VERSICOR INC /CA
Form 8-K
March 17, 2003

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported):

March 17, 2003

Versicor Inc.

(Exact Name of Registrant As Specified in Charter)

Delaware	**000-31145**	**04-3278032**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

455 South Gulph Road, King of Prussia, PA 19406

(Address of Principal Executive Offices) (Zip Code)

(610) 491-2200

(Registrant s telephone number, including area code)

Not Applicable

(Former Name or Former Address, if Changed Since Last Report.)

Item 9. Regulation FD Disclosure

In a conference call held today at approximately 4:45 p.m. (Pennsylvania time), members of our management presented selected Phase III clinical trial data regarding our product candidate, anidulafungin, for esophageal candidiasis. Furnished below is a copy of the script of today s presentation.

Conference Call Script March 17, 2003, 4:45 PM EST

Phase III Trial Results With Anidulafungin for Esophageal Candidiasis

Operator: Introduces Dr. Dov Goldstein, Versicor s chief financial officer.

I. Dov: Welcome

Thank you for joining us this afternoon.

Before we get started, please allow me to read a legal notice. Some of the statements that we will make on this conference call will contain forward-looking statements within the meaning of the federal securities laws. The matters described in these forward-looking statements are subject to known and unknown risks, uncertainties and other unpredictable factors, many of which are beyond Versicor s control. Versicor faces many risks that could cause its actual performance to differ materially from the results predicted by its forward-looking statements, including the possibilities that clinical trials might be delayed, that the timing of the announcement of the results of clinical trials might be delayed, that the timing of the filing of any New Drug Application might be delayed, that subsequent clinical trials might indicate that a product candidate is unsafe or ineffective, that Versicor s ongoing proprietary and collaborative research might not yield useful results, that Versicor s competitors might develop superior substitutes for their products or market them more effectively and that Versicor may not be able to market or commercialize successfully any of its product candidates. Versicor s annual and quarterly reports contain a fuller description of these and many other material risks to which Versicor is subject. Because of these risks, Versicor s actual results, performance or achievements may differ materially from the results, performance or achievements, expressed or implied by its forward-looking statements. The information set forth in this conference call represents management s current expectations and intentions. Versicor does not assume any responsibility to issue updates to the forward-looking matters discussed in this conference call.

Now I d like to introduce Versicor s chief executive officer, Mr. George Horner, who will moderate the rest of the call. George.

II. George: Opening Remarks

Thanks Dov, and thank you all for joining us this afternoon to discuss the positive results of our Phase III clinical trial with our lead anti-fungal investigational product candidate, anidulafungin, for the treatment of esophageal candidiasis.

Anidulafungin belongs to the first new class of anti-fungal agents introduced in more than 40 years the echinocandin class. This new class promises to improve the treatment of serious fungal infections with a broad-spectrum alternative that has a low potential for developing resistance and a favorable safety profile relative to some current standard agents. We are very excited about our clinical development program for anidulafungin and these results reinforce that excitement.

Anidulafungin has the potential to become an important new agent in the physician s armamentarium to treat serious hospital fungal infections, not only for esophageal candidiasis, but also for other common and often life-threatening fungal infections, such as invasive candidiasis/candidemia and aspergillosis. Our recent merger puts us in a better position to try to commercialize this agent in the two largest pharmaceutical markets, North America and Europe. The world-wide market opportunity for echinocandins is estimated to be $1.8 billion by 2008, according to Datamonitor.

We are pleased with the results of our pivotal Phase III trial. As most of you probably learned from the press release we issued this afternoon, we met our primary endpoint that demonstrates that anidulafungin is as effective as the current standard-of-care agent, oral fluconazole, in treating esophageal candidiasis and also has a good safety profile.

These data and positive results from our previous trials, keep us on schedule to submit a New Drug Application to the Food and Drug Administration by the end of April of this year, which will be one of the most important milestone achievement in our Company s history thus far.

I d now like to introduce our chief medical officer, Dr. Tim Henkel, who will review the results of the Phase III esophageal candidiasis study in more detail. After that, we will open up the call for some questions and answers.

III. Tim: Clinical Results Summary Review

Thanks, George.

First I d like to review the study design, followed by a summary of the headline results.

