HEMISPHERX BIOPHARMA INC
Form DEFA14A
July 14, 2016

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

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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 Outlines Key Elements of Strategic Growth Plan and Commitment to Transparency

PHILADELPHIA – July 14, 2016 – Hemispherx Biopharma (NYSE MKT: HEB) ("Hemispherx" or the "Company") today announced key elements of its strategic growth plan as well as additional measures being implemented under the Company's commitment to transparency. The aim of both the strategic growth plan and commitment to transparency is to drive the creation of incremental stockholder value through the advancement of the Company's lead products, both independently and with potential partners.

Following the management changes in February 2016, the Hemispherx executive team developed and implemented a new business plan focused on achieving long-term company growth. This plan is centered on four key strategic initiatives:

1) Aggressively seeking out licensing opportunities and/or senior co-development partnerships for product candidates in the disease indications which have been in in-vivo testing,
2) Utilizing licensing fees to advance development of prioritized unlicensed indications,
3) Monetizing underutilized assets; and
4) Strictly adhering to the newly adopted financial austerity measures.

"We have been aggressively executing this multi-faceted strategic plan. We are approaching several milestones in the execution of this plan, and anticipate reaching certain key value inflection points in the coming months," said Thomas K. Equels, CEO of Hemispherx.

In addition to the development and implementation of this new corporate strategy, Hemispherx management has initiated a new, company-wide commitment to transparency with a goal of providing stockholders greater insight into developments at the Company. Under this initiative, Hemispherx has launched a new corporate website and begun holding investor conference calls in conjunction with the filing of the Company's quarterly financials. In-line with its commitment to transparency, the Company announced the availability of a new Corporate Overview presentation, which is available at http://ir.hemispherx.net/Events_Presentations.

For European stockholders, Hemispherx has posted Letter to Stockholders for its upcoming annual meeting translated into French, German and Dutch. These letters can be found at http://ir.hemispherx.net/Annual_Stockholder_Meeting.

Mr. Equels added, “The continued execution of our strategic growth plan is critical to the future success of the Company, however, keeping stockholders informed of our accomplishments is equally important. The launch of our new website was a significant step in this regard, and we are pleased to follow that up with the availability of the new corporate overview presentation. I hope you will take the time to go to our website and read this document. Further, as an accommodation to our many European stockholders, I am pleased to provide the French, German and Dutch translations of our most recent Letter to Stockholders. Please review this letter carefully in preparation for our upcoming Stockholder Meeting. Going forward, we are committed to more frequent, proactive communication with our stockholders and hope that they will share in our excitement for what the future holds.”

About Hemispherx Biopharma:

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® 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. 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.

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 "potential," "potentially," "possible," 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, below, 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.

Disclosure Notice:

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; and numerous other factors discussed in this release and in the Company's filings with the Securities and Exchange Commission. The production of new Alferon® API inventory will not commence until the validation phase is complete. While the facility is approved by FDA under the Biological License Application ("BLA") for Alferon®, this status will need to be reaffirmed by a successful Pre-Approval Inspection by the FDA prior to commercial sale of newly produced inventory product. The validation phase is delayed until we are able to repair the damage caused by a flood that occurred on January 5, 2016 at the facility. While we have made progress in repairing the damage at the facility, we cannot assure when all repairs required to be made prior to seeking Pre-Approval Inspection by the FDA. 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. With regard to our NDA for Ampligen® to treat CFS, we note that there are additional steps which the FDA has advised us to take in our seeking approval. The final results of these efforts and/or any other activities could vary materially from Hemispherx's expectations. Any failure to satisfy the FDA regulatory requirements or the requirements of other countries could significantly delay, or preclude outright, approval of Ampligen® in the United States and other countries. No evidence is suggested that Ampligen® will be commercially approved for any treatment or that Alferon N Injection® will be commercially approved for potential new treatment indications or for new manufacturing procedures. No assurance can be given that new management's new business plan and focus will prove successful.