HEMISPHERX BIOPHARMA INC
Form DEFA14A
August 31, 2015

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE 14A
(Rule 14a-101)
INFORMATION REQUIRED IN PROXY STATEMENT
SCHEDULE 14A INFORMATION
Proxy Statement Pursuant to Section 14(a)
of the Securities Exchange Act of 1934
(Amendment No. )

Filed by the Registrant x
Filed by a Party other than the Registrant ¨
Check the appropriate box:

¨ Preliminary Proxy Statement
¨ Confidential, for Use of the Commission Only (as Permitted by Rule 14a-6(e)(2))
¨ Definitive Proxy Statement
x Definitive Additional Materials
¨ Solicitation Material Pursuant to Rule 14a-11(c) or rule 14a-12

Hemispherx Biopharma, Inc.
(Name of Registrant as Specified in its Charter)

(Name of Person(s) Filing Proxy Statement, if Other Than the Registrant)

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Hemispherx Biopharma Fully Aligns Executive Bonus Programs to Accelerate Product Revenue Opportunities and Market Entry

….Recent Manufacturing Open House Highlights Two Unique Products

New Brunswick, NJ – August 31, 2015 - Hemispherx Biopharma (NYSE MKT: HEB) recently hosted a Stockholder Open House in their manufacturing and Research and Development (R&D) facility in New Brunswick, NJ, showcasing its progress on all fronts and the near completion of its Alferon® manufacturing program as well as developments in its Ampligen® R&D program. During the tour, stockholders were taken throughout the Alferon® and Ampligen® manufacturing suites and also visited our Research and Development labs, where there has been a significant amount of resources spent on developing a biomarker for Ampligen® to treat Chronic Fatigue Syndrome (CFS). It was emphasized that to achieve accelerated commercial success in the short term, additional funding will be required to go from completion of construction to final Food and Drug Administration (FDA) approval of the Alferon® facility. Consistent with that, all available corporate resources must be directed to achieving this approval. Accordingly, all executive bonus programs, including contract bonuses, have been deferred until these Alferon® manufacturing goals have been achieved and adequate funds are generated to meet our additional research needs for our experimental therapeutic Ampligen®.

The Company's facility and equipment upgrades should lead to an innovative and efficient process for producing Alferon N Injection®, currently the only available FDA-approved natural alpha interferon. The construction of a new bioreactor with continuous flow manufacturing technology throughout is done, subject to required preapproval steps. This entire modern process is expected to dramatically lower costs of production, produce enhanced yields, allow real-time monitoring, create flexibility for tailored batch sizes, and improve operational safety. Comparisons show production efficiencies with this 'state of the art' system, compared to the old manual method, can lead to a 100-fold increase in volume compared to the individual flasks that were used previously. Alferon® was originally produced, at the time of FDA approval, in six-liter volume flasks, equivalent to twelve vials at a time, using a manual process that was extremely labor intensive. Based upon more than ten successful test batches using the new system, we know the new 600 liter bioreactor can produce 1,200 vials at a time, creating a larger amount of product with heightened efficiency, production run reliability and safety.

Tom Equels, President of Hemispherx, stated; "Dr. Carter, our CEO, and I are major stockholders. We are active investors in the Company and by deferring all bonuses until success is achieved we are putting 'Our money where our mouth is!' We were pleased to present our significant progress over the past two years, to our stockholders at the open house. The progress toward completion of our upgraded manufacturing facility is a very significant milestone in our quest for commercial success, making what we believe will be a breakthrough in the efficient high volume production of natural multi-species human alpha interferon. Although synthetic/recombinant alpha interferon comprise a multibillion dollar market, there is a significant percentage of interferon patients who, due to the development of neutralizing antibodies to recombinant interferon, may no longer respond to synthetic/recombinant alpha interferon treatments. Alferon® N is comprised of multiple subspecies of natural alpha interferon. The incidence of antibodies induced against natural interferon is very low (less than 0.2%). An analysis of relapsed and refractory NAB positive patients who switched treatment to natural interferon, such as leukocyte derived Alferon N Injection® (alpha-n3) or Wellferon® (alpha-n1), showed that in 33/40 (82%) of those relapsed or refractory patients switching to natural

interferons, the clinical response was restored (Strayer, et al. J Interferon and Cytokine Research (2012) 32(3):95-102). Because of these scientific observations, we firmly believe a strong market exists in the United States for our FDA approved use (See Below) and internationally, where we have already been approved in Argentina for use in any interferon-treatable disease where a patient has become refractory to synthetic/recombinant interferon. A widened indication for use of Alferon® N in patients who are no longer responsive to synthetic interferon, as in Argentina, has not been reviewed and/or approved by the FDA.

