UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

[redacted] Individually and On Behalf of All Others Similarly Situated, Plaintiffs, v. HEMISPHERX BIOPHARMA, INC., WILLIAM A. CARTER, THOMAS EQUELS, and CHARLES T. BERNHARDT, Defendants.	**Case No.** **CLASS ACTION** **COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

CLASS ACTION COMPLAINT

Plaintiff [redacted] ("Plaintiff"), individually and on behalf of all other persons similarly situated, by her undersigned attorneys, for her complaint against defendants, alleges the following based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through her attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Hemispherx Biopharma, Inc. ("Hemispherx" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased Hemispherx securities between March 19, 2012 and

December 17, 2012, inclusive (the "Class Period"), seeking to recover damages caused by defendants' violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Hemispherx is a biopharmaceutical company that focuses on the development of nucleic acids to enhance the natural anti-viral defense systems of the human body. The Company's lead product, Ampligen® ("Ampligen"), is undergoing clinical trials for the treatment of Myalgic Encephalomylitis/Chronic Fatigue Syndrome.

3. Throughout the Class Period, Defendants made a host of materially false and misleading statements regarding the safety and efficacy of Ampligen, and touted purportedly positive results from Ampligen's clinical trials. As a result of the foregoing, the Company's statements were materially false and misleading at all relevant times.

4. On December 18, 2012, the FDA published an FDA staff report concerning Ampligen's safety and efficacy. Specifically, the report concluded that the Company's studies were "ill-defined and invalid" with signals of efficacy that were inconsistent between clinical trials, and based on the limited quality of the data, "it is difficult to draw conclusions regarding potential safety signals," but the "review identified nine potential safety concerns associated with Ampligen."

5. As a result of this disclosure, Hemispherx shares declined $0.276 per share or nearly 43%, to close at $0.368 per share on December 18, 2012.

6. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant damages.

JURISDICTION AND VENUE

7. The claims asserted herein arise under and pursuant to Sections 10 (b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R § 240.10b-5.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Hemispherx maintains its principal place of business in this District and many of the acts and practices complained of occurred in substantial part herein.

10. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

11. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Hemispherx securities at artificially inflated prices during the Class Period and was damaged thereby.

12. Defendant Hemispherx is a corporation organized under the laws of the state of Delaware, maintaining its principal place of business at 1617 JFK Boulevard, Suite 660, Philadelphia, PA 19103. Hemispherx's common stock trades on the New York Stock Exchange Market LLC ("NYSE MKT") under the ticker symbol "HEB."

13. Defendant William A. Carter ("Carter") at all relevant times has served as the Company's President, Chief Executive Officer ("CEO"), Chief Scientific Officer and Chairman of the Board of Directors ("Board").

14. Defendant Thomas K. Equels ("Equels") at all relevant times has served as the Company's Executive Vice Chairman of the Board, Secretary and General Counsel.

15. Defendant Charles T. Bernhardt ("Bernhardt") at all relevant times has served as the Company's Chief Financial Officer and Chief Accounting Officer.

16. The defendants referenced above in ¶¶ 13 - 15 are referred to herein as the "Individual Defendants."

SUBSTANTIVE ALLEGATIONS

BACKGROUND

17. Hemispherx, a specialty pharmaceutical company, is engaged in the clinical development of new drug therapies based on natural immune system enhancing technologies for the treatment of viral and immune based chronic disorders. The Company's current strategic focus is based upon four applications of its two core pharmaceutical technology platforms Ampligen® and Alferon N Injection®. The commercial focus for Ampligen® includes application as a treatment for Chronic Fatigue Syndrome ("CFS") and as an influenza vaccine enhancer (adjuvant) for both therapeutic and preventative vaccine development. Alferon N Injection® is a FDA approved product with an indication of use for refractory or recurring genital warts. Alferon® LDO (Low Dose Oral) is a formulation currently under development targeting influenza.

