

StockWatchIndex Research Report

NYSE:HEB

The Company

Hemispherx Biopharma, Inc. is an advanced specialty pharmaceutical company engaged in the manufacture and clinical development of new drug entities for treatment of seriously debilitating disorders. Hemispherx's flagship products include Alferon N Injection®, the experimental therapeutics Ampligen® and Alferon® LDO. Alferon® LDO is FDA approved for the treatment of genital warts. Ampligen® is an experimental RNA nucleic acid being developed for globally important debilitating diseases and disorders of the immune system, including Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS). Hemispherx's platform technology includes components for potential treatment of various severely debilitating and life threatening diseases.

Hemispherx Patents

Hemispherx has patents comprising its core intellectual property estate and a fully commercialized product (Alferon N Injection®), approved for sale in the U.S. and Argentina. The FDA approval of Alferon N Injection® is limited to the treatment of refractory or recurrent external genital warts in patients 18 years of age or older.

Manufacturing - Early Access Program in Europe

The Company has entered into an agreement with Avrio Biopharmaceuticals, a FDA inspected, premier contract development and manufacturing organization (CMO), supporting the pharmaceutical, biopharmaceutical and medical device industries with GMP parenteral manufacturing and product development services from early phase through post-market life cycle management. Avrio is operating as an additional CMO for Hemispherx's experimental drug, Ampligen®. Avrio has the capabilities for the compounding and fill/finish of sterile clinical and commercial grade Ampligen® to satisfy HEB's ongoing domestic clinical studies as well as the recently initiated Early Access Program (EAP) in Europe.

Products - Orphan Drug Designation

HEB's product platform consists of its experimental compound Ampligen®, its FDA approved natural interferon product Alferon N Injection® and the experimental liquid natural interferon for oral administration, Alferon® LDO. Ampligen has US orphan drug status for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS), malignant melanoma and renal cell carcinoma. It has also obtained EMA orphan drug designation for Ebola virus disease. Ampligen is patent protected through 2029.

Partnerships

Public-private partnerships are playing an important role in advancing therapeutics for neglected diseases of the developing world. Smaller companies typically try to coordinate their preclinical development activities using specific contract research companies to complete the work at a regulatory standard and at a reduced price. Hemispherx is seeking co-development and/or licensing partners for Ampligen® with focus on Immune-Oncology, Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) and Vaccines. The company is also seeking co-development and/or licensing partners for Alferon to expedite product development and revenue generation.

"Manufacturing and clinical development of drug entities for treatment of seriously debilitating disorders"

"Drive the creation of Stockholder Value through the advancement of the Company's lead products"

Thomas K. Equels, CEO

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COMPANY

Focus on therapies based on natural immune system enhancing technologies for the treatment of viral and immune based disorders

PRODUCTS

Two Flagship Products - Ampligen® and Alferon® LDO, designed to modulate the immune system, functioning as activators of the immune response with pluripotent activity

PATENTS

Composition of matter patent for Ampligen, valid through 2029. Alferon is protected by proprietary methods that require demonstration of equivalency for the FDA

PARTNERSHIPS

HEB pursues collaborative opportunities including product out-licensing, co-research, co-development, co-promotion and co-marketing with research institutes, pharmaceutical companies and biotech companies

The US demand for Drug Delivery Programs is expected to grow at a 10.4 % CAGR to \$134 Billion by 2021.

MANUFACTURING

Hemispherx owns and operates a 43,000 sq. ft. GMP facility in New Brunswick, NJ to produce Alferon® and Ampligen®. In 2010, HEB began investing \$8 Million to up-grade the facility to a state-of-the-art bioreactor process. The construction is complete and the facility is in its final stages to start validating the facility, readying itself for a successful FDA Pre-Approval Inspection. HEB has entered into an agreement with Avrio Biopharmaceuticals as an additional CMO for the manufacture of Hemispherx's experimental drug Ampligen®.



