UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF PENNSYLVANIA

Perry Paragamian, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. VICURON PHARMACEUTICALS INCORPORATED, GEORGE F. HORNER, III, DOV A. GOLDSTEIN, and TIMOTHY J. HENKEL, Defendants.	Civ. Action No. CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

SUMMARY AND OVERVIEW

1. This is a securities class action on behalf of all purchasers of the securities of Vicuron Pharmaceuticals Incorporated ("Vicuron" or the "Company", formerly known as "Versicor") between January 6, 2003 and May 24, 2004 (the "Class Period"), against Vicuron and certain of its officers and directors for violations of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Vicuron claims to focus upon anti-infective products that have competitive advantages over existing products, such as greater potency, improved effectiveness against resistant strains and reduced toxicity. The Company claims that it devotes substantially all of its efforts to establishing its business and carrying on research and development activities related to proprietary product candidates.

3. The Company's lead product candidate, Anidulafungin, is intended for the intravenous treatment of fungal infections. Anidulafungin is the subject of late-stage clinical trials for the treatment of esophageal candidiasis, as well as for the treatment of invasive aspergillosis and invasive candidiasis/candidemia.

4. During the Class Period, anidulafungin provided hope and financial potential as the Company's first opportunity for approval of a new drug product. When adjusted for one-time charges of $94.5 million resulting from the completion of the merger of Versicor and Biosearch Italia, Vicuron reported an expanded net loss of $23.5 million in the first quarter as compared to a net loss (adjusted) of $12.6 million in the first quarter of 2003. This report was accompanied by the announcement of increased staff essential for the launch of anidulafungin and to transform Vicuron from a research and development concern into a commercial organization.

5. During the Class Period, defendants artificially inflated the price of Vicuron stock by concealing critical material information regarding the details of both the safety and efficacy of Anidulafungin. Defendants concealed key adverse information of regarding the development and

commercialization of Anidulafungin, raising serious concerns for the very approval of the drug for the treatment of esophageal candidasis and other selected indications.

6. The partial disclosure of the contents of the FDA letter on Monday, May 24, 2004, detailing the failure of Vicuron to supply data necessary to support its very claim for the use of anidulafungin for the treatment of esophageal candidasis caused Vicuron shares plummeted $8.86, to $13.04, for a loss of over 40% from the previous trading day, a loss of over 45% from its Class Period high of $23.90, on volume of over 15 million shares, causing millions of dollars in damages to members of the Class.

JURISDICTION AND VENUE

7. Jurisdiction is conferred by Section 27 of the Exchange Act. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5.

8. Venue is proper in this District pursuant to Section 27 of the Exchange Act. Many of the false and misleading statements were made in or issued from this District. The corporate headquarter of Vicuron are located in the District.

9. In connection with the acts and conduct alleged herein, Defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and the facilities of the national securities exchanges.

THE PARTIES

10. Plaintiff Perry Paragamian purchased Vicuron common stock as described in the attached certification and was damaged thereby.

11. Defendant Vicuron claims to focus on anti-infective products that have competitive advantages over existing products, such as greater potency, improved effectiveness against resistant strains and reduced toxicity. The company devotes substantially all of its efforts to establishing its business and carrying on research and development activities related to proprietary product candidates.

12. Defendant George F. Horner III was President and Chief Executive Officer of Vicuron.

13. Defendant Dov A. Goldstein was Chief Financial Officer of Vicuron.

14. Defendant Timothy J. Henkel was Chief Medical Officer of Vicuron.

15. The individuals named as defendants in ¶¶ 12-14 are referred to herein as the "Individual Defendants."

CLASS ACTION ALLEGATIONS

16. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Vicuron common stock on the open market during the Class Period (the "Class"). Excluded from the Class are defendants.

17. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Vicuron had more than 77 million shares of stock outstanding, owned by hundreds if not thousands of persons.

18. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether the Exchange Act was violated by defendants;

(b) Whether defendants omitted and/or misrepresented material facts;

(c) Whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) Whether the price of Vicuron common stock was artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

19. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

20. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

21. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

22. On January 6, 2003, the Company issued a press release entitled "Positive Phase II Results With Anidulafungin For Invasive Candidiasis/Candidemia - Phase III Trial in This Additional Indication Now Underway". The press release stated in part:

> Versicor Inc. today announced positive results from a Phase II clinical trial with the company's lead investigational product, anidulafungin, for the treatment of invasive candidiasis/candidemia, the most common hospital-based fungal infection. These infections are often deadly to the hospitalized patients who contract them.
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> Phase II Clinical Trial Results
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> The randomized, open-label Phase II clinical trial enrolled approximately 120 patients in the United States with a documented diagnosis of invasive candidiasis/candidemia. Patients were treated with a daily intravenous infusion of anidulafungin at three different dose levels for 15 to 42 days. Patients were examined for clinical and microbiological responses at the conclusion of therapy and two weeks following therapy.
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> End-of-therapy outcomes in evaluable patients demonstrated an 88 percent global response rate (23/26 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 89 percent (25/28 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 81 percent (21/26 patients) with 100 mg followed by 50 mg.

Outcomes in evaluable patients at the two-week, test-of-cure visit demonstrated an 83 percent global response rate (19/23 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 83 percent (19/23 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 68 percent (13/19 patients) with 100 mg followed by 50 mg.

Anidulafungin was well tolerated and adverse events attributable to study drug were infrequent and similar for each dose. Global response rates reported in previous clinical trials with other agents, such as fluconazole, amphotericin B and caspofungin, range from 56 percent to 81 percent in patients with invasive candidiasis/candidemia.

NDA Filing

Versicor is also evaluating anidulafungin in a Phase III trial for the treatment of esophageal candidiasis, a serious fungal infection of the esophagus. The company expects to announce results of this trial in the first quarter of 2003 and, based on these results, file a New Drug Application (NDA) with the United States Food and Drug Administration (FDA) by the end of April 2003. Another Phase III study is also underway to evaluate anidulafungin for the potential treatment of invasive aspergillosis.

"We are making excellent progress with anidulafungin, the first of three promising advanced stage product candidates we and our proposed merger partner, Biosearch Italia, are working to commercialize around the world over the next few years," said George F. Horner III, president and chief executive officer of Versicor. "Anidulafungin belongs to the echinocandin class, the first new class of antifungal agents in 40 years, which promises to revolutionize the treatment of fungal infections. Drugs in this class are distinct due to their fungicidal activity, ability to treat a broad range of fungi, low potential for development of resistance and possibly more favorable safety profile. We believe these attributes will help us differentiate anidulafungin from other agents currently used to treat serious hospital fungal infections."

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About Anidulafungin

Anidulafungin is a naturally occurring molecule that has been significantly improved through chemical modification. In vitro studies have demonstrated that anidulafungin combines both the potency and killing effects of the polyene class (e.g., amphotericin B) without the resistance problems found with the azole class (e.g., fluconazole). Anidulafungin is a broad-spectrum agent, and has been demonstrated to be highly potent in vitro against the fungi responsible for serious systemic infections. Preclinical studies have shown that five-minute exposure to anidulafungin in vitro kills more than 99 percent of Candida, including fluconazole-resistant strains. Anidulafungin has no cross-resistance with azoles or amphotericin, and in the laboratory it has proven very difficult to develop resistance to anidulafungin.

Anidulafungin also was well tolerated in the Phase I study when given in combination with cyclosporine, the leading chronic immunosuppressive drug."

23. The press release of January 6, 2003 was false and misleading for the following reasons. First, it outlined the superior potency of anidulafungin without regard to the caveats indicated by Arévalo and coworkers or to the reported phase II clinical results in patients with invasive candidiasis/candidemia. While the press release proclaimed that "***preclinical studies have shown that five-minute exposure to anidulafungin in vitro kills more than 99 percent of Candida, including fluconazole-resistant strains***", the reported phase II clinical results failed to provide any evidence to differentiate the utility of anidulafungin from fluconazole in the clinic. For example, the reported global response rates in the described phase II study varied from 68 to 83 percent, while response rates reported in comparable clinical trials with other agents, such as fluconazole, amphotericin B and caspofungin, ranged from 56 to 81 percent. **Nothing about the clinical data demonstrated that anidulafungin actually possessed superior clinical attributes.**