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

18. On March 19, 2012, the Company issued a press release announcing the publication of data on the bioactivity of Ampligen in CFS. Specifically, the Company stated the following, in relevant part:

> Hemispherx Biopharma, Inc. (NYSE Amex:HEB) (the "Company" or "Hemispherx") announced the publication of a peer-reviewed article providing the

results from the AMP-516 Phase III Clinical Trial of Ampligen® [rintatolimod, Poly (I) • (C[12,]U)], an experimental therapeutic, in the high impact, online journal, PLoS ONE. The report is entitled "A Double-Blind, Placebo-Controlled, Randomized, Clinical Trial of the TLR-3 Agonist Rintatolimod in Severe Cases of Chronic Fatigue Syndrome". Recently, researchers from the Centers for Disease Control and Prevention ("CDC") and Harvard School of Public Health published new data showing the profound economic impact of CFS on increasing healthcare costs of $452 million and decreasing CFS patient productivity by $1.2 billion in Georgia, a state with approximately 5.5 million people age 18-59 (Cost Effectiveness and Resource Allocation, 9:1, 2011).

In the current PLoS One publication, a Phase III, FDA authorized study in CFS evaluated the safety and therapeutic effectiveness of Ampligen ®, an experimental therapeutic, in 234 subjects with debilitating CFS at 12 clinical sites in the United States. The Ampligen® treatment was generally well-tolerated....

The primary endpoint, exercise tolerance, improved an average of 21% in subjects receiving Ampligen® compared to placebo and the proportions of patients with exercise improvements of at least 25% and 50% were 1.7 and 1.9-fold greater for the Ampligen® group versus placebo ($p<0.05$). An ad hoc continuous responder analysis of exercise improvement between 25% and 50% at 5% increments demonstrated a significantly greater response for patients receiving Ampligen® compared to placebo.

The Ampligen® cohort also reduced dependence on medications used to reduce symptoms of CFS compared to the placebo group ($p<0.05$), adding additional insight to the recent CDC/Harvard study which emphasizes the overwhelming economic burden of medical care for CFS sufferers.

In 2010, Hemispherx published new data showing that a greater proportion of placebo patients in this Phase III trial were found to have a significant prolongation of the EKG QT interval compared to patients who received Ampligen®. Prolongation of the QT interval, which is a risk factor for sudden cardiac death and arrhythmias, was associated with continued use of certain drugs by CFS sufferers known to prolong the QT interval (Journal of Applied Research, 10:3, 2010). CFS patients are considered to be at increased risk for catastrophic cardiac events despite their relatively young age and the preponderance of women (approximately 2-3 women for each man) who suffer from this chronically debilitating disease.

On January 11, 2012, Hemispherx announced that the FDA had granted an extension of its pending New Drug Application ("NDA") for potential treatment of CFS. The Company is currently conducting "open-label" treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder.

> The FDA originally concluded (Complete Response Letter received 11/25/09) that this Phase III study was inadequate to support approval of the NDA. However, the new analyses and other insights in the PLoS One report supplement the original study findings. The Company believes that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA.

19. On July 11, 2012, the Company issued a press release announcing that it had reached an agreement with the FDA on filing requirements for the Company's complete response in support of Ampligen New Drug Application ("NDA") for Chronic Fatigue Syndrome Treatment. Specifically, the Company stated the following, in relevant part:

> Hemispherx Biopharma, Inc. (NYSE MKT: HEB) (the "Company" or "Hemispherx") recently met with representatives of the U.S. Food and Drug Administration (the "FDA"). At that meeting, the FDA agreed to accept, for review, new analyses of data from Hemispherx's AMP-516 Phase III Clinical Trial ("AMP-516 Trial") in support of its New Drug Application ("NDA") for Ampligen ® (Poly I : Poly C 12 U). If found sufficient to support approval of the drug, these new analyses will be in lieu of an additional confirmatory Phase III study called for in the Agency's November 25, 2009, Complete Response Letter ("CRL") . The FDA has advised that whether the new analyses provide adequate evidence of Ampligen®'s efficacy in treating Chronic Fatigue Syndrome ("CFS") will ultimately be a review issue.
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> In its CRL, the FDA recommended at least one additional clinical study of Ampligen® in CFS patients, including at least 300 patients on dose regimens intended for marketing. In November 2010, Hemispherx announced the publication of new analyses of data from the AMP-516 Trial showing that patients on Ampligen® reduced their use of concomitant medications compared to patients receiving placebo. In particular, Ampligen® patients reduced their use of medications which may prolong the QT interval. Prolongation of the QT interval is a known risk factor for sudden cardiac death and arrhythmias. A greater portion of the placebo patients were found to have a significant prolongation of the QT interval compared to patients who had received Ampligen®, thereby creating a cardiac risk situation in the CFS patients. Cardiac death is one of three major causes of premature death in CFS, which affects predominantly women in their 40s....
>
> In March, 2012, a new peer reviewed analysis of data from the AMP-516 Trial was published showing that the proportions of Ampligen ® patients with exercise improvements of at least 25% and at least 50% were, respectively, 1.7 and 1.9-fold greater than those patients on placebo. A continuous responder analysis, which examined response improvements from 25% to 50% in 5% increments,