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 loading 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. Because this is a relapsing disease, clinical trials utilize end of therapy as the primary endpoint. Endoscopic success at end of therapy was the FDA agreed primary endpoint for this study. Endoscopic success at the end of therapy in clinically evaluable patients was 97.2 percent, or 242 out of 249 patients, with intravenous anidulafungin and 98.8 percent, or 252 out of 255 patients, with oral fluconazole. The statistical requirement for non-inferiority was easily met, as the lower bound of the 95 percent confidence interval, or what we often refer to as the delta , was minus 4.1 percent, well within the prospectively specified minus 10 percent limit. Clinical and mycological responses at end of therapy were high in both treatment groups. Here, too, anidulafungin was at least as effective as fluconazole in statistical terms. 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 by the two-week follow-up visit. The anidulafungin arm demonstrated 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, or 150 out of 233 patients in the anidulafungin arm and 89.5 percent, or 205 out of 229 patients in the fluconazole arm, which was a statistically significant difference. Standard of care in this disease calls for institution of maintenance therapy at the end of a course of treatment, but this was not implemented in a blinded clinical trial during the two-week follow-up. Therefore, follow-up responses in this setting have little clinical relevance.

In terms of safety, anidulafungin was as well tolerated as fluconazole. Treatment-related adverse effects were 9.3% for anidulafungin and 12.0% for fluconazole. There were no systemic infusion reactions with greater than 4,000 infusions. As expected, there was no QTc effect.

These data, along with positive data from other trials will form the basis of what we believe will be a strong NDA submission to the FDA, which, as George mentioned, we plan to file by the end of April of this year.

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 and often deadly hospital-based fungal infection; and interim safety data from an ongoing Phase III trial studying anidulafungin in aspergillosis, another serious, opportunistic fungal infection with high mortality rates.

Results from the 120-patient randomized, open-label Phase II invasive candidiasis/candidemia clinical trial demonstrated at the end of therapy an 89 percent global response rate in patients receiving a 200 mg intravenous loading dose of anidulafungin followed by a 100 mg maintenance dose per day. The response rate was 90 percent with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 84 percent 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 with a loading dose of 200 mg followed by a 100 mg

maintenance dose per day. The response rate was 85 percent with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 72 percent with 100 mg followed by 50 mg.

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.

Anidulafungin is now being studied in an ongoing Phase III clinical trial for invasive candidiasis/ candidemia.

George, I ll turn it back to you for questions. Thank you.

IV. George: Q&A

Thanks, Tim. I d now like to open the call for some questions.

V. George: Closing Remarks

Thank you again for joining us today. We look forward to seeing many of you at upcoming conferences such as the SG Cowen conference tomorrow and at Banc of America conference next week in Las Vegas. We are also planning an Analyst Day to be held in New York City this spring.

***

Cautionary Note Regarding Forward-Looking Statements

This report contains forward-looking statements describing our expectations for the future. Often the words believe, expect, anticipate, might, will, or could (or the negatives of these words) or similar expressions appear in, and can be used to identify, forward-looking statements. While we believe that the expectations expressed in our forward-looking statements are reasonable, the future can rarely be predicted with precision and actual events occurring in the future might not match the expectations described in this document. The matters discussed in our forward-looking statements are subject to uncertainty and many known (and perhaps unknown) risk factors. Some of the important risk factors that could cause our actual results to differ significantly from the results expressed or implied by our forward-looking statements are listed in our Annual Report on Form 10-K Report for the year ended December 31, 2002 under the caption Risk Factors, as well as in our other SEC filings under similar captions. Among other factors, we face the risks that: clinical trials might indicate a product candidate is unsafe or ineffective; the filing of any new drug applications might be delayed or cancelled; a filed New Drug Application might be denied resulting in an inability to market the product candidate in the U.S. or other jurisdictions; Versicor might lack the ability to successfully market products domestically and internationally; difficulties or delays in manufacturing might occur; legislation affecting drug pricing and reimbursement might cause adverse changes to the potential market for Versicor s product candidates; product liability and other types of lawsuits might be filed against the Company; Versicor s ability to protect its intellectual property both domestically and internationally might be incomplete; Versicor might fail to comply with the many complex laws and regulations affecting domestic and foreign

pharmaceutical operations; changes in generally accepted accounting principles might result in financial reporting changes that cause reported loss to increase; growth in costs and expenses might cause losses to increase; Versicor s ongoing proprietary and collaborative research might not yield useful results; and contractual milestone payments might not be paid to Versicor as contemplated and Versicor s competitors might develop superior substitutes for its products or market them more effectively. Because of the risks we face, our actual results, performance or achievements may differ materially from the results, performance or achievements, expressed or implied by our forward-looking statements. We assume no responsibility to issue updates to the forward-looking matters discussed, or incorporated by reference, in this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

VERSICOR INC.
(Registrant)

Date: March 17, 2003

By: /s/ George F. Horner III
George F. Horner III
President and Chief Executive Officer