Hemispherx Biopharma

AMEX: HEB

Re-commercialization Proceeds with some delay

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, such as Flu, and Ebola. It has two products, Alferon and Ampligen. Alferon N Injection, the key near term revenue driver, is an injectable formulation of natural alpha interferon for the treatment of refractory genital warts.

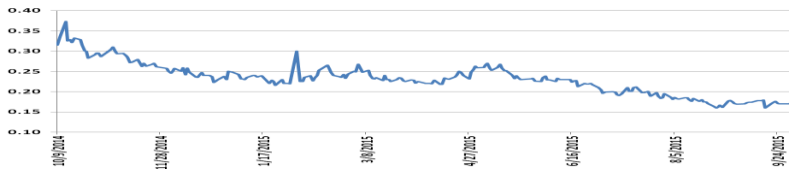
Investment Thesis

1) Alferon N Injection is an 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 $40-70M in 2016 (reduced from $70-100M, as re-commercialization of Alferon is now expected to begin later than originally anticipated, probably in mid 2016.
2) 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 greater volumes of Alferon with more consistent quality.
3) There is long term revenue potential from additional off label uses for Alferon in the U.S which may result in material revenues several years down the road. Alferon has a broader approval for patients refractory to recombinant interferon for all indications in Argentina including: genital warts, Hepatitis C, and, MS.
4) Ampligen holds promise for the treatment of Chronic Fatigue Syndrome (CFS), In the US, if and when approved by the FDA.
5) myTomorrows could provide an additional near-term revenue source with the potential for sales of Ampligen in European Countries.

HEB's stock has significant upside:

We reiterate a Strong Buy/Speculative Risk rating. We value the stock at $0.96/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.



Rating	**Strong Buy**
Risk Rating	**Speculative**
Current Price (Oct 9, 2015)	**$0.162**
12-month Price Target	**$0.96**
Implied dividend yield	**0%**
Projected total return	**+493%**
Shares outstanding (M)	246.9
Market capitalization (M)	$40.86
Long term debt (MRQ)	$0.0
Cash (MRQ)	$15.7
Enterprise value	$26.26
EV/REV (2016)	1.56
Rev Estimate (2016)	$41.0
Float as % of shares out.	98.4%
Short interest as % of Float	0.1%
Insider ownership	1.8%
Institutional ownership	6.2%
Tangible book value p/s	$0.11
Cash/share	$0.06

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	$41.0	$89.6

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)	($2.3)	$1.7

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Update - Key points

Hemispherx has two drug platforms, Ampligen and Alferon, designed to modulate the immune system. Alferon N Injection is a natural alpha-interferon derived from human leukocytes (white blood cells). Alferon N Injection is the only natural interferon approved by the FDA with an approval for treating refractory/recurring genital warts caused by the human papilloma virus (HPV). Ampligen is poly1:poly $C_{12}U$ rintatolimod, a broad-spectrum antiviral, which stimulates TLR 3 activating a natural immune response. Rintatolimod is a member of a new class of specifically-configured ribonucleic acid (RNA) compounds targeted as potential treatment of diseases, such as chronic fatigue syndrome (CFS), with immunologic effects and/or viral causation. The drug has demonstrated a good safety profile as well as reduction in the use of concomitant medications

Since our initial report earlier this year, there are several events that shareholders should factor into their investment considerations regarding Hemispherx as the company continues to move toward re-commercialization and profitability after an externally-induced delay.

1. The timing of the Alferon N Injection commercial re-launch has been pushed out toward the middle of 2016.
2. Armada Health Care is an important marketing program for re-commercialization. Further, HEB's renewal with Armada for two years (vs. earlier one year renewals) demonstrates confidence in Armada's ability to help commercialize Alferon.
3. Emerge Health has partnered to market Alferon in Australia and New Zealand.
4 Ampligen, although not FDA approved, has shown efficacy particularly in patients with severe chronic fatigue syndrome (CFS) which may allow sales under certain early access programs.
5. myTommorows is a specialty marketing company interested in selling Ampligen to early access programs and thus, this represents a potential opportunity for generating sales of Ampligen in Europe.

Alferon's Commercial Re-launch Delayed by Termination of Leukocyte Supply

Hemispherx ceased all Alferon manufacturing in 2010 to upgrade its Alferon manufacturing plant to a state-of-the-art bioreactor process. Construction of this bioreactor facility, at a cost of over $8 million, is complete and the facility is operational. The FDA needs to approve the upgraded manufacturing process in order for Alferon sales to re-start.

Hemispherix's timeline for the revalidation of its newly upgraded manufacturing facility in New Brunswick, New Jersey, was disrupted somewhat by the announcement in August 2015 that Baxalta subsidiary, Bio Life Plasma Services, was unexpectedly terminating its sole-source contract to supply blood derived leukocytes which are essential to the Alferon manufacturing process, before the contracted termination date.