> showed a greater improvement in exercise tolerance for patients receiving Ampligen ® versus placebo at every 5% increment above 25%....

20. On May 7, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended March 31, 2012 which was signed by Defendants Carter and Bernhardt. In addition, the Form 10-Q contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Carter and Bernhardt stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q represented the following, in relevant part:

> In July 2008, the FDA accepted for review our NDA for Ampligen® to treat CFS, originally submitted in October 2007. We are seeking marketing approval for the first-ever treatment for CFS. At present, only supportive, symptom-based care is available for CFS patients. The NDA for Ampligen® is also the first ever accepted for review by the FDA for systemic use of a toll-like receptor therapy to treat any condition. In November 2009, we received a Complete Response Letter ("CRL") from the FDA which described specific additional recommendations related to the Ampligen® NDA. In accordance with its 2008 Complete Response procedure, the FDA reviewers determined that they could not approve the application in its present form and provided specific recommendations to address the outstanding issues. We intend to take the appropriate steps to seek approval and commercialization of Ampligen®. Most notably, the FDA stated that the two primary clinical studies submitted with the NDA did not provide credible evidence of efficacy of Ampligen® and recommended at least one additional clinical study which shows convincing effect and confirms safety in the target population. The FDA indicated that the additional study should be of sufficient size and sufficient duration (six months) and include appropriate monitoring to rule out the generation of autoimmune disease. In addition, patients in the study should be on more than one dose regimen, including at least 300 patients on dose regimens intended for marketing. We are examining those two major studies for further insight into efficacy and safety. In the Non-Clinical area, the FDA recommended among other things that we complete rodent carcinogenicity studies in two species. While as part of the NDA submission we had requested that these studies be waived, this waiver had not been granted by the FDA in their CRL. Under the Product Quality section of the CRL, the FDA recommended that we submit additional data and complete various analytical procedures. The collection of these data and the completion of these procedures is already part of our ongoing Quality Control, Quality Assurance program for Ampligen® manufacturing under current Good Manufacturing Practice ("cGMP") guidelines

> and our manufacturing enhancement program. On January 14, 2010, we submitted reports of new preclinical data regarding Ampligen® to the FDA that we believed to be sufficient to address certain preclinical issues in the FDA's CRL. We do not anticipate receiving feedback until we re-file our NDA.
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> In January 2012, in response to our request for an additional extension, we were informed that, rather than grant additional formal requests for extension, FDA would instead await our complete response to the CRL. Therefore, unless we are informed by the FDA of the need to seek another formal extension, our NDA will remain open while we continue to prepare our response to the CRL. We are currently conducting an open-label treatment protocol in the U.S. and evaluating new diagnostic modalities to provide additional insights into the CFS disorder. It is our plan that the new analyses and other insights will supplement the original study findings. We believe that continued efforts to understand existing data and to advance the development of new data and information, will ultimately support a re-filing of the NDA. Thus, the Company is pursuing the filing of an amended NDA in response to FDA comments in the CRL.