INVESTMENT HIGHLIGHTS

- Hemispherx Biopharma Reaches Agreement with Avrio Biopharmaceuticals for the Accelerated Production of Ampligen®
- Hemispherx Announces First Shipment of Rintatolimod (Ampligen®) to Early Access Program in Europe
- Hemispherx Biopharma Bolsters Manufacturing and Scientific Capabilities Through Key Consulting and Management Appointments.
- Hemispherx Outlines Key Elements Of Strategic Growth Plan And Commitment To Transparency
- Hemispherx Biopharma Renews Sales, Marketing, Distribution And Supply Agreement With GP Pharm
- Hemispherx Updates The Status Of The Alferon® Manufacturing Facility
- Hemispherx Enters into Agreement with MyTomorrows For The Early Access Program For Rintatolimod In Europe
- Hemispherx Biopharma Retains Huron Consulting Group To Support Partnering Strategy
 And Planning For Alferon® And Ampligen®
- Hemispherx Biopharma Enters Into Alfa-N3 Interferon Clinical Trial, Sales, Marketing, Distribution, And Supply Agreement With Saudi Arabia's Premier Pharma Company In Fight Against The Deadly MERS Disease

CAPITALIZATION

Symbol
Exchange
Current Price
52 Week Range
Average Volume
Shares Authorized
Shares Outstanding
Float
Market Cap

HEB
NYSE
\$0.18
\$0.06 - \$0.20
660,000
350 Mill
249 Mill
243 Mill
\$43.5 Million

MARKET PROJECTED AT \$319 Billion IN 2021

Debilitating diseases are a complex mosaic of an estimated 6,000 –8,000 conditions. Several jurisdictions, including the US and the EU, have successfully introduced legislation providing a number of economic incentives that stimulate the development of products for debilitating diseases.

US demand for drug delivery products are expected to expand 10.4 percent annually from \$168 Billion in 2016 to \$319 billion by 2021 according to "Research and Markets"

INCREASING NUMBER OF APPROVALS

In 2014 alone, 49 new orphan drugs were approved (more than in any other single year), according to the National Organization for Rare Disorders(NORD); 467 additional orphan designations were requested, representing a nearly 25% increase over 2013.

THE BUSINESS OF NEW DRUG DEVELOPMENT IS BOOMING

HEB is currently pursuing several of key growth markets including immuno-oncology and infectious diseases such as Ebola, seasonal influenza and pandemic strains. The immune-oncology market is expected to be approximately \$14 billion by 2029 and grow to \$24 billion by 2024. The worldwide seasonal vaccine sales are expected to exceed \$4 billion. Both areas along with CNS drugs account for more than 68 percent of the overall pharma industry pipeline.

HEB is intensifying its pursuit of collaborative opportunities with Universities and private companies to advance its product platform and take advantage of these trends.



DRUG DEVELOPMENT FOR DEBILITATING DISEASES

Once a potential therapeutic drug or biologic has been discovered, the process of developing the therapeutic for a particular disease, begins with preclinical development and continues through increasingly complex and demanding phases of clinical testing to support approval for manufacturing and marketing. The process of complying with existing regulations and final approval is complicated and requires solid expertise in the field and an experienced research and management team.



This work, which is expensive and risky, has traditionally been done within pharmaceutical and biotechnology companies. Approximately 10 percent of potential therapeutics that effectively pass preclinical development reach the market, and the cost for each is estimated to average from \$100 million to more than \$1 billion, depending on the disease.

Product Candidate	Country	Indication
Ampligen®	USA	CFS/ME
Ampligen®	USA	HIV
Ampligen®	USA	Metastatic Melanoma
Ampligen®	USA	Renal Cell Carcinoma
Ampligen®	European Union	Ebola Virus Disease
Alferon N Injection®	European Union	MERS

SWI INVESTMENT OPINION

Hemispherx Biopharma, Inc. is competing in a large and fast growing market that is not necessarily dominated by the large pharmacy companies. Smaller companies, who may be bringing a first product to market, can compete successfully and often times collaborate with Universities or larger companies for their research and clinical trials. Eventually, these companies represent a premier acquisition target for the large pharma concerns.

