

HEMISPHERX BIOPHARMA INC
Form DEFA14A
May 18, 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

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

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)

Payment of Filing Fee (Check the appropriate box):

No fee required.

Fee computed on table below per Exchange Act Rules 14a-6(i)(1) and 0-11.

- 1) Title of each class of securities to which transaction applies:
- 2) Aggregate number of securities to which transaction applies:
- 3) Per unit price or other underlying value of transaction computed pursuant to Exchange Act Rule 0-11:
- 4) Proposed maximum aggregate value of transaction:
- 5) Total fee paid:

Fee paid previously with preliminary materials.

Check box if any part of the fee is offset as provided by Exchange Act Rule 0-11(a)(2) and ..identify the filing for which the offsetting fee was paid previously. Identify the previous filing by registration statement number, or the Form or Schedule and the date of its filing.

- (1) Amount Previously Paid:
- (2) Form, Schedule or Registration Statement No.:
- (3) Filing Party:
- (4) Date Filed:

Transcript of First Quarter Conference call held on Tuesday, May 17, 2016 at 1:00 PM EDT

Hemispherx Biopharma, Inc.

05/17/16

1:00 PM EDT

OPERATOR: Good afternoon ladies and gentlemen and welcome to the Hemispherx Biopharma conference call. At this time all lines have been placed on a listen only mode. Before management begins to speak, the company has the following statement: to the extent that statements on this conference call are not strictly historical, all such statements are forward looking, are based upon the current beliefs and expectations of the company's management, are subject to significant risk and uncertainties and are made pursuant to The Safe Harbor Provisions of The Private Securities Litigation Reform Act of 1995.

We are obliged by law to provide certain legal and binding disclaimers before we begin. Words such as intends, plans, potential, believes, 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 its plans will be achieved. These forward looking statements are neither promises nor guarantees of future performance and are subject to a variety of risk and uncertainties, many of which are beyond Hemispherx control, which could cause actual results to differ materially from these contemplated in these forward looking statements. For example because numerous risks and uncertainties exist, despite our efforts and belief regarding approvals, we cannot assure Ampligen will ever be commercially approved for any treatment or that Alferon N injection, will ever be commercially approved for potential new treatment indications or for the new manufacturing procedures underway. Examples of such risks and uncertainties include the risks described in Hemispherx' 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 forward looking statements which speak only as of the date hereof and Hemispherx undertakes no obligation to update or revise the information discussed on this conference call, 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.

With that covered, it is now my pleasure to turn the floor over to your host Mr. Thomas Equels, President and Chief Executive Officer of Hemispherx Biopharma. Sir, the floor is yours.

MR. EQUELS: Thank you very much Paul. Good afternoon ladies and gentlemen. Thank you for joining our call. This is our second quarterly conference call under the new administration. My name is Tom Equels. I'm Hemispherx'

new Chief Executive Officer. Just yesterday, we filed our 10-Q for the first quarter ending March 31, 2016. Due to the timing of the filings for the year end financials in the first quarter filings, not much time has elapsed since our last conference call which was on March 30th; so this corporate update will be somewhat brief.

I'd like to begin with a brief discussion regarding the retention of Huron Consulting Group. Huron is a global professional services firm which we've retained, focused on assisting clients with their most complex business issues by delivering high value, quality solutions to support long term business objectives. They specialize in serving clients in the healthcare industry with a focus on life sciences; as well as many other areas but they have a very strong life sciences division.

We are looking forward to the relationship with Huron because of its deep industry and technical expertise. Huron provides advisory consulting, technology and analytic solutions with the aim at delivering sustainable, measurable results. One of the key points that I made in the March 30th., year-end conference call, for those of you who participated and remember, was that we're shifting from the old management view that Hemispherx can do it all and try to become the next Pfizer to what I think is a more realistic business plan or model for co-developing our existing technology; some of which is very late stage with existing, established pharma industry partners who are able to maximize our chances of expedited commercial success and we hope then, maximizing stockholder value.

To help us execute on this plan we've retained Huron and we expect them to support management in advancing the company's strategic plan to capitalize on all of the possible business opportunities that exist in this country and around the world for Ampligen and Alferon. Now, we strongly believe that co-development and/or the licensing of our products is the best plan for success in generating revenues quickly and obtaining regulatory approvals and meaningful, long term revenue streams.

The second major focus and the implementation of the new business plan under my management is the unified commitment to preserve capital; both short and long term so that the company can better achieve our goals. As you may have seen in yesterday's press release announcing the financial results for the first quarter ending March 31st, we posted a reduction in net loss of \$1,281,000 for the quarter. That's a 37% reduction in just the first three months of this year. This shows that our austerity plan is working.