21. On August 1, 2012, the Company issued a press release announcing the filing of its complete response to the FDA's November 25, 2009 Complete Response Letter ("CRL") in support of Ampligen's NDA for CFS. Specifically, the Company stated the following, in relevant part:

> As previously reported, at a recent meeting with the Agency, Hemispherx reached agreement on the filing requirements for the Company's complete response (please see the Company's press release and Form 8-K dated July 11, 2012). The FDA has indicated that the new submission will be reviewed on a 6 month cycle. The Ampligen® data were organized and filed with the FDA 53 days after the June 8, 2012 meeting with the Agency. At present, no drug has received FDA approval to treat CFS, a chronic, seriously debilitating disease.
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> The FDA has agreed to accept, for review, further analyses of data from Hemispherx's AMP-516 Phase III clinical trial and other Ampligen® trials (AMP-502 and AMP-516C) in lieu of the additional confirmatory Phase III study originally called for in the Agency's CRL. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen® New Drug Application ("NDA").
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> Included in the additional AMP-516 study analyses submitted to the FDA is an examination of the quality of life parameters in patients who either met or failed the primary endpoint (exercise treadmill testing or "ETT"). Hemispherx believes the data show that patients who were able to continue on a treadmill for at least

25% longer than at baseline achieved significantly greater improvement in vitality, general health perception, Karnofsky performance score, and activities of daily living compared to those that improved less than 25% in ETT.

Patients who participated in the 40-week AMP-516 study were permitted to enroll in a 24-week extension study; all patients during the extension study received Ampligen® but were not informed of the treatment they received during the initial 40-week study period. The Company believes the data show that 1) the patients who received Ampligen® over the entire 64 weeks continued to improve during the 24-week extension study, experiencing a mean improvement of 23% in treadmill duration; 2) patients who crossed over from placebo to Ampligen® experienced a mean improvement of 39% over the 24 weeks of Ampligen® treatment; and 3) the proportion of patients who improved by at least 25% in exercise duration from baseline was significantly greater for the patients who switched from placebo to Ampligen® during the last 24 weeks (30%) compared to the patients who remained on Ampligen® (11% during the last 24 weeks).

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In November, 2010, Hemispherx announced the publication of new analyses of data from the AMP-516 Trial showing that patients on Ampligen®, an experimental therapeutic, reduced their use of concomitant medications compared to patients receiving placebo. In particular, Ampligen® patients reduced their use of medications that may prolong the QT interval. Prolongation of the QT interval is a known risk factor for sudden cardiac death and arrhythmias. A greater portion of the placebo patients were found to have a significant prolongation of the QT interval compared to patients who had received Ampligen®. Cardiac death is one of three major causes of premature death in CFS, which affects predominantly women in their 40s....

Also, in March, 2012, a peer reviewed analysis of data from the AMP-516 Trial was published in PLoS One ("A Double-Blind, Placebo-Controlled, Randomized, Clinical Trial of the TLR-3 Agonist Rintatolimod in Severe Cases of Chronic Fatigue Syndrome") showing that the proportions of Ampligen® patients with exercise treadmill testing improvements of at least 25% and at least 50% were, respectively, 1.7 and 1.9-fold greater than those patients on placebo. ETT is an established primary efficacy endpoint which has been used in numerous clinical trials of various chronic debilitating disorders. A continuous responder analysis, which examined response improvements from 25% to 50% in 5% increments, showed a greater improvement in exercise tolerance for patients receiving Ampligen®, an experimental therapeutic, versus placebo at every 5% increment above 25%....

22. On August 8, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended June 30, 2012 which was signed by Defendants Carter and

Bernhardt. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Carter and Bernhardt stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. The 10-Q represented the following, in relevant part:

