

HEMISPHERX BIOPHARMA INC
Form DEFA14A
August 26, 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
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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
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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 Hosts Stockholder Open House at its Manufacturing and Research Development Center in New Jersey

NEW BRUNSWICK, New Jersey - August 26, 2015 - Hemispherx Biopharma (NYSE MKT: HEB) recently hosted a Stockholder Open House at the company's newly renovated manufacturing and research development center in New Brunswick, New Jersey. The attendees had the opportunity to see the Company's facility and equipment upgrades that should lead to an innovative and efficient process for producing Alferon N Injection®, the only FDA-approved natural alpha interferon. A photo accompanying this release is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=35568>.

“The cornerstone of Hemispherx's operation is the integration of a new bioreactor with continuous flow manufacturing technology throughout. This entire modern process is expected to produce lower expense, enhanced yields, real-time monitoring, flexibility for tailored batch sizes, and improved operational safety”, said Wayne Springate, Senior VP of Operations of Hemispherx Biopharma.

“A comparison showing production efficiencies with this novel system vs. the old method is quite dramatic,” said Dr. Chris Cavalli, VP of Quality Control and Processing Development. “Historically, Alferon was produced in six-liter volume flasks, twelve vials at a time, and the process was very labor intensive. The new 600 liter bioreactor produces 1,200 vials, creating a larger amount of product with heightened efficiency.”

The 44,000 square-foot facility also houses the Company's Ampligen® manufacturing process.

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.