

VERSICOR INC /CA  
Form 10-K  
March 03, 2003

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**  
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2002

COMMISSION FILE NUMBER 000-31145

**VERSICOR INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**04-3278032**  
(I.R.S. Employer  
Identification No.)

**455 South Gulph Road, Suite 305**  
**King of Prussia, PA**  
(Address of Principal Executive Offices)

**19406**  
(Zip Code)

(Registrant's Telephone Number, Including Area Code): **(610) 491 2200**

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act: **Common Stock, \$0.001 par value**  
**Preferred Stock Purchase Rights**

**Title of Each Class**

**Name of Exchange on Which Registered**

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Common Stock, Par Value \$0.001 Per Share

NASDAQ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Rule Act Rule 12b-2). Yes  No

On February 24, 2003, Versicor had 26,446,086 shares of Common Stock outstanding and an approximate public market value of \$212.1 million (based on 19,874,311 shares of Common Stock held by non-affiliates and a closing price of \$10.67 per share of Common Stock on the Nasdaq National Market).

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On June 28, 2002, which was the last business day of Versicor's most recently completed second fiscal quarter, Versicor's public market value was approximately \$266.9 million (based on 19,842,369 shares of Common Stock then held by non-affiliates and a closing price that day of \$13.45 per share of Common Stock on the Nasdaq National Market). These public market value calculations exclude shares held on the stated dates by Versicor's officers, directors and 5% or greater stockholders. (Exclusion from these public market value calculations does not imply affiliate status for any other purpose.

Documents Incorporated By Reference: Part III: Portions of the Proxy Statement for Registrant's Annual Stockholders Meeting to be filed within 120 days of fiscal year end.

The Exhibit Index begins at page Ex-1.

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### Cautionary Note Regarding Forward-Looking Statements

In addition to historical information, this Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts included in this Annual Report on Form 10-K, regarding our strategy, future operations, financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. As contained herein, the words "expects," "anticipates," "believes," "intends," "will," and similar types of expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are based on information that is currently available to the Company, speak only as of the date hereof, and are subject to certain risks and uncertainties. The Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in the Company's expectations with regard thereto or to reflect any change in events, conditions, or circumstances on which any such forward-looking

statement is based, in whole or in part. The actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to, those discussed in the sections in this Annual Report on Form 10-K entitled "Risk Factors." Readers should carefully review the risk factors described in other documents the Company files from time to time with the Securities and Exchange Commission, including the Quarterly Reports on Form 10-Q to be filed by the Company in 2003.

All references to "dollars" or "\$" in this proxy statement/prospectus are references to United States dollars; all references to "euros" or "€" are references to European Union, or EU, euros. On February 26, 2003, the median 4 p.m. Greenwich Mean Time spot rate for the euro expressed in dollars per euro was \$1.0792 to EUR1.00.

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## PART I

### ITEM 1. BUSINESS

*The following description of our business should be read in conjunction with the information included elsewhere in this annual report on Form 10-K. The description contains certain forward-looking statements that involve risks and uncertainties. When used in this Annual Report on Form 10-K, the words "intend", "anticipate", "believe", "estimate", "plan", "expect" and similar expressions as they relate to us are included to identify forward-looking statements. Our actual results could differ materially from the results discussed in the forward-looking statements as a result of certain of the risk factors set forth below and in the documents incorporated herein by reference, and those factors described under "Risk Factors." In this Annual Report on Form 10-K, references to "Versicor," "we," "us" and "our" refer to the combined company and its subsidiaries following the merger of Versicor Inc. and Biosearch Italia S.p.A., or Biosearch, which was completed on February 28, 2003. This Annual Report contains trademarks and trade names of other entities.*

#### Overview

We are a biopharmaceutical company focused on the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of bacterial and fungal infections. We focus on seeking to develop antibiotics and antifungals that may have competitive advantages over existing products, such as greater potency, improved effectiveness against difficult to treat strains and reduced toxicity. Because the development process for anti-infective products is relatively efficient and well-defined, we believe the costs and time required to bring new anti-infective products to market can be significantly less than the time required to bring products to market in other major therapeutic categories.

We recently merged with Biosearch Italia S.p.A., a publicly listed company in Italy. Biosearch has used natural product sourcing for the discovery, development and production of novel anti-infective drugs with a primary emphasis on Europe. The merger will enhance our capabilities with respect to discovery, pre-clinical and clinical development, and manufacturing, as well as our European market presence and effectiveness. The combined company will have a greater presence in two of the three major pharmaceutical markets (North America and Europe) as well as an enhanced product portfolio for collaborations in Asia. We had previously licensed the North American rights to our lead antibiotic product candidate, dalbavancin, from Biosearch, and by acquiring the global rights we will eliminate royalties and manufacturing fees in North America, acquire the full potential of dalbavancin in Europe and enhance our commercialization effectiveness for our lead antifungal drug, anidulafungin, in both North America and Europe. As a result, we believe all of these benefits will increase our margin and profitability prospects for dalbavancin and anidulafungin upon regulatory approval in North America and Europe. We also believe that European approval can now be obtained with only a modest increase in the clinical development expenses already planned for our North American filings.

We have a two-fold approach to product discovery, development and marketing. Our primary strategy is to focus on the discovery and development of proprietary products, concentrating on injectable antibiotic and antifungal products for the hospital market. We expect to market these products to hospitals in North America through our to be developed direct sales force, which we believe we can accomplish through a targeted and cost-effective sales and marketing infrastructure. Our product candidates target disease indications that represent markets where there is demand for new therapies.

Our secondary strategy is to collaborate with major pharmaceutical companies to discover and develop orally administered antibiotic and antifungal products for the non-hospital market. Major pharmaceutical companies are generally better suited to market these products, as these products require substantial expenditures for sales and marketing to reach their full market potential. Under our

typical collaboration agreements, we are responsible for discovering the compounds and our collaborators are responsible for developing and marketing them. We expect to receive a combination of research funding, milestone payments and equity investments from our collaborators, as well as royalty fees if any products are commercialized.

Our discovery platform combines our proprietary expertise in the critical areas of functional genomics, mechanism-based rational drug design, high-throughput screening of our diversified library of microbial extracts and lead optimization. We intend to leverage our technology platform to discover and supply lead compounds both for internal development and commercialization, in the case of hospital products, and for our pharmaceutical collaborations, in the case of community products.

#### *Our Proprietary Products*

*Anidulafungin.* Our lead antifungal product candidate, anidulafungin, is intended for the intravenous treatment of serious systemic fungal infections. Anidulafungin has potent activity against the principal yeasts, such as *Candida*, and molds, such as *Aspergillus*, that cause serious fungal infections. In addition, anidulafungin has fungicidal activity, which means that it kills the fungus. This is in contrast to many widely-used antifungal agents which only inhibit fungal growth. Because of anidulafungin's novel mechanism of action, it is active against strains resistant to other agents, such as fluconazole. We believe anidulafungin will have competitive advantages over existing therapies because it combines potent fungicidal activity with a good resistance profile to date. We began a Phase III trial with anidulafungin for the treatment of esophageal candidiasis in the first quarter of 2001, and have completed patient enrollment. Assuming a successful outcome in this trial, we intend to file a new drug application, or NDA, by the end of April 2003. We have also completed a Phase II clinical trial with anidulafungin for the treatment of invasive candidiasis/candidemia and based on positive results from this trial, recently began a Phase III trial in this indication. Another Phase III trial is also underway to evaluate anidulafungin in combination with liposomal amphotericin for the potential treatment of invasive aspergillosis.

*Dalbavancin.* Our lead antibiotic product candidate, dalbavancin, is a next-generation antibiotic belonging to the same class as vancomycin, the most widely used injectable antibiotic for Staphylococcal infections. Dalbavancin is intended for the treatment of serious systemic infections, particularly those caused by *Staphylococci*. Dalbavancin is more potent than vancomycin, in particular against methicillin-resistant *Staphylococci*, a common and difficult-to-treat bacteria. Dalbavancin has bactericidal activity, which means that it kills the bacteria rather than inhibits its growth, as shown in both the laboratory and in infected animals. Because of its unique pharmacokinetic properties and the tolerability profile seen to date even at high doses, dalbavancin has the potential to be dosed weekly, which may be a significant competitive advantage over other products. We have successfully completed a Phase II trial with dalbavancin for the treatment of skin and soft tissue infections and in December 2002 announced the start of two Phase III trials for these indications. We expect to complete these trials in the first half of 2004, and plan to file an NDA for dalbavancin in the second half of 2004. In the first quarter of 2002, we also initiated a Phase II trial in catheter-related bloodstream infections.

*Ramoplanin.* Our third product candidate, ramoplanin, is a lipopeptide. Ramoplanin selectively inhibits Gram-positive bacteria including methicillin-resistant *Staphylococcus aureus* (MRSA) and all types of vancomycin-resistant *enterococci* (VRE) and Clostridia, including *Clostridium difficile*. Ramoplanin does not show a propensity to select resistant mutants *in vitro* and does not have cross-resistance with known antibiotics. Genome Therapeutics, our licensee in North America, is developing ramoplanin, in an oral non-absorbable form, for the prevention of systemic infection in hospitalized patients with VRE in their gastrointestinal tract. Our licensees have successfully completed Phase II trials with ramoplanin for the eradication of VRE in the gastrointestinal system and initiated a Phase III study for the reduction of VRE bloodstream infections in patients at risk in June 2000. Our

licensee also recently initiated a Phase II dose response trial to evaluate the safety and efficacy of ramoplanin for the treatment of *Clostridium difficile* associated diarrhea.

*BI-K-0376 (BI-Acne).* Our fourth product candidate, BI-Acne, is a novel antibiotic. BI-Acne has a new mechanism of action and shows selective activity against *Propionibacterium acnes*, a bacteria associated with acne, including drug resistant strains, while it shows modest activity against normal skin flora. As a result, it could selectively eliminate the *Propionibacterium acnes* without affecting the natural flora of the skin. We have recently completed a Phase I clinical trial with BI-Acne to assess safety and tolerability.

#### *Research Collaborations*

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Our most advanced collaboration is with Pharmacia Corporation and is aimed at discovering second and third generation oxazolidinones. The oxazolidinones represent the first new major class of antibacterial products to enter the market in over 30 years. They are active against a broad range of bacteria, including multidrug resistant *Staphylococci*, *Streptococci* and *Enterococci*. Pharmacia received approval from the Food and Drug Administration, or FDA, independent of us, for the first generation oxazolidinone called Zyvox. We have identified several structurally novel second generation oxazolidinone candidates, certain of which have either a broader spectrum of activity or improved potency. Some of these compounds also have good activity in pre-clinical *in vivo* studies when administered orally. This collaboration began in April 1999. In October 2000, Pharmacia increased its research support payments to us by 30% and, in June 2002, we amended our original agreement with Pharmacia to extend the research term an additional three years.

Our second collaboration is with Novartis Pharma AG and is designed to develop deformylase inhibitors as new antibacterial agents and to provide novel target-based screens. Deformylase is an essential enzyme in bacteria but not in human cells, and thus represents a good target for the discovery of selective inhibitors that can serve as broad spectrum antibacterial agents. We have identified several lead inhibitor molecules that are active against multidrug resistant strains, as well as respiratory pathogens such as *S. pneumoniae*, *H. influenzae* and *M. catarrhalis*. Several lead compounds have demonstrated activity in pre-clinical *in vivo* studies when administered orally, representing an example of *de novo* design of an active antibacterial agent. This collaboration began in April 1999. In January 2002, we received a fifth milestone payment as a result of our delivery of our fifth target-based screen, which we expect will be used in Novartis' high-throughput screening laboratory to identify new anti-infectives. In March 2002, we amended the original agreement in order to extend the research term an additional year and to provide that Novartis will make an additional payment upon our achievement of a new milestone. In February 2003, we amended the original agreement in order to extend the research term through March 31, 2005.

Our third type of collaboration is a program called "VITACHEM" and is designed to investigate the pharmaceutical and non-pharmaceutical utility of our collection of microbial chemicals in markets outside of the anti-infectives market. We offer two types of collaborations under the VITACHEM program: fee-for-service collaborations, under which our collaborators pay us research fees, plus milestone payments and royalties calculated as a percentage of net sales; and equal collaborations, based on cost-sharing and reward-sharing. To date, we have entered into three fee-for-service collaborations with Schering-Plough, Bayer AG and Menarini and two equal collaborations with Myriad Genetics Inc. on oncology, cardiovascular and viral targets, and Newron Pharmaceutical S.p.A. on central nervous system targets.

### *Internal Discovery Research*

In addition to our external research collaborations, we have internal research programs both in the United States and in Italy as a result of our recently completed merger with Biosearch. The objective of internal research is primarily to discover novel antimicrobials for hospital use for development by us.

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This effort combines our internal expertise in functional genomics-based target selection, novel assay development, mechanism-based rational drug design, combinatorial chemistry, high-throughput screening of our diversified library of microbial extracts and medicinal chemistry. We are currently investigating several *in vivo* active leads.

### **Our Strategy**

Our objective is to be a leader in the discovery, development and marketing of pharmaceutical products for the treatment of bacterial and fungal infections in the hospital setting. We intend to achieve this goal through the implementation of four strategies:

*Focus our discovery and development efforts on products to treat bacterial and fungal infections.* We believe that anti-infective products have significant development advantages over products in other therapeutic categories. These advantages include lower costs and shorter development cycles. In addition, this area has a greater probability of clinical success due to the higher predictive value of clinical trials in this area. Additionally, there is a growing demand for new anti-infective products. This demand is driven primarily by the aging of the population, the growing number of seriously ill patients in hospitals and an increase in immunosuppression and fungal and bacterial resistance to existing therapies.

*Target our resources on products that have potential utility in the hospital setting.* We believe that our efforts are best focused on developing products that would be administered in a hospital setting. Because of the increased number of elderly patients and the severity of illnesses among patients in intensive care units, we believe that hospitals present an addressable

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market with significant unmet needs. This strategy will also allow us to use a relatively small sales force, thereby allowing us to reach the greatest number of patients while still remaining cost-effective.

*Focus on products that have a competitive advantage over currently marketed drugs.* We intend to focus our development efforts on products that we expect to have potential advantages over currently marketed drugs. This strategy reduces the time and expense we will need to effectively educate physicians about new types of treatments and will allow us to market our relative benefits directly against our competitors' products.

*Pursue our two-fold approach to product development.* We have a two-fold approach to product development and marketing. Our primary strategy is to internally develop anti-infective products with utility in a hospital setting and market these products with our own direct sales force. For oral products with utility in treating community-acquired infections, we intend to collaborate in our development and marketing efforts with large pharmaceutical companies. This two-fold approach allows us to pursue on a proprietary basis internal development and marketing of those products for which we feel the development and marketing requirements are manageable and to out-license products that require greater resources than we are willing to commit, such as oral products.

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### Our Proprietary Product Candidates

The table below summarizes our product candidates, their target infections, their nature of activity and their development status.