> On June 8, 2012, the Company and its consultants met with the FDA to discuss certain aspects of the CRL relating to its NDA for Ampligen® for the treatment of severely debilitated patients with CFS. Upon our review of the FDA Minutes from this meeting that we received on July 6, 2012, we believe the key points from the meeting to be undertaken by the Company in conjunction with its complete response include the following:
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> The Company submitted the complete response to the FDA on July 31, 2012 in support of Ampligen ®'s NDA for CFS. If found sufficient to support approval of the drug, these new analyses will be in lieu of an additional confirmatory Phase III study called for in the FDA's November 25, 2009 CRL. The FDA also advised that whether the new analyses provide adequate evidence of Ampligen ®'s efficacy in treating CFS will ultimately be a review issue. The FDA has advised that, once submitted, the complete response will be on a six month review cycle at the FDA. The FDA's agreement to review the complete response does not commit the FDA to approve the Ampligen® NDA. Further, no guarantee can be made at this time that the facility will necessarily pass a pre-approval inspection to produce raw materials to manufacture Ampligen®, which is conducted in a separately dedicated area within the overall New Brunswick manufacturing complex. As a result of the FDA meeting, Hemispherx has redirected many of its resources to the Ampligen® NDA submission and our preparation for the FDA preapproval inspections by reassigning personnel, hiring additional staff, consultants and various independent contractors.

23. On September 14, 2012, the Company filed a Prospectus Supplement on a Form 424B5 with the SEC related to the Company's Universal Shelf Registration Statement on Form 3, declared effective by the SEC on July 2, 2012. The Prospectus Supplement was related to an offering of 20 million shares of the Company's common stock. In the Prospectus Supplement, the Company stated that the net proceeds from the offering will fund the commercialization of Alferon and Ampligen, as well as general operating expenses.

24. On October 5, 2012, the Company filed an updated Prospectus Supplement on a Form 424B5 with the SEC. The updated Prospectus Supplement allocated up to 40 million shares for public sale under the offering.

25. On November 2, 2012, the Company filed a quarterly report with the SEC on a Form 10-Q for the first quarter ended September 30, 2012 which was signed by Defendants Carter and Bernhardt. In addition, the Form 10-Q contained certifications pursuant to SOX signed by Defendants Carter and Bernhardt stating that the financial information contained in the Form 10-Q was accurate and that they disclosed any material changes to the Company's internal control over financial reporting. Also, in the Form 10-Q, the Company noted that as of September 30, 2012, the Company had sold an aggregate of 10,699,700 shares that resulted in net cash proceeds of approximately $9,268,000.

26. Specifically, the 10-Q represented the following concerning Ampligen, in relevant part:

> On June 8, 2012, the Company and its consultants met with the FDA to discuss certain aspects of the CRL relating to its NDA for Ampligen® for the treatment of severely debilitated patients with CFS. Upon our review of the FDA Minutes from this meeting that we received on July 6, 2012, we believe the key points from the meeting to be undertaken by the Company in conjunction with its complete response include the following:
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> - The FDA agreed to accept, for review, in Hemispherx' complete response new analyses of data from the AMP-516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen® NDA;
> - As Ampligen® is a new molecular entity, the FDA anticipates that the data submitted in the NDA would be presented at a public FDA Advisory Committee meeting;
> - The FDA requires that the Company's complete response include all information necessary for review at the time of filing and that it address all deficiencies identified in the CRL;
> - Our New Brunswick manufacturing facility would be expected to be ready for GMP pre-approval inspection at the time of the complete response; and

- We will include in the complete response a request for postponement of rodent carcinogenicity study requirements and a justification for this request.

The FDA also advised that whether the new analyses provide adequate evidence of Ampligen®'s efficacy in treating CFS will ultimately be an Advisory Committee ("AC") review issue. The Company submitted the complete response to the FDA on July 31, 2012 in support of Ampligen ®'s NDA for CFS. The FDA acknowledged in writing receipt of the Company's complete response stating, "We consider this a complete, class 2 response to our November 25, 2009, action letter." Based on its designation of our July 31, 2012 submission as a class 2 response, FDA has indicated that its Prescription Drug User Fee Act ("PDUFA") review goal for completing its review is February 2, 2013. The FDA's agreement to review the complete response does not commit the FDA to approve the Ampligen® NDA. Further, no guarantee can be made at this time that the facility will necessarily pass a pre-approval inspection to produce raw materials to manufacture Ampligen®, which is conducted in a separately dedicated area within the overall New Brunswick manufacturing complex. As a result of the FDA meeting, Hemispherx has redirected many of its resources to the Ampligen® NDA submission and our preparation for the FDA pre-approval inspections by reassigning personnel, hiring additional staff, consultants and various independent contractors.