I would now like to shift my discussion to our manufacturing facility and more specifically, to the re-launch of the product Alferon N injection. We had a great deal of discussion in our last call about Ampligen and Ampligen for CFS; and that may be the reason why we've received many questions from stockholders related to the manufacturing facility and Alferon N injection. Since the questions are very similar, what I'm going to do is going to go into a detailed discussion of where we're at, at the manufacturing facility in New Brunswick, New Jersey and regarding the relaunch of this product; so forgive me but this is somewhat detailed. It does address many of the questions that we received.

As you're aware from our filings as well as press releases, we've completed construction of the facility. We've purchased approximately 8-million dollars in equipment. The installation of that equipment and the construction related to that installation is complete. We believe that this enhancement project, which requires FDA approval through a manufacturing inspection, should provide for both a higher capacity and more cost effective manufacturing process for the production of Alferon N injection; which is going to be very important to its commercial success, increased volume and creating a greater profit margin.

However, we anticipated commercial sales to start but there have been some bumps in the road. The first major issue that we encountered related to a breach of our sole-source Leukocyte supply contract with BioLyte; a Brexalta (ph) subsidiary; it shut down its entire pin-plasma (ph) division without regard to the contractual obligation it had with us and that impaired our long-term, sole-source supply.

Now, we have resolved this issue I believe through identifying and developing relationships with multiple direct-source suppliers of Leukocytes and that having been said, we were in the process of locating these new suppliers but we were forced, due to the interruption in the supply of Leukocytes, to shut down the facility. Now, when we shut down the production line, there were certain malfunctions that occurred in the upstream process and we were working to restart that validation process and address those malfunctions and were making progress when we had a catastrophic event. It was a severe flood in our Alferon manufacturing facility that occurred in the area where the bioreactor is. This flood occurred on January 5, 2016. It was caused by a malfunctioning high-volume water supply pipe for the fire sprinkler system.

The pipe in question is up in an inaccessible area of the facility. It covered a large part of the bioreactor clean-room in stagnant water and silt. Fortunately, we have insurance and our insurer has been working well with us to remedy the problem. The timing in the repairs of the Alferon manufacturing facility however, are dictated by the insurance company. For example, estimates must be obtained from vendors, then reviewed and approved by the insurance company. We don't have the luxury of acting unilaterally to expedite matters because it might affect our ability to assure coverage of those expenses; and we're in a position where we can't afford to have uncovered repairs that otherwise would have been paid by the insurance company but aren't because we're acting unilaterally. So, we're working very carefully with equipment manufacturers, the construction trades and various vendors to both assess the damage and curtail the amount of down-time and continued work required to complete the FDA pre-approval inspection.

What I'm going to do now is go through some of the actual things, so you, our stockholders have a very much up to date status with regard to this issue. First, I'm going to talk about HEPA filters. These are high efficiency particulate arresting filters that are required in clean-rooms and in a manufacturing facility such as ours. All of these HEPA filters that were affected by the flood have been sent for testing by an outside contractor. That was done the last week of April and all of the filters passed that testing; so no additional work will be required on the HEPA filters.

There was damage as a result of the flood to the floor; and now I'm talking about the area where the bioreactor is and then there's a fairly large clean-room area and the floor in that part of the Alferon manufacturing facility was damaged by the flood. The floor repairs are scheduled to begin the third week of May of this year and will finish within two weeks; probably within a week.

A third item, that is requiring repair and will, some of this is going to be done in conjunction with the flooring are the walls. The walls in the bioreactor room, for those of you who came to our open house and took the tour you'll have seen this, but these walls are covered with a special elasticized material designed for clean-rooms and it's a part of our manufacturing facility. Most people think of walls as being just a wall but in this case the walls have a special function and the materials were damaged by the flood. It's requiring repairs. Those repairs are scheduled to begin, at the soonest, the last week of May and should be a week to two weeks in duration if everything goes right.

The next item I'd like to talk about are our pumps. I'm not going to go into the details of the particular pumps which were affected but we had several pumps which required inspection because they appeared to have been damaged by the flooding. Repairs were required on these pumps and in order to ensure that they were working at the standard required in a GMP facility, the pumps were repaired. They were returned to us just a couple of weeks ago. The pumps can't be installed though until the flooring is repaired, once the flooring is fully repaired the pumps will be reinstalled in the Alferon facility so that it will be ready to use, they will be ready to use in the manufacturing process.

Now, there's another item which is a PH meter and printer; which is a part of the process. It was affected by the flood and it did require repair. We're not sure exactly when these/this will be returned to us but once repaired it will be reinstalled and will have to be qualified through inspection processes for use in the manufacturing process.

A few more items: the ducts in the facility, these are the air ducts that are a part of this facility; had to be inspected and cleaned. We have to maintain a certain standard. The contracting for this work is underway and it will be performed only after some of these other repairs have been finalized. For example, the repair of the floor, the repair of the walls, that type of thing. They'll be one of the last stages.