Product Candidate/Program	Target Infections	Nature of Activity	Development Status
<b>Proprietary</b>			
Anidulafungin	<i>Esophageal Candidiasis Aspergillosis Invasive Candidiasis/Candidemia</i>	Fungicidal Fungicidal Fungicidal	Phase III(1) Phase III Phase III
Dalbavancin	<i>Skin and Soft Tissue Infections Blood Stream Infections</i>	Bactericidal Bactericidal	Phase III Phase II
Ramoplanin	<i>Prevention of Blood Stream Infections caused by VRE</i>	Bactericidal	Phase III
BI-Acne	<i>Acne</i>	Bacteriostatic	Phase I(2)
Internal Research Programs	<i>Bacterial Infections</i>		Pre-clinical <i>in vivo</i>
<b>Collaborations</b>			
Oxazolidinones (Pharmacia)	<i>Bacterial Infections</i>	Bacteriostatic	Pre-clinical <i>in vivo</i>
Deformylase Inhibitors (Novartis)	<i>Bacterial Infections</i>	Bacteriostatic/Bactericidal	Pre-clinical <i>in vivo</i>

- (1) Patient enrollment complete
- (2) Clinical trial complete.

**Anidulafungin A Novel Antifungal for the Treatment of Serious Infections**

*Clinical Efficacy of Anidulafungin*

Anidulafungin demonstrated efficacy in a Phase II clinical trial involving 29 evaluable patients with esophagitis. Esophagitis is an inflammation of the lower part of the esophagus, usually caused by a fungal infection, such as with *Candida*. This disease is most frequently encountered in AIDS patients and is a serious cause of morbidity. Patients enrolled in this trial were treated with daily intravenous infusions of anidulafungin for up to 21 days. As demonstrated by the table below, with both dosing regimens, over 80% of evaluable patients were cured or improved, as measured by an endoscope, an

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instrument permitting visual examination of the esophagus. Anidulafungin was well-tolerated at both of the doses studied.

<b>Anidulafungin Dosage (Loading/Maintenance)</b>	<b>Endoscopic Response</b>
50 mg/25 mg	13/16 (81%)
70 mg/35 mg	11/13 (85%)

A subsequent safety and tolerance study indicated that an anidulafungin loading dose of 260 mg followed by daily maintenance doses of 130 mg did not reach a protocol defined maximum tolerated dose (MTD). Based upon the proportion of complete and partial responders observed in the Phase II trials and the safety data obtained from the maximum tolerated dose study, we believe that anidulafungin may achieve improved efficacy at a dose higher than that used in the Phase II esophagitis trial, while maintaining a good side effect profile.

A pivotal Phase III trial of anidulafungin for the treatment of esophageal candidiasis, which we began in the first quarter of 2001, completed enrollment in October 2002. In this randomized, double-blind, double-dummy trial involving 600 patients, anidulafungin at a loading dose of 100 mg and daily maintenance doses of 50 mg is being compared with oral fluconazole. Treatment will continue for between 14 and 21 days, with the primary assessment of response made at the end of therapy. Additional evaluations will be made at a follow-up visit approximately two weeks later. Endoscopic response will be the primary endpoint, with both clinical responses and eradication of fungi as secondary endpoints. We have completed patient enrollment, and assuming successful outcome of the Phase III trial, we anticipate filing an NDA by the end of April 2003.

We completed a Phase II trial in invasive candidiasis/candidemia in the fourth quarter of 2002. This randomized, open-label trial enrolled approximately 120 patients in the United States with documented diagnosis of invasive candidiasis/candidemia. Patients were treated with a daily intravenous (IV) 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. End-of-therapy outcomes in evaluable patients demonstrated an 89% global response rate (25/28 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 90% (27/30 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 84% (21/25 patients) with 100 mg followed by 50 mg. Outcomes in evaluable patients at the two-week, test-of-cure visit demonstrated an 83% global response rate (20/24 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 85% (22/26 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 72% (13/18 patients) with 100 mg followed by 50 mg. Anidulafungin was well-tolerated and adverse events attributable to the study drug were 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% to

81% in patients with invasive candidiasis/candidemia.

We began a Phase III trial in invasive candidiasis/candidemia in December 2002. In this double-blind, randomized trial we will enroll approximately 300 patients in the United States, Canada and Europe to study the safety and efficacy of a 200 mg loading dose followed by a 100 mg maintenance dose of anidulafungin versus fluconazole. Patients will receive daily IV infusions of either anidulafungin or fluconazole for 10 to 42 days. The primary endpoint is global assessment of clinical and microbiological responses at the end of IV therapy.

We began a Phase III trial of anidulafungin for the treatment of aspergillosis in the fourth quarter of 2001. Aspergillosis is an extremely serious disease, with a very high rate of mortality, for which new therapies are urgently needed today. For this reason, and because our Phase I trial demonstrated that higher doses of anidulafungin were well-tolerated by volunteers, we have taken an anidulafungin dose

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of a 200 mg loading dose followed by daily maintenance doses of 100 mg directly into our Phase III trial. This open-label, non-comparative study will enroll up to 60 hospitalized patients with a diagnosis of invasive aspergillosis. A single daily intravenous infusion of anidulafungin and a single daily intravenous infusion of a lipid-complexed formulation of amphotericin B will be administered to patients for up to 90 days. The primary endpoint is combined global response, *i.e.*, clinical and radiographic responses, at the conclusion of therapy.

#### *Characteristics of Anidulafungin*

Anidulafungin, our lead antifungal product candidate, belongs to the new echinocandin class of antifungal agents. It is being developed for the treatment of serious fungal infections, including disseminated or bloodstream infections, organ infections and esophagitis, or severe infections of the esophagus. The most serious fungal infections generally occur in individuals who have impaired immune systems. *In vitro*, anidulafungin is fungicidal, which means that it kills, rather than just inhibits, fungi. Anidulafungin is active against strains resistant to azoles, such as fluconazole.

Anidulafungin is a chemically modified derivative of a natural product that was chosen for development because of its improved properties over existing treatments. In May 1999, we obtained an exclusive worldwide license for its development and commercialization from Eli Lilly.

As compared with current therapies, we believe that anidulafungin has a number of advantages, including the following:

*Novel mechanism of action.* Anidulafungin belongs to a new class of antifungal drug that only recently has been developed for human use. It selectively inhibits an enzyme, found only in fungi, which is critical for the production and integrity of the fungal cell wall. This mechanism is completely different from that of the polyenes, such as Amphotericin B, and the azoles, such as fluconazole. The mechanism of action of anidulafungin has advantages, including fungicidal activity and lack of cross-resistance with traditional therapies. In addition, this novel mechanism of action may allow for synergistic combinations with polyenes or azoles and may result in better outcomes for patients with the most difficult-to-treat infections.

*Potent broad spectrum.* Anidulafungin has shown highly potent *in vitro* activity against diverse groups of fungi, both yeasts and molds, that cause life-threatening infections. Anidulafungin is particularly potent against *Candida*, including fluconazole-resistant strains, and *Aspergillus*, the two most common types of fungi causing serious human infections. The following figure illustrates the *in vitro* potency of anidulafungin against *Candida albicans*, as measured by the MIC<sub>90</sub>, or the concentration of drug that inhibits the growth of 90% of the fungal strains, on a logarithmic scale. The figure demonstrates that to inhibit the growth of *Candida albicans*, less anidulafungin is needed as compared with existing agents caspofungin, amphotericin B and fluconazole.



Source:  
NIAID MSG 33-34 Survey

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*In vitro* data demonstrate that to inhibit growth of *Aspergillus fumigatus*, far less anidulafungin is needed as compared with existing agents itraconazole and amphotericin B (*Antimicrob. Agents Chemother.* (1998) 42:2726).

As compared with other antifungal agents, these data illustrate that anidulafungin is more potent than available therapies. Anidulafungin also demonstrated impressive activity in a variety of animal models of *Candida* and *Aspergillus* infection. These included quite severe infections in immunosuppressed animals, such as disseminated infections and pulmonary aspergillosis. Efficacy was shown against different species and strains of *Candida*, including strains resistant to fluconazole. For example, in animal models the number of *Candida* in the liver, spleen, kidneys and lungs were reduced by 99.99% at the anidulafungin dosage of 0.5 mg/kg. In animals infected with *Aspergillus*, 80% of those treated with 2.5 mg/kg/day of anidulafungin survived until the end of the experiment (ten days), whereas all untreated animals died within four days.

*Fungicidal.* Anidulafungin kills fungi. This is an important characteristic of its novel mechanism of action, which affects the integrity of the protective cell wall of fungi. This may be an advantage over the widely-used azole class of antifungal agents, which are fungistatic, meaning that they merely inhibit the growth of fungi and do not kill them. For example, when comparing anidulafungin to fluconazole, a fungistatic agent, anidulafungin's killing power is clearly demonstrated: after twelve hours of exposure to anidulafungin, more than 99.5% of the exposed fungus was killed and after twelve hours of exposure to fluconazole, none of the exposed fungus was killed.

Patients that are severely immunosuppressed may be more effectively treated with a therapy that is fungicidal rather than fungistatic.

*Low potential for developing resistance.* As shown in the figure below, in the laboratory it has proven very difficult to develop resistance to anidulafungin. The lines represent the amount of anidulafungin and fluconazole needed to inhibit the growth of *Candida*. As more days pass in the experiment, the amount of fluconazole required to inhibit the fungus increases, while the amount of anidulafungin required to inhibit the fungus is unaffected.

*Well-tolerated in humans.* In 20 separate Phase I, II and III clinical trials, over 800 volunteers and patients have received anidulafungin and it has been well-tolerated. Amphotericin B, which belongs to the polyene class of compounds, is an effective fungicidal drug. However, even with the newer lipid formulations, the use of polyenes may be associated with severe side effects and use is sometimes limited by toxicity. The other major class of antifungal drugs, the azoles, is better tolerated than the polyenes, but they lack fungicidal activity against *Candida*.

## **Dalbavancin A Next-Generation Antibiotic for the Treatment of Serious Gram-Positive Infections**

### *Clinical Experience with Dalbavancin*

Phase I dose-ranging trials in normal volunteers have been concluded. High single doses, up to 1120 mg, and multiple doses, consisting of a loading dose of 1000 mg and repeat daily doses up to 100 mg for six days, were evaluated in these trials. The pharmacokinetics of dalbavancin with these dosage regimens were reproducible and followed the predictions made on the basis of preliminary Phase I and modeling studies. The safety and tolerability profile was very good, with no dose-limiting toxicities encountered. We have successfully completed a Phase II trial with dalbavancin for the treatment of skin and soft tissue infections and in December 2002 announced the start of two Phase III trials for this indication. We also started a Phase II trial in catheter-related bloodstream infections in the first quarter of 2002. Both the Phase III skin and soft tissue infections trials and the Phase II catheter-related bloodstream infections trial will include dose arms that evaluate the efficacy and safety of weekly administration of dalbavancin.

### *Characteristics of Dalbavancin*

Dalbavancin is a novel next-generation glycopeptide antibiotic, a chemically modified derivative of a natural product. We are developing dalbavancin as an alternative to vancomycin for the treatment of serious Gram-positive infections, predominantly in hospitalized patients. Dalbavancin has potent *in vitro* activity against Gram-positive bacteria. In particular, we are targeting infections caused by *Staphylococci*, including methicillin-resistant strains, the principal indication for vancomycin. Serious infections caused by *Staphylococci* include skin and soft tissue infections, bloodstream infections and osteomyelitis. An additional advantage of dalbavancin is its ease of administration, because of its once weekly dosing regimen and its safety and tolerability profile to date.

In the second quarter of 2002 we completed a Phase II clinical trial of dalbavancin for the treatment of skin and soft tissue infections. This randomized, controlled study showed that dalbavancin given once a week for two weeks had numerically higher clinical and microbiological response rates than a variety of standard care regimens, including vancomycin, given for a mean duration of 15 days for the treatment of skin and soft tissue infections. As in all other clinical studies to date, dalbavancin was also shown to be very well tolerated. The trial enrolled 62 hospitalized patients with skin and soft tissue infections involving deep skin structures or requiring surgical intervention, such as abscesses, infected ulcers, burns and cellulitis. Patients were treated with one of two dalbavancin-dosing regimens or a standard of care agent, which was specified by the investigator prior to randomization. Patients were examined for clinical and microbiological responses at the conclusion of therapy and two week following therapy. The primary endpoint was clinical response at follow-up in evaluable patients. Outcomes in evaluable

patients demonstrated a 94.1% clinical success rate (16/17 patients) with two doses of dalbavancin given one week apart (at day one and day eight), compared with 76.2% (16/21 patients) for the standard care arm (given daily for 7-21 days) and 61.5% (8/13 patients) for the single dose dalbavancin arm (given day one). Microbiological success was 72.7% (8/11 evaluable patients) with two weekly doses of dalbavancin compared with 64.3% (9/14 patients) for standard of care and 27.3% (3/11 patients) for the single dose dalbavancin arm. Dalbavancin was well-tolerated and adverse events were infrequent and similar across the study arms. There were no trends in any laboratory abnormalities in patients receiving dalbavancin. We also initiated a Phase II trial in catheter-related bloodstream infections in the first quarter of 2002.

In December 2002 we started two Phase III trials with dalbavancin for the treatment of skin and soft tissue infections. These randomized, double-blind trials will each enroll approximately 550 hospitalized patients who will be examined for overall clinical and microbiological responses at the conclusion of therapy. In the first trial, patients with complicated skin and soft tissue infections will receive either a one gram intravenous dose of dalbavancin on study day one followed by a 500 mg dose

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on study day eight or approved doses of linezolid for 14 days. In the second study, patients with uncomplicated skin and soft tissue infections will receive either a one gram intravenous dose of dalbavancin on study day one, with the option of adding a 500 mg dose on study day eight, or intravenous cefazolin, followed by oral cephalexin. On day eight, the investigator will decide the duration of the study medication therapy (seven or fourteen days) based on the clinical status of the patient.

We believe dalbavancin has the following advantages over current therapies:

*Greater potency.* In the laboratory, dalbavancin demonstrated better activity against a range of Gram-positive bacteria, including all of the staphylococcal species, in particular against MRSA and MRSE. These organisms are among the most difficult to treat successfully and vancomycin is one of the few treatment options currently available. As shown in the figure below, dalbavancin was more potent *in vitro* than other marketed and experimental antibiotics belonging to the glycopeptide class against MRSA and MRSE. The figure demonstrates that to inhibit the growth of MRSA and MRSE, less dalbavancin is needed as compared with existing agents vancomycin, teicoplanin and the investigational agent, oritavancin. Activity is expressed as the MIC<sub>90</sub>.

Source:  
*JAC (1999), 44:179*

This data illustrates that dalbavancin is more potent than other glycopeptide therapies. Dalbavancin also demonstrated impressive potency in a number of animal model infections, caused by a variety of Gram-positive bacteria, including those resistant to methicillin. Dalbavancin was

efficacious against *Staphylococcal endocarditis* in animal models, as well as against *Streptococcus pneumoniae* pulmonary infection in normal and immunosuppressed animal models. Pharmacodynamic studies in animal models demonstrated bactericidal activity in the animals coupled with good tissue penetration and distribution of dalbavancin.