27. The statements referenced in ¶¶ 18-22; 25-26 above were materially false and/or misleading because they misrepresented and failed to disclose that Ampligen could not demonstrate the requisite safety and efficacy, as its clinical trials were not properly designed and had insufficient safety data to explain safety signals that arose during the clinical trials.

THE TRUTH IS REVEALED

28. On December 18, 2012, the FDA published an FDA reviewer report on the Company's Ampligen submission. The report concluded that the additional data submitted by the Company in support of Ampligen's approval were insufficient to demonstrate its safety and efficacy, given the inconsistency in the data sets, noting that methodology for one trial was "ill defined and invalid." The FDA report concluded, in relevant part:

Major Efficacy Results for CFS: Studies AMP-502 and AMP-516 were submitted as the primary sources of efficacy data for Ampligen in the treatment of CFS. These studies were heterogeneous as they had different durations and different primary endpoints. Study AMP-502 was initially planned for 48 weeks, but was stopped at 24 weeks. In contrast, Study AMP-516 was 40 weeks. In Study AMP-

502, the primary endpoint was KPS. In contrast, the primary endpoint in Study AMP-516 was ETT duration.

Study AMP-502 was modified repeatedly during its conduct in ways that were not clearly specified or documented. In addition, there were no formal statistical analysis plans in the protocol dated October 19, 1990. During the conduct of the study, there were multiple protocol violations, including assessment of "baseline" values over many months, instead of the protocol specified 6 weeks. The Applicant's statistical analysis AMP-502 was completed. Based on the analysis outlined in this statistical analysis plan, the Applicant obtained statistical significant results for change in KPS from baseline to 24 weeks in the Ampligen group compared to the placebo group. The Applicant also reports statistically significant results for ETT duration; however the Applicant's analysis removes seven patients who had difficulty with the initial ETT protocol that was used. In the FDA analysis using the intention to treat (ITT) population that includes these seven patients, the results are no longer statistically significant. From a regulatory standpoint, studies with multiple, significant protocol changes and violations are generally considered hypothesis generating.

Study AMP-516 was a subsequent study of Ampligen efficacy. Unlike Study AMP-502, there was no statistically significant effect of Ampligen on change in KPS at Week 40 from baseline in Study AMP-516. In addition, the analyses specified in the protocols before the data were unblinded do not produce statistically significant results for ETT duration. In this resubmission, the Applicant uses post-hoc analyses applying the benchmarks of 25% and 50% improvement in ETT duration to demonstrate statistically significant results. However, Ampligen did not lead to statistically significant improvements in KPS or any secondary endpoints of quality of life, including signs and symptoms of CFS, SF-36 vitality and general health perception results, activities of daily living (ADL), and Symptoms Checklist 90-revised cognitive deficit subscale (SCL-90-R CD).

The Applicant also provides supportive evidence of efficacy from Study AMP-516C and analyses in the "targeted subgroup for treatment," which are patients with CFS for duration 1-10 years. Study AMP-516C was a 24-week extension of Study AMP-516 in which all patients received Ampligen. The Applicant notes that patients who received placebo in Study AMP-516 and then Ampligen in Study AMP-516C had statistically significant improvements in ETT duration compared to those who received Ampligen in both AMP-516 and 516C. However, these results cannot be used to evaluate the efficacy of Ampligen as they are not a direct comparison of Ampligen to placebo. The FDA analysis that directly compared the change in ETT duration by treatment group (ETT duration for patients who received Ampligen in the 24-week extension compared to ETT duration during the 20 weeks that these patients received placebo) did not reveal statistically significant improvements in ETT duration.