Further, in our Ampligen® program we are developing compelling data on the relationship between natural killer (NK) cells and severe CFS. We are also in the process of evaluating the relationship between responders to our experimental therapeutic, Ampligen®, and NK cell levels in severe CFS victims. We believe that this further evaluation of the potential use of NK as a biomarker for severe CFS victims is an important component in moving Ampligen®, an experimental therapeutic, along the path to approval in the United States and in other countries. Our recently announced relationships with Emerge and myTomorrows provides an early access platform for our experimental therapeutic Ampligen for CFS patients in Europe and Australia."

About Hemispherx Biopharma

Hemispherx Biopharma, Inc. is a specialty pharmaceutical company headquartered in Philadelphia, Pennsylvania and engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based disorders. Hemispherx's flagship products include Alferon N Injection® and the experimental therapeutics Ampligen® and Alferon® LDO. Ampligen® is an experimental RNA nucleic acid being developed for globally important debilitating diseases and disorders of the immune system, including Chronic Fatigue Syndrome. Hemispherx's platform technology includes components for potential treatment of various severely debilitating and life threatening diseases including cancers. Because both Ampligen® and Alferon® LDO are experimental in nature, they are not designated safe and effective by a regulatory authority for general use and are legally available only through clinical trials. 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. The Company's Alferon N Injection® approval in Argentina includes the use of Alferon N Injection® (under the brand name "Naturaferon") for use in any patients who fail, or become intolerant to recombinant interferon, including patients with chronic active hepatitis C infection. The Company wholly owns and exclusively operates a GMP certified manufacturing facility in the United States for commercial products. For more information please visit www.hemispherx.net.

Disclosure Notice

The information in this press release includes certain "forward-looking" statements including without limitation statements about additional steps which the FDA may require and Hemispherx may take in continuing to seek commercial approval of the Ampligen® NDA for the treatment of Chronic Fatigue Syndrome in the United States. The production of new Alferon® API inventory will not commence until the capital improvement and validation phases are complete. While the facility is approved by FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed upon the completion of the facility's enhancements prior to commercial sale of newly produced inventory product. If and when we obtain a reaffirmation of FDA BLA status and have begun production of new Alferon® API, we will need FDA approval as to the quality and stability of the final product to allow commercial sales to resume. The final results of these and other ongoing activities could vary materially from Hemispherx's expectations and could adversely affect the chances for approval of the Ampligen® NDA in the United States and other countries. Any failure to satisfy the FDA regulatory requirements or the requirements of other countries could significantly delay, or preclude outright, approval of the Ampligen® NDA in the United States and other countries. The re-launch of Alferon® N as a commercial product cannot commence until all regulatory approvals have been obtained.

Information contained in this news release, other than historical information, should be considered forward-looking and is subject to various risk factors and uncertainties including, but not limited to, general industry conditions and competition; general economic factors; the Company's ability to adequately fund its projects; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Company's ability to accurately predict the future market conditions; manufacturing difficulties or delays; dependence on the effectiveness of the Company's patents and other protections for products; and the exposure to litigation, including patent litigation, and/or regulatory actions; as well as numerous other factors discussed in this release and in the Company's filings with the Securities and Exchange Commission. The final results of these efforts could vary materially from Hemispherx's expectations. Finally, the projection of savings above is subject to change based upon operational requirements of the company and the possibility that additional finance and accounting staff may be required to accomplish the Company's goals and objectives.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as “intends,” “plans,” and similar expressions are intended to identify forward-looking statements. The inclusion of forward-looking statements should not be regarded as a representation by Hemispherx that any of its plans will be achieved. These forward-looking statements are neither promises nor guarantees of future performance, and are subject to a variety of risks and uncertainties, many of which are beyond Hemispherx’s control, which could cause actual results to differ materially from those contemplated in these forward-looking statements. Examples of such risks and uncertainties include those set forth in the Disclosure Notice, above, as well as the risks described in Hemispherx’s filings with the Securities and Exchange Commission, including the most recent reports on Forms 10-K, 10-Q and 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Hemispherx undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise revise or update this release to reflect events or circumstances after the date hereof.

Important Information

This press release may be deemed to be a solicitation of a proxy by the Company and its management related to the upcoming annual meeting of the Company's stockholders scheduled to be held on September 16, 2015 (the "Annual Meeting"). The Company has filed a definitive proxy statement related to the Annual Meeting with the Securities and Exchange Commission (the "SEC"). Company stockholders are advised to read such document, because it contains important information. Stockholders may access such document without charge at the SEC's web site (www.sec.gov) and on the Company's website (http://www.hemispherx.net/content/investor/annualmeeting.asp). They also will be able to obtain a copy of the definitive proxy statement, without charge, by directing a request to the Company in writing at Corporate Secretary, Hemispherx Biopharma, Inc., 1617 JFK Boulevard, Suite 500, Philadelphia, Pennsylvania 19103. Information regarding the security ownership and other interests of the Company's executive officers and directors is included in the Company's definitive proxy statement.