The relaunch of Alferon N as a commercial product cannot begin until all regulatory approvals have been obtained. The Baxalta breach of contract was particularly damaging for Hemispherx because the company was in the process of re-validating its

New Brunswick facility that manufactures Alferon N injection and the blood supply was a critical component of the manufacturing process. This has caused a delay in the re-certification of the New Brunswick plant, probably extending it until the middle of 2016. The facility in New Brunswick is approved by the FDA under the Biological License Application for Alferon but this status will need to be reaffirmed upon completion of the facility's enhancements prior to commercial sale of newly produced inventory.

When the company obtains reaffirmation of FDA Biological License Application status and has begun production of new Alferon API the company will also need FDA approval as to the quality and stability of the final product in order to allow commercial sales to resume.

New Contract for Supply with Gulf Coast Regional Blood Center

From now on, Hemispherx will contract with more than one supplier of leukocytes to avoid future supply-induced shutdowns. It has signed its first direct supply agreement with Gulf Coast Regional Blood Center of Houston, Texas. It will also be negotiating for direct supply agreements with other Blood Centers around the U.S. to assure an uninterrupted supply of the raw material necessary to manufacture Alferon.

It seems probable that the initial test batches will be completed by January-February 2016 and then the company can call the FDA to come to examine the new facility. Given the vagaries in FDA response times, the approval process for the facility seems likely to be complete by the middle of 2016.

Alferon N Injection Market Opportunity.

Genital warts are a common, highly infectious disease caused by the human papilloma virus (HPV) which is the most common sexually transmitted infection. This disease has high recurrence rates which contribute to medical costs, lost productivity and psychosocial impact. The prevalence of genital warts shows an incidence of recurrent warts that yields approximately 180,000 patients with recurring refractory HPV genital warts (each year). The advantage of Alferon compared to recombinant interferons is that the percentage of patients developing neutralizing antibodies is extremely low compared to very meaningful frequencies, running from above 10% to as high as 40% with recombinant interferons

The normal treatment regimen is considered to be approximately one vial of Alferon per wart over eight weeks and an estimated average of two warts per patient. Thus, the potential market at an average wholesale price of $2000 per vial, or $4000 per estimated course of treatment, is roughly $720 million. Hemispherx would need to add more bioreactors, each of which would need to be approved by the FDA, to partially meet this potential.

Armada Health Care Marketing to Specialty Pharmacies

Armada is a leader in the over $100 billion specialty pharmaceutical industry. The company provides manufacturers, health plans and wholesales distributors a total management program including customized patient programs, prescription data management services , online platforms and cost effective purchasing agreements for specialty pharmacy products. As the leader in the specialty pharmaceutical field Hemispherx management sees Armada as the ideal partner for marketing and distribution of Alferon N Injection.

Hemispherx renewed its contract with Armada Health Care for two years (July 2015 to July 2017). HEB has had one year contracts with Armada since 2011. Based on the likelihood of commercialization in mid-2016, HEB's board decided to do a two year contract.

In the U.S. Hemispherx will supply Alferon N injection to physicians and patients through Armada's national network of specialty pharmacy pharmacies. And Armada has agreed to provide ongoing sales and marketing support to Alferon's re-launch. Alferon is approved in Argentina with planned expansion to other Latin American countries, for patients refractory to recombinant interferon.

Armada is important to the HEB marketing and distribution due to its connections with over 25,000 specialty pharmacy stores. "Specialty" is typically defined as drugs which require "high touch", "white glove" involvement with the product, patient and insurance company for a product that generally requires infusion or injection. Alferon fits this description. Not only can Armada remind physicians that they have patients who should be continuing treatment but they can also remind the patients.

As the Hemispherx upgrade of its New Brunswick facility with the high-volume, state-of-the-art bioreactor will be capable of supplying greater volumes of product to the market than in the past, the company is planning a more aggressive marketing effort. Hemispherx is also establishing an in-house team to support Armada and to establish other sales channels for Alferon N injection. Once Alferon N Injection becomes available management, believes acceleration of sales might be fairly rapid.

Emerge Health PTY Ltd to Reach Australia and New Zealand with Alferon
Hemispherx and Emerge are partnering to sell Alferon N Injection under early access programs in Australia and New Zealand and to seek formal approval in those countries. Emerge will implement regulatory-compliant programs, under its exclusive license to sell, market and distribute Alferon N Injection in Australia and New Zealand, to educate physicians about Alferon. And begin distribution of Alferon in those two countries on a named-patient basis, where deemed appropriate.

Emerge and Hemispherx will collaborate on seeking regulatory approval from Australia's Therapeutic Goods Administration and New Zealand's Medicines and Medical Devices Safety Authority.

Ampligen/Rintatolimod

Ampligen is an experimental therapeutic which has potential use for Chronic Fatigue Syndrome (CFS). Chronic fatigue syndrome is a debilitating, complex disorder characterized by profound fatigue. It is also known as myalgic encephalon myelitis (ME). There is no approved drug anywhere in the world for chronic fatigue syndrome. Ampligen produces objective improvement in exercise tolerance in severe cases of CFS and it significantly reduces the amount of concomitant medications needed by patients

to help mitigate chronic fatigue syndrome symptoms. There are approximately 1 to 4 million people affected by Chronic Fatigue Syndrome in the US.

