218.292
Diluted EPS	($0.12)	($0.1)	($0.09)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29
Diluted EPS Excl. Extra Items	(0.12)	(0.1)	(0.09)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29
Weighted Avg. Diluted Shares Out.	141.017	167.326	188.292	190.0	218.292	218.292	218.292	218.292	218.292
Normalized Basic EPS	($0.08)	($0.06)	($0.06)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29
Normalized Diluted EPS	(0.08)	(0.06)	(0.06)	($0.03)	$0.05	$0.12	$0.2	$0.28	$0.29

Source: Capital IQ

Midtown Partners & Co. LLC. - Investment Ratings

Rating	Rating Description	Number of Companies Covered	Midtown Partners & Co. LLC Rating Distribution Percentage	Investment Banking Clients	Percent Banking Clients
Strong Buy	We expect these shares to increase in value by at least 20% over the next 12 months.	6	75%	0	0%
Buy	We expect these shares to increase in value by at least 10% over the next 12 months	0	0%	0	0%
Neutral	We expect these shares to remain within a range +/- 10% within the next 12 months	2	25%	0	0%
Sell	We expect these shares to decrease in value by at least 10% over the next 12 months				
Not Rated	The ratings for the subject company have been temporarily suspended by Midtown Partners & Co. LLC				

Midtown Partners & Co. LLC & Co., Inc. - Risk Ratings

Rating	Rating Description
Low	Financial results of companies with a “Low” risk rating have a high level of predictability and / or their share prices are subject to low volatility as measured by Beta
Moderate	Financial results of companies with a “Moderate” risk rating have a moderate level of predictability and / or their share prices are subject to moderate volatility as measured by Beta.
High	Financial results of companies with a “High” risk rating have a low level of predictability and / or their share prices are subject to high volatility as measured by Beta.
Speculative	Financial results of companies with a “Speculative” risk rating have a very low level of predictability and / or their share prices are subject to high volatility as measured by Beta. Investments in these shares carry very high risk.

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