*Bactericidal.* Dalbavancin kills Gram-positive bacteria. This may be an advantage over certain other therapies such as Zyvox, which is only bacteriostatic. Patients with serious infections caused by methicillin-resistant Staphylococci may be more effectively treated with a therapy that is bactericidal rather than bacteriostatic.

*Unique, flexible and infrequent dosing regimen.* Human pharmacokinetic data and studies in animal models demonstrated that dalbavancin has a long duration of action after administration and shows promise to become the first available once-weekly injectable antibiotic for the

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treatment of Staphylococcal and other serious Gram-positive hospital infections. Once-weekly dosing may allow some patients to have IV lines discontinued, which translates into fewer opportunities for local infection and blood stream infections. This may also provide pharmacoeconomic benefits, such as shorter hospital stays, less need for follow-up home IV or oral antibiotics and other reduced costs.

*Well-tolerated in humans.* We successfully completed our Phase I dose-escalation clinical trial in which dalbavancin was well-tolerated even at very high doses and its pharmacokinetics were predictable. Dalbavancin was also well-tolerated in a completed Phase II skin and soft tissue study.

## **Ramoplanin**

Ramoplanin is a novel antibiotic with excellent in vitro potency against Gram-positive bacteria including VRE. It is currently in a Phase III study being conducted by our North American licensee, Genome Therapeutics, for the prevention of VRE bloodstream infections in patients at risk.

## **BI-K-0376 (BI-Acne)**

BI-Acne is a novel topical antibiotic with activity against Propionibacterium acne including clindamycin and tetracycline resistant strains. We have completed a Phase I clinical trial with this agent as an anti-acne compound.

## **Research Collaborations**

### *Oxazolidinones collaboration with Pharmacia*

We are collaborating with Pharmacia to identify new generations of oxazolidinones. The oxazolidinones are the first major new chemical class of antibacterial products to enter the market in over 30 years. Pharmacia has received FDA approval, independent of us, for a new drug called Zyvox, the most advanced molecule in this class. Based on historical precedents for antibiotics, it is likely that the development of subsequent generations of oxazolidinones with improved potency and a broader spectrum of activity will create a major market opportunity. Oxazolidinones are active against a broad spectrum of Gram-positive pathogens, including multidrug resistant *Staphylococci*, *Streptococci* and *Enterococci*. They have a novel mechanism of action involving inhibition of an early step in protein biosynthesis. This process is also inhibited by antibiotics such as tetracycline. Oxazolidinones have no cross resistance to other classes of antibiotics.

We began working on oxazolidinones at a time when several large pharmaceutical companies were already actively involved in this area. Our scientists used their expertise in combinatorial chemistry to optimize leads around the core oxazolidinone structure and identified several novel lead structures with good *in vivo* activity when administered orally. Pharmacia signed a collaboration agreement with us in March 1999. We have identified several novel molecules with an enhanced spectrum of activity, including activity against the pathogen *H. influenzae*, improved potency against multidrug resistant bacteria including MRSA, MRSE, VRE and penicillin-resistant *Streptococcus pneumoniae*. Several compounds have also demonstrated good activity in pre-clinical *in vivo* studies when administered orally and are therefore undergoing advanced *in vivo* testing. Advanced *in vivo* testing includes testing the efficacy of the compounds with increased dosages, the absorption of the

compound in the blood, the differences between the oral formulation and the intravenous formulation and the toxicity of the compound.

We entered into our collaboration agreement with Pharmacia Corporation in March 1999. Pursuant to this agreement, we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. We supply research, product leads and other specified

intellectual property to the collaboration. Pharmacia has the right to conduct the development of any product candidates and the manufacture and sale of any products resulting from the collaboration. In connection with the collaboration, Pharmacia made an equity investment in us of \$3.8 million and paid us research support and license fee payments. We have assigned to Pharmacia one U.S. patent application and a corresponding Patent Cooperation Treaty patent application relating to this collaboration. Both applications involve the methodology of preparing oxazolidinones, libraries and pharmaceutical compositions. Under the terms of the agreement and in consideration of our research obligations, we are entitled to receive funding from Pharmacia to support some of our full-time researchers. If Pharmacia's development efforts achieve specified milestones, Pharmacia is obligated to pay us additional milestone payments of up to \$14 million for each compound. We are entitled to receive royalties on the worldwide sales of any products developed and commercialized from the collaboration. Pharmacia is allowed to offset some of its royalty payments by the amount of previous milestone payments made to us. This agreement will terminate on a country-by-country basis with respect to a product developed under the collaboration upon the later of 10 years from the date of the first commercial sale of the product in the country or the expiration of all product patents in the country. Pursuant to an October 2000 amendment, Pharmacia increased its funding for this collaboration by 30%, and in June 2001, we received a milestone payment for the initiation of clinical development of one of the compounds. In July 2002, we and Pharmacia amended the agreement to extend the collaboration for an additional three years through March 2005.

Through December 31, 2002, Pharmacia has made aggregate payments to us under this collaboration agreement (excluding equity investments) of \$13.9 million. We do not depend upon continued milestone payments from Pharmacia to any significant extent because we have funded, and intend to fund, our drug development programs primarily with the proceeds of equity offerings. Although we currently depend upon our collaborations, in-licensing opportunities and in-house research, in the aggregate, to seek to obtain a pipeline of product candidates, we do not depend to any significant extent on any individual collaboration.

#### *Deformylase Inhibitors collaboration with Novartis*

We are collaborating with Novartis to develop deformylase inhibitors as antibacterial agents. Deformylase is an essential enzyme present in bacteria but absent in human cells, thus representing a good target for the discovery of inhibitors that can serve as broad spectrum antibacterial agents. Deformylase is a metal-containing enzyme, or metalloenzyme. If this metal is removed or interfered with, the enzyme can no longer function. Since it is possible to design molecules that bind to metals, this makes it especially attractive for the design of mechanism-based drugs. Captopril, the first drug to be rationally designed using this approach, is an inhibitor of a metalloenzyme called Angiotensin Converting Enzyme, or ACE. The design of Captopril, which is used to treat hypertension and congestive heart failure, represented a major pharmaceutical breakthrough. Deformylase offers an excellent opportunity for integrating this principle of mechanism-based drug design with our combinatorial chemistry based approach.

Based on our scientists' experience in the Captopril field, we initiated a highly focused chemistry effort targeting the rational design and synthesis of deformylase inhibitors. We designed a set of pharmacophoric libraries specifically suited for metalloenzyme targets and also developed new synthetic methodologies for the preparation of these libraries. Screening these libraries against deformylase led to the identification of several molecules with excellent enzymatic and whole-cell inhibitory activity. Our proprietary "Gene to Screen" technology helped identify those leads that inhibited bacterial growth by specifically inhibiting deformylase. Through proper integration of combinatorial chemistry with medicinal chemistry, more specific lead series were further optimized with excellent selectivity, as well as activity against clinically significant multidrug resistant bacteria. Novartis has filed patent applications on the novel structures that we have synthesized. Many of these compounds have demonstrated good *in*

*vivo* activity in pre-clinical studies when administered orally. We are in the process of selecting a compound for development by Novartis, from the advanced lead molecules that we have available.

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We entered into our collaboration agreement with Novartis in March 1999. Pursuant to this agreement, we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of \$3.0 million and provides us with funding to support some of our full-time researchers. Under the terms of this agreement, we have established with Novartis a joint research committee and we are responsible for performing the three-year research plan developed by the committee. In return, Novartis has agreed to pay us a fee. We are also entitled to receive payments of up to \$13.0 million for our compounds or up to \$7.25 million for Novartis compounds upon Novartis' achievement of certain research milestones. In addition, we granted Novartis, and Novartis granted us, reciprocal research licenses. We also granted Novartis an exclusive worldwide commercial license, pursuant to which it may develop, manufacture and sell products resulting from this collaboration. For each product that Novartis develops and launches in specified countries, we are entitled to receive royalties on worldwide sales of the product and additional payments if the product contains one of our compounds and a lesser sum if the product contains a Novartis compound. Novartis may offset some of its royalty payments by the amount of previous milestone payments made to us. We have the option to co-promote with Novartis in hospitals in the United States and Canada any product that contains one of our compounds as an active ingredient, but we will not be entitled to royalties from sales of the product in that territory if we exercise our co-promotion option. This agreement terminates on a country-by-country basis with respect to a product developed under the collaboration upon the later of 10 years from the date of the first commercial sale of the product in the country or the time at which the product is no longer covered by a pending or issued patent in the country. In addition to the work on deformylase inhibitors, we have been delivering to Novartis under the agreement a series of screening assays based on novel anti-bacterial targets. For each screen that Novartis accepts as validated, we receive a milestone payment. In August 2001 and January 2002, Novartis paid us our fourth and fifth milestone payments, respectively, as a result of our delivery of our fourth and fifth target-based screens, which we expect will be used in Novartis' high-throughput screening laboratory to identify new anti-infectives. In March 2002, the collaboration agreement was amended to extend the research term by an additional year, through March 2003, and to provide that Novartis shall make an additional payment to us upon our achievement of a new milestone. In February 2003, the collaboration agreement was amended to extend the research term by an additional two years, through March 2005. Through December 31, 2002, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of \$11.1 million. We do not depend upon continued milestone payments from Novartis to any significant extent because we have funded, and intend to fund, our drug development programs primarily with the proceeds of equity offerings. Although we currently depend upon our collaborations, in-licensing opportunities and in-house research, in the aggregate, for a sustained pipeline of product candidates, we do not depend to any significant extent on any individual collaboration.

### *VITACHEM Program*

Although natural products have found their widest use as antibiotics, they also represent an important source of structural diversity for other therapeutic uses as well. We are currently involved in exploiting this opportunity through collaborations with other companies. We developed the VITACHEM program to investigate the pharmaceutical and non-pharmaceutical utility of our collection of microbial chemicals in markets outside of the anti-infectives market. To facilitate the efforts of our collaborators, we have established a number of self-contained, but integrated research modules which can be offered to collaborators, including:

microbial chemical libraries;

high-throughput screening;

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product fractioning; and

laboratory-scale fermentation.

Each collaborator can request from VITACHEM the combination of modules best suited to the specific collaboration.

There are two types of collaborations under the VITACHEM program:

*fee-for-service* collaborations, in which our collaborators provide us with short-term as well as medium/long-term revenues in the form of research fees plus, milestone payments and royalties calculated as a percentage of net sales;

*equal* collaborations, based on cost-sharing and reward-sharing.

To date, we have entered into three fee-for-service collaborations, with Schering-Plough, Bayer AG and Menarini, and two cost- and reward-sharing collaborations with Myriad Genetics Inc. on oncology, cardiovascular and viral targets, and Newron Pharmaceutical S.p.A. on central nervous system targets.

#### *The Roberto Lepetit Consortium for Biotechnologies*

In February 1998, we established in conjunction with the University of Bologna and the University of Palermo the "Roberto Lepetit Consortium for Biotechnologies," a non-profit organization aimed at the promotion of the development of biotechnologies through advanced research activities in collaboration with academic institutions with a view to utilizing new technologies and products for industrial purposes. The headquarters of the Consortium are located at our offices in Italy.

#### **Internal Discovery Research**

We use a variety of approaches combining the best drug discovery tools available. Thus, we integrate our capabilities in the areas of lead optimization, functional genomics and mechanism-based rational drug design and high-throughput screening of our diversified library of microbial extracts to fill both our proprietary and collaborators' product pipelines.

#### *Lead Optimization*

Several members of our scientific staff are pioneers in the application of combinatorial chemistry to drug discovery. We have focused our efforts on the practical applications of this powerful technology for the discovery and development of new antibacterial agents. We believe that the best use of combinatorial chemistry is in lead optimization via preparation of hundreds of discrete, well-characterized compounds based on core lead structures. We have analyzed the antibacterial field to arrive at potential lead optimization candidates that are either previously abandoned molecules, or are molecules on which work is still being done. In both cases, we have chosen molecules that have the potential for significant improvements in potency, spectrum of activity or other properties. Our expertise allows us to develop combinatorial methods for modifying structurally complex molecules. Once a suitable molecule for lead optimization is selected, we establish a proprietary position by using combinatorial chemistry to prepare new analogs that fall outside the patent scope of our likely competitors. Following the discovery of novel bioactive lead structures, we integrate our combinatorial and medicinal chemistry efforts to prepare individual molecules that can be navigated efficiently through pre-clinical testing. Once an *in vivo* active lead has been established, we determine whether the molecule best fits our proprietary product or our collaborators' product portfolios. The successful execution of this strategy has been demonstrated by our collaborative oxazolidinone project with Pharmacia. We are currently working on one internal research program using this approach.

#### *Functional Genomics and Mechanism-Based Rational Drug Design*

The complete genetic blueprints, or genomes, of the majority of clinically relevant bacteria are now accessible through the Internet. We take a highly focused and practical approach to using this genomic information by carefully selecting targets that have a mechanism suited to rational drug design. To facilitate efficient integration of mechanism-based drug discovery with combinatorial chemistry, we select mechanism-based families of targets such as metalloenzymes. We search genomes for characteristic genetic signatures and compare different genomes to identify targets that are present in a clinically relevant spectrum of bacteria. We use genetic techniques to establish that any target selected is essential for growth, and confirm this in several relevant bacterial species. Once we have carefully selected the target, we begin a highly focused chemistry effort using mechanism-based drug design. We then apply our "Gene to Screen" technology that allows us to increase or decrease the amount of target gene product, which is usually an enzyme, inside a cell by use of a special genetic regulator. Our ability to vary the concentration of a target enzyme inside a cell has proved an important support tool for our chemists, as they can then confirm whether a potent enzyme inhibitor stops the growth of bacteria by inhibiting the same enzyme. Our "Gene to Screen" technology allows our chemists to select leads that have the correct mechanism, without the inhibition of other enzymes that could result in toxicity. This integrated approach has been validated by our metalloenzyme program with Novartis to develop deformylase inhibitors. We are currently working with one additional metalloenzyme target to build on this success in our novel molecules programs.

#### **Diversified Library of Microbial Extracts**

The facilities and staff of our research center in Italy are geared to the discovery of novel natural products with clinically useful properties, especially those with antibiotic activity. Our high-throughput screening process consists of three basic steps:

1. generating a large number of structurally diverse natural product libraries;
- 2.

screening these extract libraries against specific biological targets to look for useful activity; and.

3.

isolating and identifying the structure responsible for any interesting activity found.

The natural products we study are made by microbes found in the soil and other sources. Our scientists have internationally recognized expertise in isolating rare and unusual genetically diverse soil microbes and have now accumulated a unique collection of about 50,000 microbes. Each of these microbes is capable of producing a unique mixture of natural products when grown in liquid media. Depending on the media that they grow in, microbes can produce different mixtures of molecules. Concentrated extracts of these fermented media represent an invaluable source of chemical structural diversity. Thus a library containing about 150,000 of these extracts has been created. New microbes and extracts are continually being added to this collection.

Other scientists are skilled in identifying relevant biological targets and in creating screening tests that can be used to search this library. Automated and miniaturized test systems are in place to assist in the management of the large number of samples to be handled.