24. Nevertheless, the reiteration of claims of superior potency and utility of anidulafungin in the treatment of a broad range of fungi made by defendants in the January 6, 2003 press release were consistent with the previous claims of the defendants and complimentary to the seemingly favorable Phase II results for the esophageal candidiasis indication as described in SEC Form S-4 filed on August 29, 2002. In the S-4, defendants noted that as many as 85% of patients treated with the drug for esophageal candidiasis demonstrated an improved response to treatment after 21 days. If defendants had made any effort to explain the curious differences in their Phase II studies, using criteria such as potency, inadequate concentration of the antifungal agent at the site of the infection, impaired host defense mechanisms or other host–fungus and antifungal agent interactions, defendants would have warned their shareholders of highly material undisclosed risks and uncertainties facing the development of anidulafungin.

25. In addition to the lackluster report of the Phase II studies in patients with invasive candidiasis/candidemia given in the January 6, 2003 press release, defendants noted that the Phase III trial for the treatment of esophageal candidiasis was still "under evaluation". ***Since defendants were already on notice that the superior potency of anidulafungin had failed to translate into superior efficacy in the phase II clinical trials in patients with invasive candidiasis/candidemia, defendants sought to delay the results of the Phase III clinical trial for the treatment of esophageal candidiasis until after the merger with Biosearch Italia S.p.A. was completed.***

26. Defendants used the artificially inflated value of the Versicor stock as currency to fund a stock for stock merger valued at over $517 million. In doing so, defendants could make the merger as anti-dilutive as possible.

27. On March 3, 2003, the Company issued a press release entitled "Versicor And Biosearch Italia S.p.A Complete Merger To Create International Company Focused On Anti-Infectives". The press release stated in part:

> "This merger creates one of the strongest product pipelines in the biotechnology industry and worldwide ownership of our two leading product candidates: anidulafungin and dalbavancin," said George F. Horner III, president and chief executive officer of Versicor. "It also creates significant functional synergies, financial critical mass and a powerful research engine that promises to continue to improve our pipeline with important new compounds in the years ahead. With complementary distribution strategies in the United States and Europe, together we will more efficiently pursue our shared goal of bringing exciting new antibiotic and anti-fungal agents to market as soon as possible."
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> Merger Details
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> Effective March 1, 2003 at 12:01 a.m. (Milan time), Biosearch merged into Versicor in a stock-for-stock exchange. As a result of the merger, Biosearch shareholders received 1.77 shares of newly-issued Versicor common stock in exchange for each Biosearch ordinary share. The new company has a total of 47.8 million shares outstanding, composed of 26.4 million outstanding Versicor shares of common stock and 21.4 million shares of Versicor common stock to be issued to Biosearch shareholders. Versicor was advised by Lehman Brothers and Biosearch was advised by SG Cowen and Livolsi & Partners.

28. On March 17, 2003, the Company issued a press release entitled "Versicor Announces Positive Phase III Clinical Trial Results With Anidulafungin for Esophageal Candidiasis; Trial Meets Primary Endpoint; Company Plans to File NDA On Schedule." The press release stated in part:

> Versicor Inc. (Nasdaq: VERS; Nuovo Mercato: VER) today announced positive results from a pivotal Phase III clinical trial with the company's lead investigational product candidate, anidulafungin, an anti-fungal agent, and reiterated its intention to file a New Drug Application for anidulafungin with the United States Food and Drug Administration (FDA) by the end of April of this year.
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> The trial showed that anidulafungin is as effective as fluconazole, the standard-of-care for the treatment of esophageal candidiasis, a painful and debilitating fungal infection of the esophagus that commonly affects patients with compromised immune systems. Anidulafungin belongs to the first new class of anti-fungal agents, called echinocandins, introduced in more than 40 years.
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> "That the primary endpoint in this study was fulfilled marks an important benchmark for the development of anidulafungin," said Dr. Thomas J. Walsh, co-author on the study and Senior Investigator at the National Cancer Institute and Chief of the Immunocompromised Host Section. "This large clinical trial demonstrates proof of principle that this echinocandin is comparable to fluconazole in treatment of esophageal candidiasis in humans." Dr. Walsh further observed, "The data are consistent with our preclinical studies demonstrating the safety and efficacy of anidulafungin in experimental esophageal candidiasis. The new class of echinocandins offers broad-spectrum alternatives in the treatment of invasive fungal infections that include candidiasis and aspergillosis. Compounds within this class have low potential for emergence of resistance, an excellent safety profile, and minimal drug- drug interactions. Anidulafungin promises to be an important addition to our current antifungal armamentarium for treatment of invasive fungal infections in seriously ill patients."
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> "This data, along with positive data from the previous trials, will form the basis of what we believe will be a strong NDA submission to the FDA," said Timothy J. Henkel, M.D., Ph.D., Versicor's chief medical officer.
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> The NDA submission will include data from the Phase III esophageal candidiasis trial; data from a previously reported Phase II study in invasive candidemia/candidiasis, the most common hospital-based fungal infection with high mortality rates; and interim safety data from an ongoing Phase III trial studying anidulafungin in aspergillosis, another serious, opportunistic fungal infection with high mortality rates.
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> Phase III Esophagael Candidiasis Clinical Trial Results Summary