Hemispherx is aggressively pursuing such collaborations to advance its technology platform and product development. This includes pursuing product outlicensing, co-research, co-development, co-promotion, and co-marketing with research institutes, pharmaceutical companies and biotech companies domestically and internationally.

The company has made several changes to the Company's executive management team to provide effective and competent leadership that can properly position the Company to achieve its commercial goals and increase stockholder value. HEB aggressively pursues alliances with partners that have the capital and expertise needed to commercialize the many potential therapeutic aspects of its experimental drug Ampligen® and the approved drug Alferon®.

Assuming the timely access to additional working capital, we believe that this strategy will result in accelerated product development, increasing revenues and a drastically increasing share price.

HEMISPHERX TEAM

MANAGEMENT

Thomas K. Equels, M.S. J.D. is the Executive Vice Chairman, Chief Executive Officer, President, Secretary & General Counsel, was named Chief Executive Officer in February 2016, served as President since August 2015 and has been a Director since 2008. Mr. Equels previously served as Chief Financial Officer from December 2013 to February 2016. While serving full-time at Hemispherx, Mr. Equels has been 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 in Management from Troy. He is a member of the Florida Bar Association and the American Bar Association.

ADAM PASCALE was named Chief Financial Officer in February 2016, in addition to his current responsibilities as Chief Accounting Officer. Mr. Pascale has been employed with Hemispherx since 1996, with more than three decades of public accounting experience and prior public company experience. He earned a Bachelor of Arts (BA) degree in Accounting and Finance from Rutgers University. Mr. Pascale served for several years as a CPA prior to joining Hemispherx, and is a member of both the American and the Pennsylvania Institutes of Certified Public Accountants.

DAVID R. STRAYER, M.D. was appointed Chief Scientific Officer in February 2016 and has served as the Medical Director since 1986. Dr. Strayer is the foremost medical expert on Ampligen and Alferon in the world. 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 has served as Senior Vice President of Operations since May 2011 after joining 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 our Rockville facility to our New Brunswick location as well as coordinated the relocation of manufacturing polymers from South Africa to our production facility in New Brunswick. Previously, Mr. Springate served as President for a worldwide manufacturing and distribution company in New York and oversaw operations at several locations throughout the United States and overseas.

BOARD OF DIRECTORS

WILLIAM M. MITCHELL, M.D., Ph.D., was appointed Chairman of the Board in February 2016 after serving as a Director since July 1998. Dr. Mitchell is a Professor of Pathology, Microbiology & Immunology at Vanderbilt University School of Medicine and is a board certified physician. Dr. Mitchell earned a M.D. from Vanderbilt and a Ph.D. from Johns Hopkins University, where he served as House Officer in Internal Medicine (Osler Service), followed by a Fellowship at its School of Medicine.

Thomas K. Equels, M.S. J.D. Executive Vice Chairman, Chief Executive Officer, President, Secretary & General Counsel

PETER W. RODINO, III, Esq., was appointed Lead Director in September 2015 and has served as a member of to the Board of Directors since July 2013. Mr. Rodino has broad legal, financial, and executive experience. In addition to being President of Rodino Consulting LLC and managing partner at several law firms during his many years as a practicing attorney, he served as Chairman and CEO of Crossroads Health Plan, the first major Health Maintenance Organization in New Jersey. He also has had experience as an investment executive in the securities industry and acted as trustee in numerous Chapter 11 complex corporate reorganizations. Mr. Rodino holds a B.S. in Business Administration from Georgetown University and a J.D. degree from Seton Hall University . More detail about all board members at http://www.hemispherx.net/board-of-directors.



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