And in conjunction with that, there is going to be a requirement that we deal with the insulation around the ducts and the ceiling tiles that were damaged by the water and silt from the failed system and they, wet insulation of course and damaged ceiling tiles have been removed. The manufacturing department is in the process of contacting, to get quotes for replacement of the insulation and tile. Once that's been done and gets approved by the insurance company we will vigorously begin that process. But again, that's the kind of thing that is in the later stages of the total project.

There's a need for air balancing of the air-conditioning system. That will be required after the duct cleaning, after the insulation and ceiling tiles have been repaired and replaced. Once the air balancing is complete, we hope to have the air-conditioning or HVAC system qualified for use in a manufacturing facility.

Now, because of but not directly related to the flood, but because we're in a stage, a down-stage related to the flood damage and we have an air-conditioning chiller that is very old and over the years has required some expensive repairs, we've taken this opportunity to purchase a new, high efficiency, York 200-Ton Chiller to replace the old existing equipment that will provide both the Alferon and the Ampligen manufacturing clean-rooms, those air handlers with cold air; and we're doing this now so as to integrate the new York chiller with the repairs to the facility.

Currently the manufacturing process is on hold while we're making these repairs. It's clear that we're going to have to have additional funds to commence the restart. There are a number of ways that we can address that but there is no question that we'll have to, because we're basically shut down in the Alferon facility; bring back certain people and engage in expenses that will allow us to restart. It's important to note that, at the time that the contract was breached by BioLyte, we're actually doing runs in the new facility creating clinical grade Alferon for purposes of testing the process. So to some extent, we've got to go back to scratch on re-validating that process and it's an unfortunate result but we'll try and address that issue in detail once we know we're ready to go back into production.

A third and final topic today for purposes of this call is something we've disclosed in our SEC filings and I talked about in our last call. We're on notice from the stock exchange that because the price of our stock is below the level that they deem appropriate. Unless the stock price rises, we will have to deal with an issue that could affect our listing with the New York Stock Exchange. We've got until September 15th to demonstrate compliance and the Board of Directors is determined that absent of a substantial increase in the price of our stock, we will have to face the possibility of de-listing.

We believe that the de-listing of the common stock would adversely affect Hemispherx and its stockholders. Among other things, we believe that de-listing would negatively impact liquidity, marketability and the trading place of our common stock and interfere with our ability to execute on the plans that we have to unlock the value of our asset. The board believes that a reverse stock split, if needed, would help regain compliance with the New York Stock Exchange's low price concerns and potentially provide a number of benefits to Hemispherx and its existing stock holders, including but not limited to increasing interest by brokers and institutional investors and decreasing stockholder transactional costs. For these and other reasons that will be described in greater detail in the upcoming proxy statement, we're going to be seeking stockholder approval of a reverse stock split, with the board having discretion as to whether or not the reverse stock split is to be affected and the exact ratio of the reverse stock split to be set within a range determined by the board and submitted to the stockholders in the proxy.

Please understand that if the stockholders fail to vote in favor of the reverse split proposal, our continued New York Stock Exchange listing will be in jeopardy. The primary consequence of this is, that while the company would go on the ability for stockholders to trade in a vigorous open market might be impaired; so I firmly believe that approval of a reverse stock split is critical to the restoration of stockholder value.

We will be filing a proxy statement with the Securities and Exchange Commission which will include a proposal requesting stockholder approval of the reverse stock split. My discussion of the reverse stock split in this call does not constitute a solicitation of any vote or approval and is not a substitute for any proxy statement or other document we will file with the SEC in connection with the proposed reverse stock split. Stockholders are strongly urged to read the proxy statement when it's filed as it will contain very important information. The definitive proxy statement when available will be mailed to all of our stockholders. Stockholders may obtain free copies of the proxy statement when filed without charge at the SEC's website: www.sec.gov and copies of the proxy materials will also be posted in the investor relations section of the company's website at www.Hemispherx.net around the last week of June.

I hope all of you that are on the call get a chance to look at our new website. One of the first things that we've done is to update the old website and with any new venture like that it's going to be a work in progress but we think it provides you with a more modern, more easily accessible venue for accessing information about the company. Again, those proxy materials will be posted in the investor relations section of the website, once they're posted around the last week of June.

At this point in time we've had some additional questions; via email, that we'd like to address. That being the case, I'd like to turn this over to Dianne Will, our investor relations representative, for the purposes of going over those questions.

MS. WILL: Thank you Tom. We have solicited written questions from our stockholders and interested parties; to the extent that the presentation that Mr. Equels has already provided answers, the questions will not be addressed. Because several questions address the same issue, we have grouped the questions by topic and will answer the most appropriate questions by topic.