This randomized, double-blind, double-dummy Phase III clinical trial studied the safety and efficacy of intravenous anidulafungin versus oral fluconazole in the treatment of approximately 600 patients with a documented diagnosis of esophageal candidiasis in the United States, South Africa, Thailand and Argentina.

Patients in the anidulafungin arm were treated with a 100 mg intravenous loading dose of anidulafungin on day one along with an oral placebo, followed by daily 50 mg anidulafungin infusions plus oral placebo for 14 to 21 days. Patients in the fluconazole arm were treated with a 200 mg dose of oral fluconazole on day one along with an intravenous placebo, followed by daily 100 mg oral fluconazole doses and an infusion of placebo for 14 to 21 days. Treatment ended when the patient remained symptom-free for seven days, with a maximum of 21 days on therapy.

Patients were examined for endoscopic, clinical and mycological responses at the conclusion of therapy and two weeks following therapy. The primary efficacy endpoint was endoscopic success at the end of therapy (EOT) in clinically evaluable patients, which was 97.2 percent (242/249 patients) with anidulafungin and 98.8 percent (252/255) with oral fluconazole. The statistical requirement for non-inferiority was easily met, as the lower bound of the 95 percent confidence interval ("the delta") was minus 4.1 percent, well within the prospectively specified minus 10 percent limit. In addition, anidulafungin was well-tolerated, with an adverse event and laboratory safety profile comparable to oral fluconazole.

Esophageal candidiasis in an immunosuppressed population is typically recurrent and, as expected, a significant percentage of patients in both arms relapsed, with the anidulafungin arm demonstrating a higher relapse rate than the fluconazole arm. Endoscopic success at the two-week follow up in clinically evaluable patients was observed in 64.4 percent (150/233) of patients in the anidulafungin arm and 89.5 percent (205/229) of patients in the fluconazole arm, which was a statistically significant difference.

"Both treatments proved highly effective at the end of therapy based on endoscopic response, the most objective measure, as well as clinical and mycological responses, which were secondary endpoints," added Dr. Henkel. "End-of-therapy response, rather than follow-up, is most significant in this disease because almost all patients eventually relapse. As expected in this trial population, relapse rates in both groups were substantial. However, this has little clinical relevance because current clinical guidelines and standard practice call for follow-up prophylactic therapy."

In terms of safety, anidulafungin was as well tolerated as fluconazole. The most common treatment-related adverse events included phlebitis, nausea and thrombocytopenia. There were no systemic infusion reactions and no evidence of hepatic toxicity."

29. In speaking to statistically significant difference in relapse rates favoring fluconazole, defendant Henkel indicated, "this has little clinical relevance because current clinical guidelines and standard practice call for follow-up prophylactic therapy." However, Dr. Henkel actually knew and

concealed the fact that FDA had already determined clinical relapse to be a clinical relevant factor in the registration studies for caspofungin acetate. Thus the only purpose for defendant Henkel's statement was to mislead investors, by making claims about "typical approaches" in patient care necessary to dismiss the relevance of the relapse rate data. Henkel did so, to conceal the fact that the data presented a serious, if not insurrmountable obstacle in providing FDA with satisfactory evidence of efficacy and safety necessary to support an NDA the esophageal candidiasis indication.