When a positive hit is found with a screen, the next step requires special expertise in isolating and identifying the one molecule in the mixture that is responsible for the activity of interest. Many natural products have complicated chemical structures and our scientists are skilled at rapidly identifying the composition of these molecules. An important part of this process is to determine as early as possible whether the active molecule is a new compound or has already been discovered. This process is referred to as dereplication and we have developed a sophisticated system to rapidly address this problem.

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Once a new natural product has been identified, our research center in Italy has pilot plant facilities for scale-up and purification of larger quantities of material. New molecules can be tested in *in-vivo* models at the center's vivarium and the efficacy and pharmacokinetics established. As discussed above, chemists at both our research centers are capable of improving the properties of these natural products by selective modification of the molecule; this is referred to as lead optimization.

Our research center in Italy has a long and rich history in the development of important antibiotics having been responsible for the discovery of rifampin, teicoplanin, dalbavancin, ramoplanin and BI-Acne. Although natural products have found their widest use as antibiotics, it is clear that they also represent a tremendous source of structural diversity for other therapeutic uses as well. We are currently involved in exploiting this opportunity through collaborations with other companies.

### **Licensing Agreements**

#### *Eli Lilly*

In May 1999, we entered into a license agreement with Eli Lilly to obtain an exclusive worldwide license for the development and commercialization of anidulafungin. The license agreement provides for a number of payments from us to Eli Lilly, as follows: (i) an up-front payment for the license; (ii) periodic milestone payments bearing on achieving certain goals related to intravenous and oral formulations; (iii) payments during the period 2000 through 2002 for product inventory; and (iv) royalty payments based upon the net sales of the applicable products. We have also granted to Eli Lilly an option to license the exclusive worldwide rights to any oral formulation of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, Eli Lilly will pay us an up-front fee and royalties based on net product sales, and will reimburse us for any milestone payments paid plus the value, on a cost-plus basis, of all prior development expenses attributed to the development and commercialization of the oral formulation of anidulafungin.

#### *Genome Therapeutics*

In October 2001, we entered into a licensing agreement with Genome Therapeutics Corp. to grant to Genome Therapeutics the right to develop and commercialize ramoplanin, one of our proprietary product candidates, in North America. Under the terms of the agreement, Genome Therapeutics paid us an initial payment of \$2.0 million. Thereafter, Genome Therapeutics will make further milestone payments to us of up to an additional \$8.0 million in a combination of cash and notes convertible into Genome Therapeutics stock. In addition to purchasing the bulk material from us, Genome Therapeutics will fund the completion of clinical trials and pay us a royalty on product sales. The combined total of bulk product sales and royalties is expected to be greater than 20% of Genome Therapeutics' net product sales. In return, Genome Therapeutics has exclusive rights to develop and market oral ramoplanin in the USA and Canada. We retain the rights to market ramoplanin outside these territories.



## Sales and Marketing

We intend to market and sell our proprietary products through a direct sales force in the United States and Canada and the UK, Germany, Italy, France and Spain, also known as the "five major European markets". Because we are targeting the hospital market, we believe we can hire a relatively small sales force which will be sufficient to provide full coverage. Our management has experience in building specialty pharmaceutical sales forces. We expect to collaborate with other pharmaceutical companies to market our collaboration products in non-hospital markets in the United States and Canada and the five major European markets, and in overseas markets.

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## Manufacturing

In June 2001, we entered into a manufacturing, development and supply agreement with Abbott pursuant to which Abbott would manufacture final formulation of anidulafungin. In August 2002, we agreed with Abbott to terminate this agreement. Eli Lilly has supplied us with sufficient anidulafungin echinocandin-B nucleus to finish clinical trials and market the drug for several years. We currently obtain some active ingredients from ChemSym Laboratories, a department of Eagle-Picher Technologies, L.L.C. The Aventis plant in Brindisi, Italy, will be our initial manufacturing site for anidulafungin and dalbavancin, and subsequently, we intend to manufacture in our own manufacturing plant in Pisticci, Italy, which is currently under construction.

## Intellectual Property

The proprietary nature of, and protection for, our products, product candidates, processes and know-how are important to our business. We seek patent protection in the United States and internationally for our product candidates and other technology. Our policy is to patent or in-license the technology, inventions and improvements that we consider important to the development of our business. In addition, we use license agreements to selectively convey to others rights to our own intellectual property. We also rely on trade secrets, know-how and continuing innovation to develop and maintain our competitive position.

Based on available information as of December 31, 2002, we have four issued U.S. patents and nine U.S. patent applications. We have acquired proprietary and exclusive rights worldwide to develop, make, use and sell anidulafungin in particular fields in connection with our license agreement with Eli Lilly. This license agreement covers 14 U.S. patents, 12 U.S. patent applications, 71 foreign patents and 125 foreign patent applications. Dalbavancin patents include three issued U.S. patents, two issued Canadian patents and several pending U.S. and Canadian patent applications. Our collaborative agreement with Pharmacia with respect to the development of oxazolidinones includes two U.S. patents and eleven U.S. patent applications. Our collaborative agreement with Novartis includes three U.S. patent applications.

The material patents included in our owned and licensed portfolio expire between 2008 and 2016. We expect to continue to protect our proprietary technology with additional filings as appropriate.

## Competition

We believe our products will face intense competition from both existing therapies and new generations of antibiotics and antifungals. We expect to compete against existing therapies on the basis of greater potency, improved effectiveness and reduced toxicity. Several pharmaceutical and biotechnology companies are actively engaged in research and development related to new generations of antibiotic and antifungal products. We cannot predict the basis upon which we will compete with new products marketed by others. Many of our competitors have substantially greater financial, operational, sales and marketing, and research and development resources than we have. Companies that market or are known to be in active development of antibiotic or antifungal products in our target markets include Bristol-Myers Squibb Co., Schering-Plough Corp., Aventis S.A., Fujisawa Pharmaceutical Co. Limited, Janssen, a division of Johnson & Johnson Inc., J.B. Roerig, a division of Pfizer Inc., Merck & Co. Inc., Cubist Pharmaceuticals Inc., Enzon, Gilead Sciences Inc. and InterMune.

## Governmental Regulation and Product Approval

Regulation by governmental authorities in the United States and other countries is a significant factor in the manufacture and marketing of pharmaceuticals and in our ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous

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pre-clinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries. In the United States, various federal, and in some cases state statutes and regulations also govern or impact upon the manufacturing, safety, labeling, storage, record-keeping and marketing of such products. The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations, require the expenditure of substantial resources. Regulatory approval, when and if obtained, may be limited in scope which may significantly limit the indicated uses for which a product may be marketed. Further, approved drugs, as well as their manufacturers, are subject to ongoing review, and the discovery of previously unknown problems with such products may result in restrictions on their manufacture, sale or use or in their withdrawal from the market.

#### *Pre-Clinical Stages*

The process for new drug approval consists of pre-clinical stages, which occur prior to studies on human volunteers, and clinical trials, which involve testing the compound on human volunteers in clinic settings. Pre-clinical stages include the following:

*Drug discovery.* In the initial stages of drug discovery before a compound reaches the laboratory, tens of thousands of potential compounds are randomly screened for activity against an assay assumed to be predictive for particular disease targets. This drug discovery process can take several years. Once a company locates a "lead compound," or starting point for drug development, isolation and structural determination may begin. The development process results in numerous chemical modifications to the screening lead in an attempt to improve the drug properties of the lead. After a compound emerges from this process, the next steps are to conduct further preliminary studies on the mechanism of action, further *in vitro* screening against particular disease targets and finally, some *in vivo* screening. If the compound passes these barriers, the toxic effects of the compound are analyzed by performing preliminary exploratory animal toxicology. If the results demonstrate acceptable levels of toxicity, the compound emerges from the basic research mode and moves into the pre-clinical phase.

*Pre-clinical testing.* During the pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of the compound against the targeted disease, and the compound is evaluated for safety. These tests typically take approximately two years to complete, and must be conducted in compliance with the FDA's Good Laboratory Practice regulations.

*Investigational new drug application.* During the pre-clinical testing, an IND is filed with the FDA to begin human testing of the drug. The IND becomes effective if not rejected by the FDA within 30 days. The IND must indicate the results of previous experiments, how, where and by whom the new studies will be conducted, the chemical structure of the compound, the method by which it is believed to work in the human body, any toxic effects of the compound found in the animal studies and how the compound is manufactured. All clinical trials must be conducted in accordance with the FDA's Good Clinical Practice regulations. In addition, an Institutional Review Board at the hospital or clinic where the proposed studies will be conducted, must review and approve the IND. The Institutional Review Board also continues to monitor the study. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. In addition, the FDA may, at any time during the 30-day period or at any time thereafter, impose a clinical hold on proposed or ongoing clinical trials. If the FDA imposes a clinical hold, clinical trials cannot commence or recommence without FDA authorization and then only under terms authorized by the FDA. In some instances, the IND application process can result in substantial delay and expense.

Some limited human clinical testing may be done under a physician's IND in support of an IND application and prior to receiving an IND. A physician's IND is an IND application that allows a single individual to conduct a clinical trial. A physician's IND does not replace the more formal IND process,

but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

#### *Clinical Trials*

Clinical trials are typically conducted in three sequential phases, but the phases may overlap.

*Phase I clinical trials.* After an IND becomes effective, Phase I human clinical trials can begin. These tests usually involve between 20 and 80 healthy volunteers or patients and typically take one to two years to complete. The tests study a drug's safety profile, and may include the safe dosage range. The Phase I clinical studies also determine how a drug is absorbed, distributed, metabolized and excreted by the body, and the duration of its action.

*Phase II clinical trials.* In Phase II clinical trials, controlled studies are conducted on an expanded population of patients with the targeted disease. The primary purpose of these tests is to evaluate the effectiveness of the drug on the volunteer patients as well as to determine if there are any side effects. These studies generally take approximately one year, and may be conducted concurrently with Phase I clinical trials. In addition, Phase I/II clinical trials may be conducted to evaluate not only the efficacy of the drug on the patient population, but also its safety.

*Phase III clinical trials.* This phase typically lasts one to two years and involves an even larger patient population. During the Phase III clinical trials, physicians monitor the patients to determine efficacy and to observe and report any reactions that may result from long-term use of the drug.

#### *New drug application*

After the completion of all three clinical trial phases, if there is substantial evidence that the drug is safe and effective, an NDA is filed with the FDA. The NDA must contain all of the information on the drug gathered to that date, including data from the clinical trials. NDAs are often over 100,000 pages in length.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. In such an event, the NDA must be resubmitted with the additional information and, once again, is subject to review before filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the Federal Food, Drug and Cosmetic Act, the FDA has 180 days in which to review the NDA and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification regarding information already provided in the submission. The FDA may refer the application to an appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee. If the FDA evaluations of the NDA and the manufacturing facilities are favorable, the FDA may issue either an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter, authorizing commercial marketing of the drug for certain indications. If the FDA's evaluation of the NDA submission or manufacturing facilities is not favorable, the FDA may refuse to approve the NDA or issue a not approvable letter.

#### *Marketing approval*

If the FDA approves the NDA, the drug becomes available for physicians to prescribe. Periodic reports must be submitted to the FDA, including descriptions of any adverse reactions reported.

#### *Phase IV clinical trials and post marketing studies*

Even after the drug is on the market, the FDA may request additional studies (known as Phase IV) to evaluate long-term effects. In addition to studies requested by the FDA after approval, these trials and studies are conducted to explore new indications. The purpose of these trials and studies and related publications is to broaden the application and use of the drug and its acceptance in the medical community.

#### *Orphan drug designation*

The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which is generally a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for seven years.

#### *Approvals outside of the United States*

Steps similar to those in the United States must be undertaken in virtually every other country comprising the market for our products before any such product can be commercialized in those countries. The approval procedure and the time required for approval vary from country to country and may involve additional testing. There can be no assurance that approvals will be granted on a timely basis or at all. In addition, regulatory approval of prices is required in most countries other than the United States. There can be no assurance that the resulting prices would be sufficient to generate an acceptable return to us.

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As of December 31, 2002, we had 28 full-time development employees. Like many other biotechnology companies in our stage of development, we rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials.

### *Governmental Support of Medical Research and Training*

In order to encourage scientific and medical research and training, both Italy and the European Union, or EU, have instituted targeted investment programs.

### *Italian Investment Programs*

Italian law provides that companies carrying out certain research and/or training projects may qualify to receive government grants and/or subsidized loans. Italian grants and subsidized loans are awarded by the Ministero Istruzione Università Ricerca, or MIUR, and/or the Ministero Attività Produttive, or MAP, and disbursed by an authorized bank, as instructed by MIUR and/or MAP, as applicable.

In order to be awarded grants or subsidies, eligible companies must submit a detailed request to MIUR and/or MAP, as applicable, describing their business and specifying the proposed project. MIUR and/or MAP, as applicable, will then evaluate the request and decide whether to make an award. Each grant and subsidy which is awarded will be paid, depending on the actual progress of the project (a portion of the grants may, however, be disbursed in advance by the authorized bank if instructed by

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MIUR and/or MAP, as applicable). The companies receiving the grants must comply with certain conditions relating to, among other things, the geographical, technical and timeline development of the projects and the characteristics and location of the companies receiving the grants. MIUR and/or MAP, as applicable, are entitled to discontinue or revoke the grants and subsidies under limited circumstances.

Due to the nature of our medical research activities, many of our projects and programs in Italy have qualified for and received grants and subsidized loans from MIUR and/or MAP. Biosearch has received from the Italian authorities government grants and subsidized loans relating to our:

oncology project (research activities);

genomics project (training and research activities); and

antibiotics project (training and research activities).

In addition, in May 2002, our antimicrobial drugs project was approved by MAP, which might result in our receipt of a related grant and a subsidized loan. We have also applied to MIUR for a grant and subsidized loan for a project for identification and implementation of new research technology.

The grant and subsidy agreements entered into between us and the authorized bank, San Paolo IMI S.p.A., provide, in part, that:

notice of any structural and organizational changes affecting us (including the change of our directors) and/or our business (including the award of further grants or subsidies) must be provided in advance to the authorized bank;

consent to any merger, de-merger or transformation of us must be received in advance from the authorized bank; and

any default by us under any of the agreements can cause the termination of all the agreements concerning the payment of grants and subsidies and our obligation to repay some or all of the amounts received by us with interest.

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Based on the above, in order to seek to avoid the termination of the grants and subsidies and repayment of the amounts received with interest, we contacted the authorized bank in order to start the procedure to obtain its consent to the merger insofar as retaining the existing grants and subsidies are concerned. Within 120 days of the date of our recent merger with Biosearch, we will contribute the assets of former Biosearch into one of our Italian subsidiaries, Versicor Italy S.r.l. We face the risk that one or both of the transfers might not be approved by the applicable bank and/or by the applicable Italian authorities, in which case we might be required to repay some or all of the grants and subsidies received prior to the completion of the merger. In addition, since Versicor Italy S.r.l. is an Italian company, we expect that it will be eligible to receive new grants and subsidies in the future. However, there can be no assurance that Versicor Italy S.r.l. will qualify or be approved for any grants or subsidies that may be applicable to it.