> The data from Studies AMP-502, 516, and 516C were reviewed at the time of the Applicant's initial submission on April 25, 2008. At that time, they were not felt to provide substantial evidence of efficacy and the Applicant was told that at least one additional study showing convincing evidence of efficacy would be needed to support approval. Rather than performing an additional study, the Applicant submitted post-hoc analyses in a subgroup of patients from Study AMP-516. Specifically, the Applicant defines a "targeted subgroup for treatment" who are CFS patients with disease duration for 1-10 years. These analyses are based on the hypothesis that patients with CFS for a shorter duration are more likely to have a spontaneous recovery and thus may be more likely to respond to drug therapy. The Applicant submitted two published articles (van der Werf 2002; Vercoulen JH 1996) to support this hypothesis. However, the Applicant's rationale for utilizing the cutoff of 10 years is unclear and there is no evidence that patients who may spontaneously improve are more likely to respond to Ampligen. The analyses remove 37 subjects with disease duration of more than 10 years from the original ITT population for Study AMP-516. It would be unusual for posthoc analyses in a subgroup of patients to provide adequate evidence of efficacy for approval.
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> In summary, Study AMP-502 suggested Ampligen treatment improved KPS, yet the study conduct raises questions about the reliability of the results. In addition, these results were not replicated in Study AMP-516. Whether these studies provide substantial evidence of Ampligen efficacy will be discussed at the Advisory Committee meeting.

29. Analysts and the media immediately reported the FDA's critical review of the Ampligen submission. For example, *TheStreet* published an article entitled, *Hemispherx Lied to Investors and SEC About Ampligen*. The article disclosed the following:

> Hemispherx Biopharma lied to investors and to the Securities and Exchange Commission by failing to disclose serious concerns raised by the U.S. Food and Drug Administration about its chronic fatigue syndrome drug Ampligen.
>
> An FDA advisory panel convenes Thursday to review Ampligen and vote on whether or not recommend the drug as a new therapy for chronic fatigue syndrome. On Tuesday, FDA made public a sharply critical clinical review of Ampligen in which agency staff raised "multiple concerns" with the efficacy and safety of the drug.
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> Hemispherx knew as early as this past summer that FDA wasn't likely to approve Ampligen, according to new information released Tuesday by the FDA. Hemispherx withheld this significant information from investors and the SEC.

During a meeting held in June between Hemispherx and FDA officials, the agency noted the following regarding Ampligen:

"You [Hemispherx] propose new post-hoc analyses of data from Trial 516 and a post-marketing trial (AMP-520) to support approval. ***It would be unusual for this type of data to provide adequate evidence of efficacy.*** *However, the adequacy of the data will ultimately be a review issue, and it is reasonable for you to submit a complete response. This complete response needs to address all of the issues defined in the complete response letter dated November 25, 2009. As Ampligen is a new molecular entity, we anticipate that the data submitted in your NDA would be presented at a public Advisory Committee meeting... The standards for approval require the same evidence of efficacy and safety, regardless of approval pathway."* [Emphasis added.]

The bolded sentence is the Hemispherx lie. This important nugget of information from the June meeting with FDA was omitted from the company's press releases and SEC filings.

Here is how Hemispherx describes the same June meeting with FDA in its most recently filed 10-Q:

On June 8, 2012, the Company and its consultants met with the FDA to discuss certain aspects of the CRL [Complete Response Letter] relating to its NDA for Ampligen for the treatment of severely debilitated patients with CFS. Upon our review of the FDA Minutes from this meeting that we received on July 6, 2012, we believe the key points from the meeting to be undertaken by the Company in conjunction with its complete response include the following:

The FDA agreed to accept, for review, in Hemispherx's complete response new analyses of data from the AMP-516 Trial. Whether these data provide adequate evidence of efficacy will ultimately be a review issue, and there can be no assurance the FDA will conclude the data are adequate to support approval of the Ampligen NDA..."

Hemispherx makes no mention of FDA's warning, which is clearly material information for investors:

"It would be unusual for this type of data to provide adequate evidence of efficacy."

Instead, Hemispherx spun the outcome of June FDA meeting as much more positive, even suggesting to investors that FDA was more willing to review and possibly approve Ampligen due to new federal regulations -- the so-called FDASIA legislation -- aimed at accelerating the approval of drug for serious diseases without treatment options.

> Hemispherx issued a press release on July 11, claiming the company and FDA "reached an agreement" on new filing requirements for Ampligen. Hemispherx shares were valued at 34 cents on July 11, rising to a high of 89 cents in late September -- a 161% increase. During this period, Hemispherx sold 10.7 million shares of stock through an "At The Market" equity financing facility, netting $9.3 million.
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> It's hard to imagine a scenario under which Hemispherx's stock would have almost tripled in value and $9 million could have been raised from investors had the company disclosed publicly the FDA's warning that Ampligen data submitted wasn't likely sufficient to get the drug approved.
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> Hemispherx deceived investors and the SEC, then raised money on this lie of omission.