30. On March 26, 2003, defendants issued a press release entitled "Vicuron Pharmaceuticals is New Name for Versicor". The press release indicated in part:

> Versicor Inc. today announced that it has changed its corporate name to Vicuron Pharmaceuticals (pronounced ViCUREon) Inc., and will begin trading today under the new ticker symbol MICU, which stands for Medical Intensive Care Unit. The new name is borne out of the February 28, 2003 merger of Versicor and Biosearch Italia, which created an international biopharmaceutical company focused on the hospital market.
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> "The merger and new corporate identity represent our focused drive to become a dominant force in the hospital market on both sides of the Atlantic," said George F. Horner III, president and chief executive officer of Vicuron. "The new company has one of the strongest pipelines in the biotechnology industry for tough-to-treat hospital infections and our expanded presence better positions us to commercialize our lead products in the world's two largest pharmaceutical markets: North America and Europe. The new name, which is effective immediately, reflects Vicuron's vision to become a hospital-based biopharmaceutical company that provides vital medicine for serious indications."
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> Rich Product Pipeline and Commercial Strategy
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> Vicuron's lead products are in Phase III clinical development. Anidulafungin, a novel anti-fungal agent for serious hospital fungal infections is nearing regulatory filing in the United States by the end of April and in Europe in the second half of this year. Dalbavancin, a novel injectable hospital antibiotic for the treatment of serious Gram-positive infections is currently in two Phase III clinical trials.

31. The press release of March 26, 2003 indicated that although the Company had selected a new name, ticker symbol and "corporate identity", defendants had no intention of changing their plans to file an New Drug Application ("NDA") for anidulafungin by the end of April 2003. Defendants restated this intention, despite their concealment of their knowledge of the

fact that the adverse Phase III study results for relapse rate actually undermined the label claim sought for the esophageal candidiasis indication. In furtherance of their concealment, defendants now concealed the fact that the goal of a US filing by April 2003 had become a business decision, independent of the underlying quality of the clinical trial data.

32. On April 28, 2003, defendants issued a press release entitled, "Vicuron Submits New Drug Application For Anidulafungin To FDA Powerful Antifungal Agent Could Represent Advance in Novel Echinocandin Class". The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for anidulafungin, a novel antifungal agent for the treatment of esophageal candidiasis, a painful and debilitating infection of the esophagus that commonly affects patients with compromised immune systems. Anidulafungin belongs to the first new class of antifungal agents, called echinocandins, introduced in more than 40 years.
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> "This is the most important corporate milestone achievement in our relatively brief history, and our development team has done an excellent job executing this filing expeditiously," said George F. Horner III, president and CEO of Vicuron. "Echinocandins such as anidulafungin promise to revolutionize the treatment of fungal infections, and represent a growing market opportunity in the United States and Europe. Drugs in this class are distinct due to their fungicidal activity, ability to treat a broad range of fungi, low potential for development of resistance and favorable side effect profile. Anidulafungin is further distinguished by its quicker achievement of steady state, strong in vitro potency, ability to be given at high doses and favorable drug interaction profile. We believe anidulafungin promises to become an important treatment for serious fungal infections and that these attributes should enable us to position it competitively within the new echinocandin class."
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> Vicuron's request for marketing clearance is based largely on the results of a pivotal Phase III trial that statistically showed intravenous anidulafungin is as effective as oral fluconazole, the current standard-of-care, in treating esophageal candidiasis. Based on results from this study, anidulafungin is well-tolerated with an adverse event and laboratory safety profile comparable to oral fluconazole. The file also includes safety and efficacy data from a large Phase II study with anidulafungin in invasive candidemia/candidiasis, as well as safety data from a Phase III trial studying anidulafungin in combination with a liposomal amphotericin for the treatment of invasive aspergillosis and a number of additional Phase I and Phase II clinical trials.
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> "The pivotal Phase III results in addition to positive data from our Phase II trial studying anidulafungin in invasive candidiasis and candidemia, a life-threatening fungal infection, form the basis of what we believe is a strong NDA submission," said Timothy J. Henkel, M.D., Ph.D., Vicuron's chief medical officer. "We look forward to working with the FDA to process this application as efficiently and

> quickly as possible. We plan to file for registration in Europe and Canada in the second half of this year."
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> Vicuron will present Phase II data with anidulafungin in invasive candidemia/candidiasis, the most common hospital-based fungal infection, at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) conference in the United Kingdom in May.
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> With the aging population and the growing number of immunocompromised patients, serious hospital-based fungal infections represent a large and growing market opportunity. The worldwide market for echinocandins is estimated to be $1.8 billion by the year 2008, according to Datamonitor.