Tom, the first question is: what are the under-utilized assets and what is the status of their sale?

MR. EQUELS: It's actually an under-utilized asset. If I may, if I may describe the property and buildings which we own in New Brunswick New Jersey, there are two separate lots that are adjacent to each other and each lot has a building on it. One of the larger buildings is our manufacturing facility and then there is a very substantial building there but it's a storage building; and it's not necessary for our operations. So, the truly under-utilized asset is that storage building which we have listed for sale and we're aggressively trying to sell for 1.8-million dollars.

Now with the same broker, we have advised them that we would also entertain a lease-back arrangement or financing with regard to the manufacturing facility, but that's at a much higher number, 8-million dollars and we would still

retain ownership and operational control of the manufacturing facility. So, the only under-utilized asset that we're talking about is that storage building and it's my intention to try and sell that in 2016 if it's humanly possible.

MS. WILL: Thank you Tom. The second question we have for you is: please give an update on the status of Ampligen and CFS.

MR. EQUELS: With regard to Ampligen and CFS, we had an extensive discussion on that issue in our last call just a little more than a month ago; and it's addressed in some detail in our filings. But rest assured that, we're doing everything we can internally and working with government agencies to try and move the ball forward for purposes of obtaining a commercial approval. Many, many people who are in desperate need of a therapy for CFS will have access to Ampligen if at all possible. I have to say that when you're asking for governmental approvals, you cannot predict when or if the government will ever approve something like this but we're going to make every effort to get that approval.

MS. WILL: Thank you Tom. The next question I have for you is: is Hemispherx in play for a contract with the government for the Zika virus?

MR. EQUELS: In answering that question, that's the way the question was received by us but I have to step back a little bit here. Let me talk first a little bit about Ampligen and how Ampligen works.

Ampligen our experimental therapeutic, has a very dramatic effect on the human immune system; and it's been established in various experiments, animal experiments that it plays a role as a host-base, immune system driven anti-viral but it's an early on-set anti-viral. When we look at the Zika virus and when we look at the experiences with Ampligen as an early onset therapeutic in many other viruses, for example Ebola, there's a possibility that Ampligen would have a very positive effect with Zika in the early stages of infection.

However, there have been no tests or experiments that would justify a contract for Zika; so our focus is on trying to facilitate testing, experimental testing and we're seeking opportunities to engage in that experimental testing. If those experiments provide a basis for going further, then we would expect that there would be clinical activity, testing Ampligen with the Zika virus. And at some stage, if that were successful the possibility of contracts would exist.

The question itself has got the cart way before the horse to use the old saying. We have to solicit and obtain experimental results with the Zika virus before anybody will consider governments specifically, contractual activities related to the Zika virus.

MS. WILL: Thank you Tom and the final question for you today is: what is the status of co-development and/or licensing partners?

MR. EQUELS: The company is placing a high priority on that activity. Our relationship with Huron is to facilitate those types of activities. However, I can only say the following: we have commenced actual talks but they're preliminary in nature and they're confidential; so I have to respect the fact that as we begin this process, we're not going to be in a position to be giving a quarterly blow-by-blow on discussions and negotiations and those types of activities, by their nature are confidential until they're finalized and ready to be announced if they're successful. And whether they'll be successful or not, still remains to be seen. We're certainly going to give 110% effort at Hemispherx to create these opportunities though.

MS. WILL: Okay, that was your final question Tom. Thank you. Thank you ladies and gentlemen.

MR. EQUELS: Thank you Dianne.

MS. WILL: This concludes today's presentation. You may disconnect your lines and have a wonderful day.

END

Important Information

Hemispherx intends to file a proxy statement with the Securities and Exchange Commission (the "SEC"). This communication is not a substitute for any proxy statement or other document Hemispherx may file with the SEC in connection with a proposed reverse stock split. Stockholders are urged to read the proxy statement, when filed as it will contain important information. Any definitive proxy statement(s) (if and when available) will be mailed to stockholders of Hemispherx. Stockholders may obtain free copies of the proxy statement, when filed, without charge, at the SEC's website (www.sec.gov). This document does not constitute a solicitation of any vote or approval.

Participants in Solicitation

Hemispherx and its directors and executive officers and other members of management and employees are potential participants in the solicitation of proxies in respect of the proposed transaction. Information regarding Hemispherx's directors and executive officers is available in its Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 29, 2016. Additional information regarding the interests of such potential participants will be included in the proxy statement to be filed with the SEC by Hemispherx in connection with the proposed transaction and in other relevant documents filed by Hemispherx with the SEC. These documents can be obtained free of charge from the sources indicated above. Additional information regarding the participants in the

proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement and other relevant materials to be filed with the SEC when they become available.