### *Regional Investment Programs*

Biosearch Manufacturing S.r.l., one of our Italian subsidiaries, has been awarded a grant by Regione Basilicata, a local authority in southern Italy, for the construction of a new manufacturing plant. This grant will be paid to our subsidiary in installments in accordance with the completion of various stages of the construction work, and can be revoked or reduced if our subsidiary does not comply with its obligations thereunder. In order to maintain eligibility for the entire grant awarded by Regione Basilicata, our subsidiary must also comply with certain requirements relating to, among other things, number of its employees, its turnover levels and its independence of other companies. Following our recently completed merger with Biosearch, we anticipate that subject to compliance with the terms

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and conditions of the grant, a significant portion of the awarded grants will be available to our subsidiary post-merger.

### *European Union Investment Programs*

Under EU law, we benefit from EU grant programs for our:

Eurocellwall project;

Megatop project; and

Actapharm project.

The agreements relevant to these grants, which are governed by Belgian law, provide that the grants may be awarded only to EU entities or entities of an "Associated State" that has entered into a convention with the EU. The United States has not entered into such a convention. As a result, we will not be eligible for these grants post-merger and we expect that the EU Commission will require us to repay any subsidies already paid to us, totaling approximately EUR251,630.

Within 120 days of our recently completed merger with Biosearch, we will contribute the assets of former Biosearch to our subsidiary, Versicor Italy S.r.l. In the name of our subsidiary, we may from time to time in the future, apply to MIUR and the EU Commission for additional grants and subsidies. However, there can be no assurance that our subsidiary will in the future qualify or be approved for any grants or subsidies that may be applicable to it.

### **Website Access to Our Periodic SEC Reports**

Our Internet address is [www.versicor.com](http://www.versicor.com). We make our periodic SEC reports (Form 10-Q and Form 10-K) and current reports (Form 8-K) available free of charge through our website as soon as reasonably practicable after they are filed electronically with the SEC. We may from time to time provide important disclosures to investors by posting them in the investor relations section of our website, as allowed by SEC rules.

Materials we file with the SEC may be read and copied at the SEC's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website at [www.sec.gov](http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding our company that we file electronically with the SEC.

### **Employees**

As of December 31, 2002, we employed 79 persons, 40 of whom hold Ph.D. or M.D. degrees. Seventy-two employees are engaged in research and development, and seven support administration, finance, management information systems and human resources. In addition, Biosearch employed 128 persons at December 31, 2002, 29 of whom hold Ph.D. or M.D. degrees. We believe that we maintain good relations with our employees.

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## RISK FACTORS

*In addition to the other information included or incorporated by reference in this annual report, you should carefully consider the following factors in evaluating Versicor or an investment in any of Versicor's securities. Versicor's actual future results and trends might differ materially from its historical results or trends to date, or those anticipated in Versicor's forward-looking statements, depending on a variety of factors, including the factors set forth in this section. Additional risks not presently known to Versicor or that Versicor currently deems immaterial might also harm Versicor's business.*

### Risks Related to our Business

**If we are unable to develop and successfully commercialize our product candidates, we might not generate significant revenues or become profitable.**

To date, we have not commercialized any products or recognized any revenue from product sales and none of our product candidates are approved for sale. Successful commercialization of a new drug product requires significant investment in research and development, pre-clinical testing and clinical trials, regulatory approval, and sales and marketing activities. Most of our product candidates are in early stages of development, and four are in clinical trials. Our efforts to commercialize our product candidates are subject to a variety of risks inherent in the development of biopharmaceutical products based on new technologies. These risks include the following:

Pre-clinical testing and clinical trials are protracted, expensive and uncertain processes. It might take us and our collaborators several years to complete the testing process, and failure can occur at any stage of the process. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful.

Any or all of our new drug marketing applications might be denied by the U.S. Food and Drug Administration, or FDA, and analogous foreign regulators.

Our product candidates, even if found to be safe and effective, might be difficult to develop into commercially viable drugs or to manufacture on a large scale or might be uneconomical to market commercially.

Third-party proprietary rights might preclude us from marketing our drugs.

Third parties might market superior drugs or be more effective in marketing equivalent drugs.

Even if our product candidates are successfully developed and effectively marketed, the size of their potential market might change such that our sales revenue is less than initially contemplated.

In any such case, we might never generate sufficient or sustainable revenues to enable us to become profitable.

**We expect to incur losses for the foreseeable future and might never achieve profitability.**

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We have incurred net losses since our inception in 1995. Before deemed dividends and accretion to redemption value of our preferred stock, our net losses were \$1.1 million in 1995, \$4.8 million in 1996, \$6.3 million in 1997, \$12.6 million in 1998, \$29.2 million in 1999, \$15.3 million in 2000, \$32.8 million in 2001 and \$48.8 million in 2002. As of December 31, 2002, our accumulated deficit was \$152.6 million. Our losses to date have resulted principally from:

research and development costs (including non-cash stock compensation expenses) relating to the in-licensing and development of our product candidates, which represented approximately 81% of our aggregate operating expenses from our inception through December 31, 2002; and

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general and administrative costs (including non-cash stock compensation expenses) relating to our operations, which represented approximately 19% of our aggregate operating expenses from our inception through December 31, 2002.

Subsequent to December 31, 2002, we merged with Biosearch, which also has incurred net losses since its inception in 1996. Biosearch's net losses were EUR25.6 million for 2000, EUR10.9 million for 2001 and EUR9.5million for 2002. As of December 31, 2002, Biosearch's accumulated deficit was EUR45.8 million. Biosearch's losses to date have resulted principally from:

research and development costs (including non-cash stock compensation expenses) relating to the discovery, development and manufacture of Biosearch's product candidates, representing 83% of Biosearch's aggregate operating expenses from January 1, 2000 through December 31, 2002;

general and administrative costs (including non-cash stock compensation expenses) relating to Biosearch's operations, representing 22% of Biosearch's aggregate operating expenses from January 1, 2000 through December 31, 2002; but

these expenses were partially offset by amortization of negative goodwill, less losses on trading securities in the net amount of (5%) of Biosearch's aggregate operating expenses from January 1, 2000 through December 31, 2002.

We expect to incur substantial and increasing losses for the foreseeable future as a result of increases in our research and development costs, including costs associated with conducting pre-clinical testing and clinical trials, and charges related to purchases of technology or other assets. We expect that our operating losses will fluctuate significantly from quarter to quarter as a result of increases or decreases in its research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, or other factors. Our company's chances for achieving profitability will depend on numerous factors, including success in:

qualifying for and receiving grants and subsidies;

developing and testing new product candidates;

licensing rights to our product candidates to third parties;

receiving regulatory approvals;

manufacturing products;

marketing products; and

competing with products from other companies.

Many of these factors will depend on circumstances beyond our control. We cannot assure you that we will become profitable.

**Our revenues are subject to significant fluctuations, which makes it difficult to draw meaningful comparisons from period-to-period changes in our operating results.**

We expect that substantially all of our revenues for the foreseeable future will result from payments under collaborative arrangements. To date, these payments have taken the form of up-front payments, reimbursement for research and development expenses and milestone payments. Milestone payments to our company under collaborative arrangements are subject to significant fluctuation in both timing and amount. As a result, comparisons of our revenues and results of operations between periods might not produce meaningful indications of our progress toward commercializing one or more product candidate. Moreover, the historical revenues of Versicor and Biosearch on a stand-alone basis

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might not be indicative of our future performance or of our ability to continue to achieve additional milestones and to receive additional milestone payments from our collaborators.

**If we cannot enter into new in-licensing arrangements, our product portfolio and potential profitability could be harmed.**

An important component of our business strategy is to in-license drug compounds discovered by other pharmaceutical and biotechnology companies or academic research laboratories, in order to develop them ourselves. Currently we in-license anidulafungin from Eli Lilly. Anidulafungin is our lead antifungal product candidate and one of our four product candidates in clinical development. Under our license arrangement with Eli Lilly, we acquired exclusive worldwide rights to anidulafungin. This license arrangement will terminate on a country-by-country basis upon the later of 10 years from the date of the first commercial sale of anidulafungin in the country or the expiration of all product patents in the country.

Competition for new promising compounds can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

**If we do not establish and maintain collaborations or if our collaborators do not perform, we will be unable to develop our joint product candidates.**

We have entered into collaborative arrangements with third parties to develop product candidates. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we do not maintain our existing collaborative arrangements or do not enter into additional collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

In addition, our dependence on collaborative arrangements with third parties subjects us to a number of risks, including the following:

The collaborative arrangements might not be on terms favorable to us. Agreements with collaborators typically allow the collaborators significant discretion in electing whether to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborators devote to the product candidates or their prioritization of the product candidates, and our collaborators might choose to pursue alternative products.

Our collaborators might also not perform their obligations as expected. Business combinations or significant changes in a collaborator's business strategy might adversely affect a collaborator's willingness or ability to complete its obligations to us.

Moreover, we could become involved in disputes with our collaborators which could lead to delays in, or the termination of, our development programs with them, as well as time-consuming and expensive litigation or arbitration.

Even if we fulfill our obligations under a collaborative agreement, our collaborators can generally terminate the agreements under specified circumstances.



If any collaborator were to terminate or breach their agreement with us, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing products could be harmed.

**If clinical trials for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could harm our business and cause our stock price to decline.**

Before obtaining regulatory approvals for the commercial sale of any products we might develop, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting pre-clinical testing and clinical trials is a protracted, time-consuming and expensive process. Completion of clinical trials might take several years or more. Our commencement and rate of completion of clinical trials might be delayed by many factors, including:

slower than expected rate of hospital and patient recruitment;

inability to manufacture sufficient quantities of the study drug for use in clinical trials;

unforeseen safety issues;

lack of efficacy during the clinical trials;

inability to adequately follow patients after treatment;

governmental or regulatory delays; or

a decision to expand clinical trials or add studies to increase the statistical significance of the results.

In addition, the results from pre-clinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In general, a number of new drugs have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations, which might delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections might be encountered as a result of many factors, including perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development.

As of December 31, 2002, we have four product candidates in clinical trials: anidulafungin in Phase III; dalbavancin in Phase III; ramoplanin in Phase III; and BI-Acne which has completed Phase I. Patient follow-up for these clinical trials has been limited and more trials will be required before we will be able to apply for regulatory approvals.

Clinical trials conducted by us or by third parties on our behalf might not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin, dalbavancin, ramoplanin or BI-Acne or any other potential product candidates. Such a failure might delay development of our other product candidates and hinder our ability to conduct related pre-clinical testing and clinical trials. It might also cause regulatory authorities to prohibit us from undertaking any additional clinical trials for our other product candidates. Our other product candidates are in pre-clinical development, and we have not submitted investigational new drug applications, or INDs, to commence clinical trials involving these compounds. Our pre-clinical development efforts might not be successfully completed and we might not file further INDs. Any delays in, or termination of, our clinical trials would harm our development and commercialization timelines, which could cause our stock price to decline. Any of these events could also impede our ability to obtain additional financing.

**If our third-party clinical trial managers do not perform, clinical trials for our product candidates might be delayed or unsuccessful.**

As of December 31, 2002, we had 28 full-time clinical development employees in the United States and four in Italy. We expect to continue to rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. If

these third parties fail to perform satisfactorily under the terms of our agreements with them, clinical trials for our product candidates might be delayed or unsuccessful. Furthermore, the FDA and/or other regulatory agencies of the EU or Italy, might inspect some of our clinical investigational sites, our collaborators' records and our facilities and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that our clinical trials were not in compliance with applicable requirements, we might be required to repeat the clinical trials.

**If our future products are not accepted by the market, we are not likely to generate significant revenues or become profitable.**

Even if we obtain regulatory approval to market products in the future, we might not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any pharmaceutical product that we might develop will depend on a number of factors, including:

demonstration of clinical efficacy and safety;

cost-effectiveness;

potential advantages over alternative therapies, including fewer side effects or easier administration;

reimbursement policies of government and third-party payors; and

the effectiveness of our marketing and distribution capabilities.

Physicians will not recommend therapies using any of our future products until clinical data or other factors demonstrate their safety and efficacy as compared to other drugs or treatments. Even if the clinical safety and efficacy of therapies using any of our future products is established, physicians might elect not to recommend the therapies for a number of other reasons, including the possibility that the mode of administration of our future product might not be effective for their patients' indications and location. For example, many antibiotic or antifungal products are typically administered by infusion or injection, which requires substantial cost and inconvenience to patients and might not be practical in non-hospital settings.

Physicians, patients, third-party payors and the medical community might not accept and utilize any product candidates that we or our collaborators develop. If none of our future products achieve significant market acceptance, we are not likely to generate significant revenues or become profitable.

**If we are unable to attract and retain skilled employees and consultants, we will be unable to develop and commercialize our product candidates.**

We are highly dependent on our skilled management and scientific staff. In order to pursue our product development, marketing and commercialization plans, we might need to hire additional personnel with experience in clinical testing, government regulation, manufacturing, marketing and finance. We might not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among high technology enterprises, including biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Most of our management and scientific staff do not have employment contracts. If we lose a significant number of these persons, or are unable to attract and retain qualified personnel, our business, financial condition and results of operations might be harmed. We do not maintain key person life insurance on any of our personnel.

In addition, we rely on consultants and members of our scientific and clinical advisory boards to assist us in formulating research and development strategies. All of these consultants and the members of our scientific and clinical advisory boards are employed by others, and they

might have commitments

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to, or advisory or consulting agreements with, others that might limit their availability to us. If we lose the services of these advisors, our achievement of our development objectives might be impeded, and our business, financial condition and results of operations might be harmed. Finally, except for work performed specifically for and at our direction, the inventions or processes discovered by our scientific and clinical advisory board members and other consultants will not become our intellectual property, but will be the intellectual property of the individuals or their institutions. If we desire access to these inventions, we will be required to obtain appropriate licenses from the owners. We face the risk that we might not be able to obtain such licenses on favorable terms or at all.

**If our third-party manufacturers do not produce our product candidates on a timely basis, clinical trials and commercialization of our product candidates could be delayed.**

We currently do not have manufacturing facilities capable of manufacturing products in quantities necessary for large-scale trials or marketing. The Aventis plant in Brindisi, Italy, will be our initial manufacturing site for anidulafungin and dalbavancin, and subsequently we intend to manufacture products in our own manufacturing plant in Pisticci, Italy, which is currently under construction. To the extent that our manufacturing capabilities are insufficient to produce all of the necessary active ingredients for our current and future product candidates, we anticipate that we might need to rely on third parties to manufacture some or all of these active ingredients. We currently obtain some active ingredients from ChemSyn Laboratories, a department of Eagle-Picher Technologies, L.L.C. However, there are a limited number of facilities in which our product candidates can be produced, and third-party manufacturers have limited experience in manufacturing anidulafungin, dalbavancin, ramoplanin and BI-Acne in quantities sufficient for conducting clinical trials or for commercialization.