33. The press release of April 28, 2003 was false and misleading for a number of reasons. First, defendants knew that their claim regarding the novelty of echinocandins was misleading, since the echinocandin caspofungin was already approved and marketed for the very same indication defendants were seeking. Indeed, defendants considered their competitive position in SEC form S-4 on August 29, 2002, pointing out that anidulafungin was a significantly more potent broad spectrum antifungal than caspofungin.

34. Defendants also knew from their clinical investigations that "in vitro" potency did not correlate with clinical response in the case of anidulafungin. While it was true that anidulafungin was nearly twenty times more potent "in vitro" than fluconazole, the Phase III study results had demonstrated that clinical response to anidulafungin had been adversely impacted by other relevant factors, so much so that relapse rates for esophageal candidiasis were greater for anidulafungin, versus fluconazole. Moreover, this difference in relapse rates were statistically significant. Nevertheless, defendants brazenly stated that they had conducted "a pivotal Phase III trial that ***statistically showed*** intravenous anidulafungin is as effective as oral fluconazole, the current standard-of-care, in treating esophageal candidiasis."

35. On June 6, 2003, defendants filed a press release entitled, "Vicuron Pharmaceuticals, Inc. Files Shelf Registration Statement". The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that it filed a shelf registration statement on Form S-3 with the Securities and Exchange Commission (SEC). If the

> SEC declares the shelf registration statement effective, the company will be able to offer and sell up to $70 million of its shares of common stock from time to time in one or more public offerings.
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> A registration statement relating to these securities has been filed with the SEC but has not yet become effective. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This press release shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

36. On June 30, 2003, defendants issued a press release entitled, "Vicuron Pharmaceuticals Announces FDA Acceptance For Review Of Anidulafungin New Drug Application." The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that the U.S. Food and Drug Administration (FDA) has accepted the company's anidulafungin New Drug Application (NDA) for review. Anidulafungin belongs to the first new class of anti-fungal agents, called echinocandins, introduced in more than 40 years.
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> The filing and subsequent acceptance of this NDA follows the successful completion of a pivotal Phase III trial that statistically showed intravenous anidulafungin is as effective as oral fluconazole, the current standard-of-care, in treating esophageal candidiasis. Based on results from this study, anidulafungin is well-tolerated with an adverse event and laboratory safety profile comparable to oral fluconazole. The NDA also includes safety and efficacy data from a large Phase II trial with anidulafungin in invasive candidemia/candidiasis, as well as safety data from a Phase III trial studying anidulafungin in combination with liposomal amphotericin for the treatment of invasive aspergillosis and a number of additional Phase I and Phase II clinical trials.
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> "With the aging population and a growing number of immuno-compromised patients serious hospital-based fungal infections represent a growing unmet medical need for which more effective treatments are required," said George F. Horner III, president and CEO of Vicuron. "This NDA acceptance brings us one step closer to realizing our goal of bringing vital medicines to the market for these seriously ill patients."

37. Defendants reiterated their false and misleading statements regarding the effectiveness of anidulafungin in relation to fluconazole. Defendants knew that the Phase III study results had demonstrated that clinical response to anidulafungin had been adversely impacted by other relevant factors, so much so that relapse rates for esophageal candidiasis were greater for anidulafungin, versus fluconazole. Moreover, this difference in relapse rates were statistically

significant. Even though FDA acceptance of the NDA did not represent a review of the merits of the application, defendants nevertheless announced the acceptance for filing, to promote their false and misleading statements.

38. On July 18, 2003, defendants issued a press release entitled, "Vicuron Pharmaceuticals Prices Public Offering Of 6 Million Shares Of Common Stock At $13.85 Per Share." The public offering was valued at over $83 million. The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that it has priced its public offering of 6 million shares of its common stock at $13.85 per share. All of the 6 million shares were offered by the company. The underwriters have a 30-day option to purchase up to 900,000 additional shares of common stock from the company solely to cover over-allotments, if any.