30. Similarly, Minyanville published an article entitled, *Hemispherx Chronic Fatigue Drug Scrutinized Ahead of Panel Review*. The article disclosed the following in relevant part:

> "It would be unusual for this type of data to provide adequate evidence of efficacy. However, the adequacy of the data will ultimately be a review issue," Food and Drug Administration officials told company representatives in June....
>
> Hemispherx faces a panel of expert advisers to the FDA on Thursday. The advisers will hear arguments from the company on why the experimental drug Ampligen should be approved for sale in the US. The FDA will consider the advisers' recommendations as it decides whether to approve the medicine. The agency is expected to decide by February 2.
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> In a review of the drug posted online, staff for the FDA questioned a pair of studies of patients conducted to show Ampligen's effectiveness. "Signals of efficacy are inconsistent between the two trials," staff reviewers wrote.
>
> Throughout the report, the descriptions for the study were more blunt. A methodology used in one trial was "ill-defined and invalid." "Limited conclusions" about safety and effectiveness can be drawn from data, FDA staffers said....
>
> FDA staff reviewers raised a number of issues related to the research of the drug, including study design and execution, patient selection for the trials, and analysis of the data. What's more, the company is relying on research conducted before the FDA first rejected the drug in 2009. There are also questions about the safety of the drug, including potential liver damage. As these FDA staff reviews go, the report was scathing.

31. As a result of this disclosure, Hemispherx shares declined $0.276 per share, or nearly 43%, to close at $0.368 per share on December 19, 2012.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

32. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Hemispherx securities during the Class Period (the "Class"); and were damaged thereby. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

33. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Hemispherx securities were actively traded on the NYSE MKT. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Hemispherx or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

34. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

35. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

36. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Hemispherx;
- whether the Individual Defendants caused Hemispherx to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
- whether the prices of Hemispherx securities during the Class Period were artificially inflated because of the defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

37. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

38. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;
- Hemispherx securities are traded in efficient markets;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NYSE MKT, and was covered by multiple analysts;
- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Plaintiff and members of the Class purchased and/or sold Hemispherx securities between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

39. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

40. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

41. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

42. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances

under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Hemispherx securities; and (iii) cause Plaintiff and other members of the Class to purchase Hemispherx securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

43. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Hemispherx securities and options. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Hemispherx's finances and business prospects.

44. By virtue of their positions at Hemispherx, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

45. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants' knowledge and control. As the senior managers and/or directors of Hemispherx, the Individual Defendants had knowledge of the details of Hemispherx's internal affairs.

46. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Hemispherx. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Hemispherx's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Hemispherx securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Hemispherx's business and financial condition which were concealed by defendants, Plaintiff and the other members of the Class purchased Hemispherx securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by defendants, and were damaged thereby.

47. During the Class Period, Hemispherx securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased shares of Hemispherx securities at prices artificially inflated by defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said securities or

would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Hemispherx securities were substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Hemispherx securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

48. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

49. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period, upon the disclosure that the Company had disseminated false statements to the investing public related to its prospects for FDA approval.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

50. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

51. During the Class Period, the Individual Defendants participated in the operation and management of Hemispherx, and conducted and participated, directly and indirectly, in the conduct of Hemispherx's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Hemispherx's NDA submission to the FDA.

52. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to

Hemispherx's financial condition and results of operations, and to correct promptly any public statements issued by Hemispherx which had become materially false or misleading.

53. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Hemispherx disseminated in the marketplace during the Class Period concerning Hemispherx's financial prospects. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Hemispherx to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Hemispherx within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Hemispherx securities.

54. Each of the Individual Defendants, therefore, acted as a controlling person of Hemispherx. By reason of their senior management positions and/or being directors of Hemispherx, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Hemispherx to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Hemispherx and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

55. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Hemispherx.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Date: December 21, 2012