Difficulties are often encountered in manufacturing new products, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and other regulations, production costs, and development of advanced manufacturing techniques and process controls. Any contract manufacturer might not perform as agreed or might not remain in the contract manufacturing business for the time we require to successfully develop, produce and market our product candidates. If any of our contract manufacturers fails to perform satisfactorily under its agreements with us, such as by failing to deliver the required quantities of our product candidates for clinical use on a timely basis and at commercially reasonable prices, and if we do not find a replacement manufacturer or develop our own manufacturing capabilities, clinical trials involving our product candidates, or commercialization of our products, could be delayed.

**If we do not establish successful marketing and sales capabilities or do not enter into successful marketing arrangements with third parties, we will not be able to commercialize our future products and will not become profitable.**

We intend to sell a portion of our future products through our own sales force. At present, however, we have no sales and marketing infrastructure and we lack any experience in direct marketing, sales and distribution. Our future profitability will depend in part on our ability to develop a direct sales and marketing force to sell our future products, if any, to our target market. We might not be able to attract and retain qualified salespeople or be able to build an efficient and effective sales and marketing force. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts might not be successful. If we are unable to enter into third-party arrangements, then we must substantially expand our marketing and sales force in order to achieve commercial success for certain products, and to compete with other companies that have experienced and well-funded marketing and sales operations.

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**We might seek additional funding, which could dilute our stockholders or impose burdensome financial restrictions, and if we do not obtain necessary funding, we might be forced to delay or curtail the development of our product candidates.**

We expect to incur increasing research and development and general and administrative expenses over the next several years. Based on our current plans and assumptions, we estimate that our cash and liquid assets at December 31, 2002 will be sufficient to fund our operating losses for at least 24 months. However, if our plans change and/or our assumptions are inaccurate, we might need to seek capital sooner than anticipated. Some of our more significant plans and assumptions relate to:

payments received or made under possible future collaborative agreements;

continued progress in the research and development of our future products;

costs associated with protecting our patent and other intellectual property rights;

costs associated with developing marketing and sales capabilities; and

the rate of market acceptance of any future products.

Other than with respect to our new \$1.5 million line of credit for equipment financing that we entered into in January 2003, we have no committed sources of additional capital. To the extent our capital resources are insufficient to meet our future capital requirements, we will have to raise additional funds to continue the development of our product candidates. We might also seek additional funding much earlier than we would otherwise need, in order to take advantage of attractive opportunities in the capital markets.

We might seek to raise funds from a traditional lender or through public or private debt or equity offerings. To the extent we raise additional capital through the sale of equity or convertible debt securities, the securities could be sold at a discount to prevailing market price and the issuance of those securities could result in dilution to our stockholders. Moreover, the incurrence of debt financing could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness, and we might be subject to restrictive covenants as a result of such debt financing. This could render us more vulnerable to competitive pressures and economic downturns and could impose restrictions on our operations.

If adequate funds are not available from any of those sources, our business might be harmed. We might be required to delay, reduce the scope of, or eliminate one or more of our research and development programs or otherwise significantly curtail operations. In addition, we might be required to obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to certain technologies or drug candidates that we would not otherwise relinquish in order to continue independent operations.

**If we make any more strategic acquisitions, we will incur a variety of costs and might never realize the anticipated benefits.**

We recently merged with Biosearch and, if appropriate opportunities become available, we might attempt to acquire additional products, product candidates or businesses that we believe are a strategic fit with our business. Currently, however, we are not a party to any additional acquisition agreements. If we pursue any transaction of that sort, the process of negotiating the acquisition and integrating an acquired product, product candidate or business might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we might never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or

impairment expenses related to goodwill and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

**If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss.**

Our operations include the controlled use of hazardous materials, primarily small quantities of toxic biological materials and chemical compounds which we store, collect, combine, analyze and, at times, produce in connection with our research and manufacturing activities. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we might be held liable for any resulting damages. We do not currently maintain separate insurance to cover contamination or injuries relating to hazardous materials, and such liabilities might not be covered by our general liability insurance coverage.

**Risks Related to our Recent Merger with Biosearch and International Expansion**

**The ongoing integration of Versicor and Biosearch management following the recent merger will present significant challenges.**

Our merger with Biosearch was only recently completed and we will face significant challenges in combining our management and internal control and disclosure systems in a timely and efficient manner. This integration will be complex and time-consuming because, among other

things, our executive officers will be located in separate U.S. and Italian offices. Our U.S. management team has recently relocated from the San Francisco Bay Area to King of Prussia, Pennsylvania, while the management of our Italian branch will remain in Gerenzano, Italy. If we are unable to integrate our management and internal systems successfully, we might not achieve the anticipated potential benefits of the merger.

**When Nasdaq's currently proposed director-independence rules are adopted, compliance with both the new rules and our bylaws, as amended by the merger agreement, might require us to increase the size of our board.**

We have eight directors on our board, four of whom were associated with Versicor prior to the merger and the other four of whom were associated with Biosearch. In connection with the merger, we amended our bylaws in a manner that is intended, among other things, to maintain an even balance of legacy Versicor directors and legacy Biosearch directors on the board for three years from the date of the completion of the merger. If we decide to add additional directors to the board during that three-year period, our bylaws effectively require us to add an even number of directors (with one-half of the additional directors proposed by the four legacy Versicor directors and the other half proposed by the four legacy Biosearch directors) in order to maintain an equal number of legacy Versicor and Biosearch directors on the board.

Our bylaws might make it more difficult for us to comply with Nasdaq's recently proposed director-independence rule. Although Nasdaq's proposed rule is still subject to change, the current version announced by Nasdaq on October 9, 2002 (as we expect it to be modified in light of the SEC's rule proposals of January 9, 2003 and January 15, 2003), includes the following requirements, among others:

*Majority of Independent Directors.* Nasdaq's proposed rule will require that a majority of our board must be comprised of independent directors, and a director will not be "independent" if, among other disqualifications, in any of the past three years he or his non-employee family members received more than \$60,000 from our company, other than for his service as a director, or if the director is a controlling shareholder or officer of an entity to which our company has

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made payments in excess of \$200,000 or 5% of either entity's gross revenues. We believe that two of our eight directors currently qualify as independent under the proposed standards.

*Three Completely Independent Audit Committee Members.* Nasdaq's proposed rule will provide that a director is ineligible to serve on our three-member audit committee if (a) he is not independent (as described above) or (b) he receives any payments from our company (other than in his capacity as a board or committee member) or (c) he controls directly or indirectly 10% or more of our company's stock. In addition, Nasdaq's proposed rule will require that our audit committee must include at least one "audit committee financial expert" (as defined by the SEC), and that if any of the audit committee members are not financially literate, we must disclose and explain those members' lack of expertise in our annual proxy statements. We believe that only one of our directors will be eligible to serve on the audit committee under the proposed standards. (We believe that same director will qualify as an audit committee financial expert under the proposed definition.)

*Compliance Deadline.* Nasdaq's proposed rule provides that if compliance with the new rule requires any changes to our board, we will be required to comply commencing with our 2004 annual meeting; by contrast, the SEC's January 9, 2003 proposal provides that the compliance deadline will be April 26, 2004.

If the Nasdaq proposal is adopted, we will comply with the new rules in their final form. In order for a majority of our directors to be independent, we would need to (a) ask up to three of our non-independent directors to resign followed by appointment of three new independent directors and/or (b) increase the size of our board by adding up to six additional independent directors. Any increase in the size of our board or change in its membership might give rise to inefficiencies, which might cause some board actions to be delayed.

**We might be required to repay some or all of the Italian and/or EU research grants and loan subsidies previously received by Biosearch and we might not qualify or be approved for new grants and subsidies.**

Biosearch and its subsidiary historically funded a portion of their operations through research grants and loan subsidies awarded by Italian and EU authorities. Under applicable law, any transfer of those grants and subsidies (including transfer by merger) requires written approval from the Italian bank authorized to make the disbursement on behalf of the government and from the appropriate Italian or EU authorities. In connection with the merger, we applied for permission to transfer Biosearch's grants and subsidies to our Italian branch. Although the merger has recently been completed, the Italian and EU authorities have not as yet reached an official decision on whether to approve our transfer requests. If the transfers are approved, we intend to apply for further permission to contribute the grants and subsidies to Versicor Italy S.r.l., our

newly-formed subsidiary in Italy. We face the risk that one or both of the transfers might not be approved, in which case we might be required to repay some or all of the grants and subsidies received by Biosearch prior to the merger, in the aggregate amount of up to approximately \$1.6 million as of December 31, 2002 and we may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of December 31, 2002 by the authorized bank, in the aggregate amount of up to approximately \$1.1 million as of December 31, 2002 (each estimate based on exchange rates then prevailing). Regardless of whether or not we are required to repay those grants, we anticipate that our Italian subsidiary will be eligible to apply for new research grants and subsidies from both the Italian and EU authorities. However, grants and subsidies are awarded in the discretion of those authorities and we face the risk that our Italian subsidiary might not qualify or be approved for any additional grants or subsidies in the future. For a more detailed description of the Italian and EU grant and subsidy programs, see "Conditions in Italy and the European Union Governmental Support of Medical Research and Training" in our proxy statement/prospectus filed with the SEC on November 5, 2002.

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**As a result of our recently completed merger, we will operate in both the United States and Italy, which will increase our costs of doing business and might result in additional, unexpected challenges.**

As a result of our recently completed merger, our operations will be located both in the United States and Italy. This expansion will cost us time and resources that we would not have to spend if our operations were confined within one country only, such as:

our management will need to devote additional time to overseeing operations in two countries;

language barriers within our company and with contractual counterparties in Italy might result in misunderstandings, improperly executed instructions and additional translation costs, and language translations themselves might lead to inaccuracies; and

internal transportation and communications costs will increase in order for personnel, resources and ideas to be shared between the two operation centers.

The increased time and resources we spend to manage operations internationally will result in an increase in our historical cost of doing business. In addition, international operations might present other challenges. For example, the cultural differences between business operations (generally including employer-employee relations) in the United States and those in Italy might reduce some of the benefits of the merger.

**Complying with two national regulatory structures might result in administrative challenges.**

Our operations must comply with applicable laws of and rules of the United States (including California law, Delaware corporate law and the rules and regulations of the Securities and Exchange Commission and the Nasdaq National Market), the EU legal system and the Republic of Italy (including the rules and regulations of CONSOB and Borsa Italiana, which collectively regulate companies listed on Italy's public markets such as the Nuovo Mercato). Conducting our operations in a manner designed to comply with all applicable laws and rules will require us to allocate additional time and resource to regulatory compliance matters. For example:

issuing each material announcement in both English and Italian might cause administrative challenges;

submitting filings and applications with regulatory and governmental authorities in the U.S., Italy and the EU, and approving translations of each significant document into the other language, if necessary, would be time-consuming and expensive and might distract our executives from their primary focus of managing our business, and language translations themselves might lead to inaccuracies;

under Italian employment law, our relations with our employees in Italy is governed by collective bargaining agreements negotiated at the national level (and over which we have no control), which reduces the methods customarily available in the United States to motivate and discipline our Italian employees;

under European Union data protection regulations, we are unable to send without restriction private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices; and

tariffs, customs, duties, import restrictions, tax effects and other trade barriers might delay or increase the cost of relocating personnel and, if marketing approvals are obtained, commercial quantities of our products between nations.

**We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could cause costs to be greater than we expect and introduce additional volatility in our reported quarterly results.**

As a result of the recently completed merger, we are exposed to risks associated with foreign currency transactions insofar as we might desire to use dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuates, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Although our reporting currency remains the U.S. dollar, a significant portion of our consolidated revenues and costs now arise in euros, which we restate in dollars for purposes of financial reporting, based on exchange rates prevailing at the end of the applicable reporting period. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Accordingly, changes in the value of the U.S. dollar relative to the euro might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might introduce additional volatility in our reported results and accounts from period to period.

**Risks Related to Operating in Our Industry**

**If we experience delays in obtaining regulatory approvals, or are unable to obtain them at all, for one or more of our product candidates, commercialization of those products will be delayed**

Our efforts to develop and market our product candidates will be subject to extensive and rigorous domestic regulation. FDA rules govern, among other matters, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products in the United States. Any products that we market abroad will also be subject to extensive regulation by foreign governments. In order to obtain permission to sell our product candidates, we must provide the FDA and foreign regulatory authorities with clinical data demonstrating that our proposed drugs are safe in humans and effective at treating an indicated condition. None of our product candidates has been approved for sale in the United States or any foreign market, and we cannot predict whether regulatory clearance will be obtained for any product that we are developing or intend to develop. The regulatory review and approval process takes many years, is dependent upon the type, complexity and novelty of the product candidate, requires the expenditure of substantial resources, involves post-marketing surveillance, and might involve ongoing requirements for post-marketing studies. Delays in obtaining regulatory approvals might:

impede the commercialization of any drugs that we or our collaborators develop;

require us or our collaborators to comply with costly additional procedures;

diminish any competitive advantage that we or our collaborators might attain from early market introduction of a new product; and

delay or eliminate our receipt of revenues or royalties.

Any required approvals, once granted, might be withdrawn. Further, if we do not comply with applicable FDA and foreign regulatory requirements at any stage during the regulatory process, we might be subject to sanctions, including:

imposed delays in clinical trials or commercialization;

refusal by the FDA and foreign regulators to review pending market approval applications or supplements to approval applications;

product recalls or seizures;

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suspension of production;

withdrawals of previously issued marketing approvals; and

fines, civil penalties and criminal prosecutions.

We choose to develop some proprietary product candidates ourselves and to out-license other product candidates to third parties for collaborative development. The licensing or collaboration agreement will generally specify which party is responsible for directing the clinical trial process and seeking regulatory approvals. Regardless of whether the process is directed by us or by our collaborators, in each case we face the risk that our clinical trials might be unsuccessful, and that the FDA will not grant us marketing approval. We might also encounter delays or rejections based upon future changes in government regulation, legislation or FDA policy during the period of product development, clinical trials and FDA regulatory review. If we do not obtain required governmental approvals, we will be precluded from marketing the candidate for which approval was sought. If regulatory clearance for marketing a future product is granted, this clearance will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and effective.

Outside the United States, the ability to market a product is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. This foreign regulatory approval process typically includes all of the risks associated with FDA clearance described above and might include additional risks.

**If our manufacturing subsidiary or our contract manufacturers fail to comply with applicable Good Manufacturing Practice requirements, we could be subject to fines or other sanctions, or be precluded from marketing any future products.**

Manufacturing facilities are required to comply with FDA Good Manufacturing Practice regulations. Even facilities outside the United States must comply with these regulations if the manufactured products will be sold in the United States. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well as to maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. Comparable Good Manufacturing Practice regulations also apply in the EU, Italy and other foreign countries. Our contract manufacturers and our manufacturing subsidiary might not be able to comply with the applicable Good Manufacturing Practice requirements and other FDA or other EU, Italian or foreign regulatory agencies' regulatory requirements.