39. On December 18, 2003, defendants issued a press release entitled, "VICURON PHARMACEUTICALS FILES EMEA MARKETING APPLICATION FOR ANIDULAFUNGIN". The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced the filing of its Marketing Authorization Application (MAA) for anidulafungin for the treatment of esophageal candidiasis with the European Medicines Evaluation Agency (EMEA). Anidulafungin belongs to the echinocandin class, the first new class of anti-fungal agents introduced in more than 40 years.
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> "This filing comes quickly on the heels of the recent acceptance for filing of our New Drug Application by the U.S. Food and Drug Administration," said George F. Horner III, president and CEO of Vicuron. "This marks another important milestone in our strategy of commercializing our products in both North America and Europe to exploit the value of our products."

40. On January defendants issued a press release entitled, "VICURON PHARMACEUTICALS ANNOUNCES 90-DAY EXTENSION OF FDA REVIEW OF ANIDULAFUNGIN NEW DRUG APPLICATION - Approval and Launch Still Anticipated in First Half of 2004 as Planned". The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that it has received notification from the U.S. Food & Drug Administration (FDA) that the agency now anticipates completing its review of the anidulafungin New Drug Application (NDA) on May 25, 2004, which represents a 90-day extension of the original action date. The company continues to expect the launch of anidulafungin, its novel hospital anti-

> fungal agent, in the first half of 2004 as planned. The company will hold a conference call and webcast this afternoon at 5:15 p.m. EST, (details below).
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> The extension was triggered by the agency's request for additional pharmacokinetic data. According to PDUFA (Prescription Drug User Fee Act), the FDA can reset the action date to review any additional data.
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> "We are working closely with the FDA to complete their review, which we expect will be within the revised timeframe," said Timothy J. Henkel, M.D., Ph.D., Vicuron's Chief Medical Officer. "We have been in close contact with the agency throughout the process, and it is our understanding that this extension is not related to any specific concerns regarding safety and efficacy and should therefore not impact our ability to launch anidulafungin according to plan."

41. Unbenownst to investors, defendants knew from the time they had submitted the NDA that the clinical relapse rate data had undermined the viability of approval of anidulafungin for the esophageal candiasis indication. Defendants knew that the Phase III study results had demonstrated that clinical response to anidulafungin had been adversely impacted by other relevant factors, so much so that relapse rates for esophageal candidiasis were greater for anidulafungin, versus fluconazole. Moreover, this difference in relapse rates were statistically significant. Defendants knew and concealed that there were “specific concerns regarding safety and efficacy”, whether or not those concerns were directly related to the 90-day extension of the original action date on the NDA.

42. Then, on May 24, 2004, defendants issued a press release entitled, “Vicuron Pharmaceuticals Receives Approvable Letter From FDA For Anidulafungin For The Treatment Of Esophageal Candidiasis Requesting Additional Data”. The press release stated in part:

> Vicuron Pharmaceuticals Inc. today announced that it received an approvable letter from the U.S. Food and Drug Administration (FDA). However, the letter indicated that the company's NDA submission for anidulafungin does not currently support a labeling claim for the initial treatment of esophageal candidiasis.
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> In the letter, the FDA indicated that Vicuron could potentially achieve approval for anidulafungin upon the completion of Vicuron's ongoing Phase III clinical trial for the treatment of invasive candidiasis/candidemia or the completion of further clinical work in patients with candidal disease refractory to other treatments.

> "We intend to meet with the FDA to discuss all of our options with respect to the approval of anidulafungin as soon as possible, and intend to complete the Phase III trial in invasive candidiasis/candidemia by the end of this year," said George F. Horner III, President and CEO of Vicuron. "We also will take appropriate management action to reduce the expenses of the company in light of this delay."

43. While the market reaction was swift and severe, the press release issued by defendants on May 24, 2004 failed to explain the true reasons for the bizzare news that company's NDA submission for anidulafungin failed to support a labeling claim for esophageal candidiasis. Later in the day, Reuters published an account of the debacle, including the comments of defendant Goldstein, which stated in part:

> "Anidulafungin is a naturally occurring molecule that has been improved through chemical modification. Results of a late-stage clinical trial submitted to the FDA showed the drug met its main goal of clearing the infection from the esophagus.
>
> However, more patients had relapsed after two weeks than those taking fluconazole, the main current treatment.
>
> Nearly all patients with the condition relapse, since their immune systems are suppressed, said Dov Goldstein, Vicuron's chief financial officer, but 'it occurred a little more quickly in our arm than in the control arm.'"