Centers for Disease Control studies indicate that CFS can be as debilitating as MS, RA, lupus, heart disease and end-stage renal disease and COPD. It has been estimated that as many as 25% of all CFS patients are house-bound, bed-ridden, or wheelchair-bound. There is no approved therapy for CFS and Ampligen works for some patients.

myTomorrows to Reach Early-Access Programs in Europe and Turkey

myTomorrows, a Netherlands-based company, has agreed to begin to manage an early access program in all of Europe and Turkey for rintatolimod/Ampligen and will be the exclusive service provider and perform early access program activities to include the supply of rintatolimod for the treatment of chronic fatigue syndrome (CFS) to patients with that unmet medical needs.

The value proposition of myTomorrows is to provide access where no drugs have been approved specifically for unmet needs. In clinical trials rintatolimod has shown promising results for certain chronic fatigue syndrome patients, particularly those most severely affected. Not only will this collaboration create the potential for physicians to use rintatolimod under certain circumstances, but myTomorrows will collaborate with these physicians to capture data on patients treated and such data may help Hemispherx's other efforts to gain full regulatory approval in Europe, Latin America Australia, New Zealand as well is in the US. .

myTomorrows provides patients that are excluded from clinical trials access to drugs in development. Focusing on diseases with unmet needs, myTomorrows identifies the latest developments in drugs and facilitates request for access to these drugs. In most countries health authorities must grant permission for treatment with a non--registered drug. Hemispherx management believes that there could be some sales of Ampligen in Europe by end of 2015.

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**	**$40.99**	**$89.61**	**$206.94**	**$303.40**	**$392.54**
EBIT	-$14.86	-$2.31	$1.73	$63.86	$111.38	$153.78
Less: Taxes	-$5.20	-$0.81	$0.60	$22.35	$38.98	$53.82
Debt-Free Earnings	**-$9.66**	**-$1.50**	**$1.12**	**$41.51**	**$72.40**	**$99.96**
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**	**-$4.40**	**-$1.78**	**$38.61**	**$69.50**	**$97.06**
Net Debt-Free Cash Flows:	**-$22.22**	**-$5.90**	**-$0.66**	**$80.11**	**$141.89**	**$197.01**
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**	**-$3.49**	**-$0.29**	**$26.00**	**$34.11**	**$35.08**

Terminal Value Assumptions	
Terminal Revenue (2020)	$392.5
Terminal Multiple	0.8x
Terminal Value	**$294.4**
Discount Period	$3.8
Discount Factor @ 35.0%	$3.1
PV of Terminal Value	**$95.5**
PV of FCF	**$94.9**
Total EV ($MMs)	**$190.4**

DCF - Price Target - 2015	
Total EV ($MMs)	**$190.4**
Total Debt	$0.0
Total Cash	$16.1
Total Equity Value	**$206.5**
Shares Out.	**215.1**
Price Target	**$0.96**
Current Price	$0.16
Upside	**493%**

Source: Midtown Partners Estimates, Capital IQ

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**	**$41.0**	**$89.6**	**$206.9**	**$303.4**	**$392.5**
Cost Of Goods Sold	2.0	1.2	1.2	0.1	12.3	26.9	62.1	91.0	117.8
Gross Profit	**(1.8)**	**(1.1)**	**(1.1)**	**0.1**	**28.7**	**62.7**	**144.9**	**212.4**	**274.8**
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)**	**(2.3)**	**1.7**	**63.9**	**111.4**	**153.8**
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)**	**(2.3)**	**1.7**	**63.9**	**111.4**	**153.8**
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)**	**(2.3)**	**1.7**	**63.9**	**111.4**	**153.8**
Income Tax Expense	-	-	-	(10.0)	(1.5)	1.1	41.5	72.4	100.0
Earnings from Cont. Ops.	**(17.4)**	**(16.2)**	**(17.5)**	**(5.4)**	**(0.8)**	**0.6**	**22.3**	**39.0**	**53.8**
Earnings of Discontinued Ops.	-	-	-	-	-	-	-	-	-
Extraord. Item & Account. Change	-	-	-	-	-	-	-	-	-
Net Income to Company	**(17.4)**	**(16.2)**	**(17.5)**	**(5.4)**	**(0.8)**	**0.6**	**22.3**	**39.0**	**53.8**
Basic EPS	($0.12)	($0.1)	($0.09)	($0.03)	($0.0)	$0.00	$0.1	$0.18	$0.25
Basic EPS Excl. Extra Items	(0.12)	(0.1)	(0.09)	($0.03)	($0.0)	$0.00	$0.1	$0.18	$0.25
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)	($0.0)	$0.0	$0.1	$0.18	$0.25
Diluted EPS Excl. Extra Items	(0.12)	(0.1)	(0.09)	($0.03)	($0.0)	$0.0	$0.1	$0.18	$0.25
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)	($0.0)	$0.0	$0.1	$0.18	$0.25
Normalized Diluted EPS	(0.08)	(0.06)	(0.06)	($0.03)	($0.0)	$0.0	$0.1	$0.18	$0.25

Source: Capital IQ

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