**If we do not compete successfully in the development and commercialization of products and keep pace with rapid technological change, we will be unable to capture and sustain a meaningful market position.**

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies for treatment. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology companies and universities, and other research institutions. Specifically:

if anidulafungin receives FDA and international marketing approval, it will face competition from commercially available drugs such as amphotericin B (marketed by several manufacturers), fluconazole (marketed as Diflucan by Pfizer), itraconazole (marketed as Sporanox by Johnson & Johnson), and potentially from caspofungin (marketed as Cancidas by Merck), which was the first to receive FDA approval of a new class of antifungal agents called echinocandins (which

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includes anidulafungin). Merck initially obtained approval only for the narrow indication of aspergillosis salvage therapy, but might in the future expand the scope of Cancidas to include other serious fungal infections, such as esophageal and invasive candidiasis;

if dalbavancin receives FDA and international marketing approval, it will face competition from commercially available drugs such as vancomycin (marketed generically by several manufacturers), teicoplanin (marketed as Targocid by Aventis only outside of the United States), linezolid (marketed as Zyvox by Pharmacia) and quinupristin/dalfopristin (marketed as Synercid by Aventis), and drug candidates in clinical development such as daptomycin (expected to be marketed as Cidecin by Cubist), which is currently being reviewed by the FDA; and

if ramoplanin receives FDA and international marketing approval, it will face competition from commercially available drugs such as oral vancomycin (marketed generically by several manufacturers) as well as drugs focused on the treatment (as opposed to prevention) of bloodstream vancomycin-resistant enterococci infections in hospitalized patients, such as linezolid (marketed as Zyvox by Pharmacia) and quinupristin/dalfopristin (marketed as Synercid by Aventis).

Our future products, if any, might also compete with new products currently under development or developed by others in the future.

Many of our potential competitors, either alone or together with their collaborators, have substantially greater financial resources and larger research and development and marketing teams than we do. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than we do in developing, manufacturing and marketing products. As a result, these competitors' products might come to market sooner or might prove to be more effective, to be less expensive, to have fewer side effects or to be easier to administer than ours. In any such case, sales of our eventual products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

**If our intellectual property rights do not adequately protect our product candidates or future products, others could compete against us more directly, which would hurt our business.**

Our success depends in part on our ability to:

obtain patents or rights to patents;

protect trade secrets;

operate without infringing upon the intellectual property rights of others; and

prevent others from infringing our intellectual property rights.

We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that our intellectual property is covered by valid and enforceable patents or is effectively maintained as a trade secret. Based on information available as of December 31, 2002, we have 34 issued U.S. patents and 12 U.S. patent applications, 429 foreign patents and 87 foreign patent applications. Our license agreement with Eli Lilly with respect to anidulafungin covers 14 U.S. patents, 12 U.S. patent applications, 71 foreign patents and 125 foreign patent applications. Our collaborative agreement with Pharmacia with respect to the development of oxazolidinones includes two U.S. patents and 11 U.S. patent applications. Our collaborative agreement with Novartis includes three U.S. patent applications.

The patent position of biopharmaceutical companies involves complex legal and factual questions and, therefore, we cannot predict with certainty whether they will be enforceable. We have in the past and might in the future receive office actions or other notices from U.S. or foreign patent authorities

seeking to limit or otherwise qualify some patent claims. Patents, if issued, might be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties might not provide any protection against competitors. Our pending patent applications, those we might file in the future, or those we might license from third parties, might not result in patents being issued. Also, patent rights might not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of many foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

In addition to patents, we rely on trade secrets and proprietary know-how. We seek protection, in part, through confidentiality and proprietary information agreements. These agreements might not provide meaningful protection or adequate remedies for our technology in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our intellectual property rights could seriously impair our competitive position and harm our business.

**If third parties claim we are infringing their intellectual property rights, we could suffer significant litigation or licensing expenses or be prevented from marketing our future products.**

Research has been conducted for many years in the areas in which we focus our research and development efforts. This has resulted in a substantial number of issued patents and an even larger number of still-pending patent applications. Patent applications in the United States are, in most cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Our commercial success will depend significantly on an ability to operate without infringing the patents and other intellectual property rights of third parties. However, our technologies might infringe the patents or violate other intellectual property rights of third parties without our knowledge. In the event an infringement claim is brought against us, we might be required to pay legal and other expenses to defend such claim and, if our defense is unsuccessful, we might be prevented from pursuing product development and commercialization and might be subject to damage awards.

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of intellectual property legal actions, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain. Litigation might be necessary to:

enforce patents that we own or license;

protect trade secrets or know-how that we own or license; or

determine the enforceability, scope and validity of the intellectual property rights of others.

If we become involved in any litigation, interference or other administrative proceedings, we will incur substantial expense and the efforts of our technical and management personnel will be significantly diverted. An adverse determination might subject us to loss of proprietary position or to significant liabilities, or require us to seek licenses that might not be available from third parties. We might be restricted or prevented from manufacturing and selling products, if any, in the event of an adverse determination in a judicial or administrative proceeding or if we fail to obtain necessary licenses. Costs associated with these arrangements might be substantial and might include ongoing royalties. Furthermore, we might not be able to obtain the necessary licenses on satisfactory terms, if at all.

**If the government and third-party payors fail to provide adequate coverage and reimbursement rates for our future products, if any, our revenues and prospects for profitability will be harmed.**

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of reimbursement from third-party payors. Such third-party payors include government health administration authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price, and examining the cost effectiveness, of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development. Domestic and foreign governments continue to propose and

pass legislation designed to reduce the cost of healthcare. For example, in some foreign markets, the government controls prescription pharmaceuticals' pricing and profitability. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenues and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

**If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, we could be forced to pay substantial damage awards.**

The use of any of our product candidates in clinical trials, and the sale of any approved products, might expose us to product liability claims. Each of Versicor and Biosearch previously obtained limited product liability insurance coverage for clinical trials. We currently maintain, product liability insurance coverage in the amount of \$10 million per occurrence and \$10 million in the aggregate. Such insurance coverage might not protect us against all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damage awards resulting from a claim brought successfully against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.

### **Risks Related to the Securities Markets**

**Our stock price has been and is likely to continue to be volatile, and your investment could suffer a decline in value.**

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in price in response to various factors, many of which are beyond our control, including:

clinical trial data;

general economic conditions;

changes in, or failure to achieve, financial estimates by securities analysts;

future sales of equity or debt securities;

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new products or services introduced or announced by us or our competitors;

announcements of scientific innovations by us or our competitors;

actual or anticipated variations in our annual and quarterly operating results;

conditions or trends in the biotechnology and pharmaceutical industries;

announcements by us of significant acquisitions, strategic collaborations, joint ventures or capital commitments;

additions or departures of key personnel;

new regulatory legislation adopted in the United States or abroad; and

sales of our common stock.

In addition, the stock market in general, and the Nasdaq National Market, the Nuovo Mercato and the market for biotechnology and pharmaceutical stocks in particular, have experienced significant price and volume fluctuations. Over the 52-week period ending February 15, 2003, the intra-day sales prices of Versicor common stock as reported on the Nasdaq National Market ranged from a high of \$20.46 to a low of \$7.85. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company's securities. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

**We have implemented anti-takeover provisions that could delay or prevent any attempt to replace or remove the management.**

Provisions of our restated certificate of incorporation, our bylaws, as amended and restated upon completion of the merger, and our shareholder rights plan might increase the likelihood that any third party would need to negotiate with our board prior to initiating a takeover proposal for our company and could have the effect of delaying or preventing a change of control of our company. In addition, some of our stockholders have entered into a stockholders agreement in which they have agreed, for a period of three years following completion of the merger, to vote as recommended by the board on some issues. These provisions could delay or prevent an attempt to replace or remove our management.

**ITEM 2. PROPERTIES**

Our facilities in the United States currently consist of approximately 55,000 square feet of laboratory and office facilities located in Fremont, California, which is leased to us until February 2009, and an aggregate of approximately 27,000 square feet of office facilities in King of Prussia, Pennsylvania, which are leased to us under five lease agreements until September 2007.

We own offices and laboratory facilities consisting of approximately 150,000 square feet located in Gerenzano, Italy. We use approximately 70% of the square footage of these buildings and have leased a number of the offices and laboratories we are not currently using to Areta International or Newron Pharmaceuticals S.p.A. We also own land consisting of approximately 87,000 square meters in the Pisticci technical area in southern Italy through our subsidiary, Biosearch Manufacturing S.r.l., which land will be contributed to our Italian subsidiary, Versicor Italy S.r.l., within 120 days following the completion of the merger.

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We believe that these current facilities are adequate for our needs for the foreseeable future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

**ITEM 3. LEGAL PROCEEDINGS**

We are not party to any material legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

On December 6, 2002, we held a Special Meeting of Stockholders for the purpose of voting on:

1. A proposal to approve the agreement and plan of merger, as amended, by and between Versicor Inc. and Biosearch Italia S.p.A.;
- 2.

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A proposal to amend our 2001 Stock Option Plan to increase the number of shares of Versicor common stock available for awards under the 2001 Stock Option Plan by an additional 5,400,737 shares and to increase the number of shares that may be granted under the 2001 Stock Option Plan to one person during any calendar year by an additional 650,000 shares.

3.

A proposal to authorize us to adjourn the special meeting, if necessary, to permit further solicitations of proxies if there are not sufficient votes at the time of the special meeting to approve proposals 1 or 2.

The stockholders approved the following matters, with the following votes cast with respect to each proposal:

1.

Approve the agreement and plan of merger, as amended, by and between Versicor Inc. and Biosearch Italia S.p.A:

Shares Voted For	Shares Voted Against	Shares Withheld
17,785,308	4,510	2,665

2.

Amend our 2001 Stock Option Plan to increase the number of shares of Versicor common stock available for awards under the 2001 Stock Option Plan by an additional 5,400,737 shares and to increase the number of shares that may be granted under the 2001 Stock Option Plan to one person during any calendar year by an additional 650,000 shares:

Shares Voted For	Shares Voted Against	Shares Withheld
17,013,488	774,465	4,530

3.

Authorize us to adjourn the special meeting, if necessary, to permit further solicitations of proxies if there are not sufficient votes at the time of the special meeting to approve proposals 1 or 2:

Shares Voted For	Shares Voted Against	Shares Withheld
14,961,474	2,827,271 42	3,738

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

#### Price Range of Common Stock

Our common stock is listed for trading on the NASDAQ under symbol "VERS". The following table sets forth for the period from January 1, 2001 through February 24, 2003, the high and low closing prices, as reported on the NASDAQ composite trading system, for the periods shown:

	Sales Prices	
	High	Low
<b>2001</b>		
First Quarter	\$ 9.44	\$ 7.06
Second Quarter	\$ 13.87	\$ 6.63
Third Quarter	\$ 15.67	\$ 11.95
Fourth Quarter	\$ 20.99	\$ 13.66
<b>2002</b>		
First Quarter	\$ 24.16	\$ 16.75
Second Quarter	\$ 18.99	\$ 9.65
Third Quarter	\$ 12.11	\$ 8.17
Fourth Quarter	\$ 12.20	\$ 7.85
<b>2003</b>		
First Quarter through February 24, 2003	\$ 12.25	\$ 10.27

As of February 24, 2003, there were approximately 107 record holders of our common stock.

We have never declared or paid a cash dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future. We currently intend to retain our earnings, if any, for the development of our business. The declaration of any future dividends by us is within the discretion of our Board of Directors and will be dependent on our earnings, financial condition and capital requirements as well as any other factors deemed relevant by our Board of Directors.

#### Recent Sales of Unregistered Securities

On April 9, 2002, we completed a private placement of 2,993,800 shares of our common stock to selected institutional investors for gross proceeds of \$44.9 million. The private placement was conducted pursuant to Section 4(2) of, and Rule 506 of Regulation D under, the Securities Act. We subsequently registered the resale of those shares with the SEC.

#### Initial Public Offering

A Registration Statement on Form S-1 (File No. 333-33022) registering 4,600,000 shares of our common stock was declared effective by the SEC on August 8, 2000. The amount of net offering proceeds from the initial public offering and over-allotment option was approximately \$52.7 million. The net proceeds are being used for the clinical development of our product candidates as well as for general corporate and working capital purposes.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with the financial statements and the notes to those statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this document. The selected financial data for the years ended December 31, 2002, 2001, 2000, 1999 and 1998 is derived from our audited financial statements.

	Year Ended December 31,				
	2002	2001	2000	1999	1998
	(in thousands, except per share amounts)				

#### Statement of Operations Data:

##### Revenues:

Collaborative research and development and contract services	\$ 6,083	\$ 6,145	\$ 5,338	\$ 3,750	\$
License fees and milestones	258	283	533	525	

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Year Ended December 31,

Total revenues	6,341	6,428	5,871	4,275	
Operating expenses:					
Research and development non-cash stock compensation expense	791	2,359	2,073	3,315	536
Research and development other	47,398	30,253	13,458	22,157	10,893
Total research and development	48,189	32,612	15,531	25,472	11,429
General and administrative non-cash stock compensation expense	1,491	2,599	5,631	1,081	1
General and administrative other	6,693	7,001	3,260	1,505	1,385
Total general and administrative	8,184	9,600	8,891	2,586	1,386
Total operating expenses	56,373	42,212	24,422	28,058	12,815
Loss from operations	(50,032)	(35,784)	(18,551)	(23,783)	(12,815)
Other income (expense):					
Interest income	1,483	3,313	3,712	749	770
Interest expense	(247)	(316)	(482)	(6,171)	(540)
Other		(60)	18	(14)	
Net loss	(48,796)	(32,847)	(15,303)	(29,219)	(12,585)
Deemed dividends related to beneficial conversion feature of preferred stock				(35,112)	
Accretion of dividends on preferred stock			(3,486)	(3,063)	(2,527)
Net loss available to common stockholders	\$ (48,796)	\$ (32,847)	\$ (18,789)	\$ (67,394)	\$ (15,112)
Net loss per share:					
Basic and diluted	\$ (1.91)	\$ (1.42)	\$ (1.95)	\$ (127.28)	\$ (47.11)
Weighted average shares	25,516	23,090	9,638	530	321

December 31,

	2002	2001	2000	1999	1998
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(in thousands)

**Balance Sheet Data:**

Cash and cash equivalents and marketable securities	\$ 62,305	\$ 63,768	\$ 85,934	\$ 34,619	\$ 4,507
Total assets	72,736	70,697	91,596	45,233	15,865
Term loan payable, less current portion	698	1,004	3,448	4,310	5,172
Convertible and redeemable preferred stock				83,843	33,984
Accumulated deficit	(152,619)	(103,823)	(70,976)	(55,673)	(26,454)
Total stockholders' equity (deficit)	48,666	52,894	80,287	(48,796)	(27,076)

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes to those statements included elsewhere in this document. This discussion may contain forward-looking statements that involve risks and uncertainties. The words "believe," "expect," "anticipate," "estimate," "may," "will," or "could" and similar expressions or the negatives of these words or phrases are intended to identify forward-looking statements. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this document, our actual results may differ materially from those anticipated in such forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of bacterial and fungal infections. Since our inception in 1995 as a wholly-owned subsidiary of Sepracor Inc., we have devoted substantially all of our efforts to establishing our business and conducting research and development activities related to our proprietary product candidates, including anidulafungin and dalbavancin, as well as collaborative product candidates.