As a result of the partial disclosure by the Company of the FDA letter, including the shocking news regarding the lack of support for a label claim for esophageal candidiasis, the price of Vicuron shares plummeted $8.86, to $13.04, for a loss of over 40% from the previous trading day, a loss of over 45% from its Class Period high of $23.90, on volume of over 15 million shares.

44. The true facts which were known by each of the defendants, but concealed from the investing public during the Class Period, were as follows:

(a) The failure of anidulafungin to achieve superiority in all clinical measures over fluconazole in the Phase III trial for esophageal candidasis stood in stark contrast with the fact that the in vitro antifungal activity of anidulafungin was nearly twenty-fold higher than fluconazole;

(b) The failure of anidulafungin to achieve superiority in all clinical measures over fluconazole in the Phase III trial for esophageal candidasis stood in stark contrast with claims made in early-stage clinical trials that better clinical outcomes could be achieved with anidulafungin, versus fluconazole, in treating candidasis;

(c) That it was relevant to compare anidulafungin to caspofungin acetate, an approved drug similar in structure and mechanism of action, in that caspofungin acetate did not demonstrate a statistically significant higher relapse rate relative to fluconazole in similar studies for the same indication;

(d) The fact that anidulafungin demonstrated a statistically significant higher relapse rate relative to fluconazole raised concerns that anidulafungin was an inferior therapy to fluconazole and caspofungin acetate for the treatment of esophageal candidasis in immunosuppressed patients;

(e) The observation of higher statistically significant clinical relapse rates for anidulafungin relative to fluconazole or caspofungin acetate would adversely impact marketing claims for anidulafungin;

(f) The clinical relevance of the statistically significant differences in relapse rate were summarily dismissed, to facilitate a business decision to file the NDA, despite the fact that the adverse clinical relapse data clearly undermined the label claim sought, for use of anidulafungin in the treatment of esophageal candidasis;

(g) That the nature and outcome of any additional studies was uncertain, resulting at best in a greatly delayed approval of anidulafungin for esophageal candidasis or at worst insurmountable obstacles that would prevent the drug from ever being approved;

(h) That although the Phase III study for anidulafungin for the treatment of esophageal candidasis was completed during the fourth quarter of 2002, the announcement

of the results of the study were delayed until after the Company had completed its merger with Biosearch Italia S.p.A. late in the first quarter of 2003 ; and

(i) That the failure to disclose the defective nature of the anidulafungin Phase III study for esophageal candidasis would prevent investors and Biosearch Italia S.p.A. shareholders from learning the extent of the misrepresentations made to them during the Class Period.

FIRST CLAIM FOR RELIEF

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

45. Plaintiff incorporates ¶¶ 1- 45 by reference.

46. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

47. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:

(a) Employed devices, schemes, and artifices to defraud;

(b) Made untrue statements of material facts or 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; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Vicuron common stock during the Class Period.

48. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Vicuron common stock. Plaintiff and the Class would not have purchased Vicuron common stock at the prices they paid, or at all, if they had been

aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

49. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Vicuron common stock during the Class Period.

SECOND CLAIM FOR RELIEF

For Violation of Section 20(a) of the Exchange Act Against All Defendants

50. Plaintiff incorporates ¶¶ 1- 50 by reference.

51. The Individual Defendants acted as controlling persons of Vicuron within the meaning of Section 20(a) of the Exchange Act. By reason of their positions as officers and/or directors of Vicuron, and their ownership of Vicuron stock, the Individual Defendants had the power and authority to cause Vicuron to engage in the wrongful conduct complained of herein. Vicuron controlled each of the Individual Defendants and all of its employees. By reason of such conduct, the Individual Defendants and Vicuron are liable pursuant to Section 20(a) of the Exchange Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Declaring this action to be a proper class action pursuant to FRCP 23;

B. Awarding plaintiff and the members of the Class damages, interest and costs; and

C. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

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