Since 1996, we have been operating as an independent company. In August 2000, we sold 4,600,000 shares of our common stock at \$11 per share in an initial public offering, and in September 2000 the underwriters exercised an over-allotment option and purchased an additional 690,000 shares. We received total net proceeds from the initial public offering and the over-allotment of approximately \$52.7 million.

On April 9, 2002, we completed a private placement of 2,993,800 shares of our common stock to selected institutional investors at a purchase price of \$15 per share. We received net proceeds from the private placement of approximately \$41.9 million.

On February 28, 2003 we acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. We have issued 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. We also intend to issue options covering approximately 5,787,500 common shares, including options issued to replace or assume options currently held by Biosearch employees and consultants. As a result, former Versicor stockholders now own approximately 55% of our outstanding common stock and former Biosearch shareholders own approximately 45%.

Since we began our operations in 1995, we have not generated any revenues from product sales. Our lead antifungal product candidate, anidulafungin, is in Phase III clinical trials and our lead antibiotic product candidate, dalbavancin entered into Phase III clinical trials in December 2002. We also have several lead compounds in pre-clinical studies.

Our revenues in the near term are expected to consist primarily of collaborative research payments, license fees and milestone payments to be received from our collaborators. Certain of these payments are dependent on achievement of specified milestones. If the development efforts result in clinical success, regulatory approval and successful commercialization of our products, we will generate revenues from sales of these products and from receipt of royalties on sales of these products.

Our expenses have consisted primarily of costs incurred when in-licensing existing product candidates, research and development of new product candidates and in connection with our collaboration agreements, and from general and administrative costs associated with our operations. We expect licensing costs to increase as certain milestones are achieved, and our research and development expenses to increase as we continue to develop our product candidates. Following our recently completed merger with Biosearch, we also expect our general and administrative expenses to increase

as we add personnel, integrate our operations and continue to expand our research and development operations. We expect to incur sales and marketing expenses in the future when we establish our sales and marketing organization.

Since our inception, we have incurred significant losses. As of December 31, 2002, we had an accumulated deficit of \$152.6 million. We anticipate incurring additional losses, which may increase for the foreseeable future, including at least through December 31, 2003.

We have a limited history of operations. We anticipate that our quarterly results of operations will fluctuate for the foreseeable future due to several factors, including payments made or received pursuant to licensing or collaboration agreements, progress of our research and development efforts and the timing and outcome of regulatory approvals. Our limited operating history makes predictions of future operations difficult or impossible to ascertain.



## Major Research and Development Projects

Our ongoing clinical trials of anidulafungin and dalbavancin are our two most significant research and development projects, generating 35% and 17%, respectively, of our total research and development expenses (excluding non-cash stock compensation expense) since our inception.

### *Anidulafungin*

Anidulafungin is our lead antifungal product candidate. We in-licensed anidulafungin from Eli Lilly pursuant to the May 1999 agreement described below. As of December 31, 2002, the intravenous formulation of anidulafungin is in:

Phase III clinical trials for the treatment of esophageal candidiasis, patient enrollment completed;

Phase III clinical trials for the treatment of invasive candidiasis/candidemia; and

Phase III clinical trials for the treatment of aspergillosis.

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of anidulafungin. We paid \$11.0 million for the license and an additional \$3.0 million for product inventory (which we have received). As a result, we recognized \$14.0 million of research and development costs in 1999. If specified milestones are achieved on the intravenous formulation of anidulafungin in the United States and Canada, we will be obligated to make additional payments of up to \$14.0 million to Eli Lilly. We are also obligated to make additional payments of up to \$8.0 million to Eli Lilly if specified milestones on the intravenous formulation of anidulafungin are achieved in Europe, and additional payments of up to \$8.0 million if specified milestones on the intravenous formulation of anidulafungin are achieved in Japan. We are obligated to make additional payments to Eli Lilly of up to \$21.0 million if sales of an intravenous formulation of anidulafungin exceed specified targets in the United States and Canada, Europe and Japan. We believe that it is unlikely that we will be obligated to make all or a significant portion of these payments to Eli Lilly. In addition, we are obligated to make royalty payments in respect of sales of any product resulting from the compound.

We are not currently developing an oral formulation of anidulafungin and do not presently intend to do so in the future. However, under the license agreement with Eli Lilly, we are obligated to make additional payments to Eli Lilly of up to \$25.0 million if, and only if, specified milestones are achieved on an oral formulation of anidulafungin in the United States, additional payments of up to \$15.0 million if specified milestones are achieved on an oral formulation of anidulafungin in Europe, and additional payments of up to \$15.0 million if specified milestones are achieved on an oral formulation of anidulafungin in Japan. In addition, we are obligated to make additional payments to Eli Lilly of up to \$24.0 million if, and only if, sales of an oral formulation of anidulafungin exceed

specified targets worldwide. Because an oral formulation of anidulafungin is not currently feasible, we believe that it is unlikely that we will be obligated to make any of these payments to Eli Lilly. We have also granted to Eli Lilly an option to license the exclusive worldwide rights to any oral formulation of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, Eli Lilly would pay us an up-front fee and royalties based on net product sales, and would reimburse us for any milestone payments paid plus the value, on a cost-plus basis, of all prior development expenses attributed to the development and commercialization of the oral formulation of anidulafungin. However, due to the speculative nature of the oral formulation of anidulafungin, we believe that it is unlikely that we will be entitled to receive fees or royalties and reimbursement of expenses from Eli Lilly.

Research and development expense (excluding non-cash stock compensation expense) allocated to our anidulafungin project, expressed as a percentage of total research and development expense for the period (excluding non-cash stock compensation expense), was:

42% for the year 2002 compare to 37% for the year 2001 and 14% for the year 2000; and

35% in the aggregate from our inception through December 31, 2002.

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Our development administration overhead costs are included in total research and development expense for the each period, but are not allocated among our various projects.

The goal of our anidulafungin project is to obtain marketing approval from the U.S. Food and Drug Administration, or FDA, and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. To obtain the first of such approvals, we hope to file a New Drug Application, or NDA, with the FDA at the conclusion of our Phase III trials for treatment of esophageal candidiasis, which has completed patient enrollment, assuming that the clinical trial's results support a filing. That trial began in the first quarter of 2001 and, assuming successful completion of the Phase III trials, we anticipate filing an NDA for anidulafungin by the end of April 2003. Material cash inflows relating to our anidulafungin project will not commence until after marketing approvals are obtained, and then only if anidulafungin finds acceptance in the marketplace. To date, we have not received any revenues from product sales of anidulafungin. Because of the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our anidulafungin project will commence, if ever.

A failure to obtain marketing approval for anidulafungin would likely have the following results on our operations, financial position and liquidity:

because our research and development projects are independent, a failure to obtain marketing approval for anidulafungin would not necessarily interrupt our development programs for dalbavancin or our pre-clinical compounds; however, we might reduce our development staff (unless one or more of our other product candidates is then entering in late-stage clinical trials, in which case we might re-assign anidulafungin researchers to those projects);

we would be relieved of our contingent obligation to make further milestone payments and royalty payments to Eli Lilly;

we would not earn any sales revenue from anidulafungin, which would increase the likelihood that we would need to obtain additional financing for our other development efforts; and

our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all.

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### *Dalbavancin*

Dalbavancin is our lead antibiotic product candidate. We in-licensed dalbavancin from Biosearch pursuant to the February 1998 agreement described below. As of December 31, 2002, dalbavancin is in:

Phase III clinical trials for the treatment of skin and soft tissue infections; and

Phase II clinical trials for the treatment of catheter-related blood stream infections.

In February 1998, we entered into a license agreement and a collaborative agreement with Biosearch. Under the license agreement, Biosearch granted us an exclusive license to develop and commercialize dalbavancin in the United States and Canada. In exchange for the license and upon the receipt of favorable results in pre-clinical studies, we paid an initial license fee of \$2.0 million and issued 250,000 shares of our common stock to Biosearch. In May 2001 and December 2002, we paid Biosearch additional milestone payments for the start of Phase II and Phase III clinical trials, respectively.

Research and development expense (excluding non-cash stock compensation expense) allocated to our dalbavancin project, expressed as a percentage of total research and development expense for the period (excluding non-cash stock compensation expense), was:

23% for the year 2002 compared to 23% for the year 2001 and 7% for the year 2000; and

17% in the aggregate from our inception through December 31, 2002.

Our development administration overhead costs are included in total research and development expense for each period, but are not allocated among our various projects.

The goal of our dalbavancin project is to obtain marketing approval from the FDA and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. Before we can obtain such marketing approvals we will need to complete pivotal Phase III clinical trials with satisfactory results and submit a NDA to the FDA. In any case, we would not expect to file an NDA for dalbavancin until the second half of 2004, at the earliest. We are unable to estimate the costs to completion for our dalbavancin project due to the risks surrounding the clinical trial process, including the risk that we may repeat, revise or expand the scope of our ongoing clinical trials or conduct additional clinical trials to secure marketing approvals and the additional risks listed under the caption "Risk Factors Risks Related to our Business If clinical trials for our product candidates are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could harm our business and cause our stock price to decline." Material cash inflows relating to our dalbavancin project will not commence until after marketing approvals are obtained, and then only if dalbavancin finds acceptance in the marketplace. Because of the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our anidulafungin project will commence, if ever.

A failure to obtain marketing approval for dalbavancin would likely have the following results on our operations, financial position and liquidity:

because our research and development projects are independent, a failure to obtain marketing approval for dalbavancin would not necessarily interrupt our development programs for anidulafungin or our pre-clinical compounds; however, we might reduce our development staff (unless one or more of our other product candidates is then entering in late-stage clinical trials, in which case we might be able to re-assign dalbavancin researchers to those projects);

we would not earn any sales revenue from dalbavancin, which would increase the likelihood that we would need to obtain additional financing for our other development efforts; and

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our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all.

#### *Risks relating to our major research and development projects*

We face many risks that could prevent or delay the completion of our anidulafungin and dalbavancin projects, including those listed under the caption "Risk Factors Risks Related to Operating in our Industry."

#### *Development Administration*

Research and development expense (excluding non-cash stock compensation expense) comprising development administration overhead costs, expressed as a percentage of total research and development expense for the period (excluding non-cash stock compensation expense), was:

12% for the year 2002, compared to 7% for the year 2001 and 17% for the year 2000; and

8% in the aggregate from our inception through December 31, 2002.

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We do not allocate our development administration costs among our various projects because our development administration group is managed as a separate cost center and its expenditures are not always project specific.

### *Other research and development projects*

The remaining 40% of our total research and development expenses (excluding non-cash stock compensation expense) from our inception through December 31, 2002 were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pharmacia and Novartis described below.

*Oxazolidinones collaboration with Pharmacia.* In March 1999, we entered into a collaboration agreement with Pharmacia Corporation pursuant to which we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pharmacia made an equity investment in us of \$3.8 million and paid us research support and license fee payments. Under the terms of the agreement and in consideration of our research obligations, we are entitled to receive funding from Pharmacia to support certain of our full-time researchers. If specified milestones are achieved, Pharmacia is obligated to pay us additional payments of up to \$14.0 million for each compound, a portion of which may be credited against future royalty payments to which we are entitled on the worldwide sales of any drug developed and commercialized from the collaboration. In October 2000, Pharmacia increased its funding for this collaboration by 30%, and in June 2001, we received a milestone payment for the initiation of clinical development of one of the compounds. In July 2002, we agreed with Pharmacia by amendment to extend the collaboration for an additional three years through March 2005. Through December 31, 2002, Pharmacia has made aggregate payments to us under this collaboration agreement (excluding equity investments) of \$13.9 million.

Research and development expense (excluding non-cash stock compensation expense) allocated to our collaboration with Pharmacia, expressed as a percentage of total research and development expense for the period (excluding non-cash stock compensation expense), was:

7% for the year 2002, compared to 11% for the year 2001 and 22% for the year 2000; and

10% in the aggregate from January 1, 1999 through December 31, 2002.

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The goal of our collaboration with Pharmacia is to discover, synthesize and obtain marketing approval for second and third generation oxazolidinone product candidates. We supply research, product leads and other specified intellectual property to the collaboration. The collaboration also depends upon Pharmacia to develop the product candidates, to obtain marketing approval from the FDA and analogous international agencies and to manufacture and sell any products resulting from the collaboration. Material cash inflows in the form of royalties relating to this collaboration will not commence until after marketing approvals are obtained, and then only if the product finds acceptance in the marketplace. One product candidate resulting from the collaboration has entered Phase I clinical trials. In order to obtain marketing approval, Pharmacia will need to complete Phase I, II and III clinical trials with satisfactory results and submit a NDA to the FDA. Pharmacia is under no obligation to continue the development of any product candidate resulting from this collaboration. Because of this, and the substantial risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our collaboration with Pharmacia will commence, if ever.

*Deformylase inhibitors collaboration with Novartis.* In March 1999, we entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of \$3.0 million. We have also received a number of milestone payments from Novartis and are entitled to receive additional payments of up to \$13.0 million for our compounds or up to \$7.25 million for Novartis compounds upon the achievement of specified milestones. Novartis may deduct a portion of these milestone payments from the royalties it will be obligated to pay us on the worldwide sales of any drug developed and commercialized from this collaboration. As a result of progress achieved by the collaboration, in July 2002 we agreed with Novartis by amendment to extend the collaboration by an additional year through March 2003. Through December 31, 2002, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of \$11.1 million.

Research and development expense (excluding non-cash stock compensation expense) allocated to our collaboration with Novartis, expressed as a percentage of total research and development expense for the period (excluding non-cash stock compensation expense), was:

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5% for the year 2002, compared to 8% for the year 2001 and 20% for the year 2000; and

9% in the aggregate from January 1, 1999 through December 31, 2002.

The goal of our collaboration with Novartis is to discover, synthesize and obtain marketing approval for deformylase inhibitor product candidates. We are responsible for supplying research to the collaboration, according to a research plan developed by a joint research committee. Our research obligations currently extend through March 2003. Novartis provides us with funding to support some of our researchers on this project. The collaboration will depend upon Novartis to conduct the development of product candidates and to obtain marketing approval from the FDA and analogous international agencies. Material cash inflows in the form of royalties relating to this collaboration will not commence until after marketing approvals are obtained, and then only if the product finds acceptance in the marketplace. Currently all compounds identified by the collaboration are still in pre-clinical stages. In order to obtain marketing approval, Novartis will need to initiate and complete Phase I, II and III clinical trials with satisfactory results and submit a NDA to the FDA. Novartis is under no obligation to continue the development of any product candidate resulting from this collaboration. Because of this, and the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our collaboration with Novartis will commence, if ever.

In addition to the work on deformylase inhibitors, under the collaboration agreement we have been delivering to Novartis a series of screening assays based on novel anti-bacterial targets. For each screen that Novartis accepts as validated, we receive a milestone payment. In August 2001 and

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January 2002, Novartis paid us our fourth and fifth milestone payment, respectively, as a result of our delivery of our fourth and fifth target-based screens, which we expect will be used in Novartis' high-throughput screening laboratory to identify new anti-infectives.

A failure by Pharmacia or Novartis to pursue or obtain marketing approval for any product candidate resulting from our collaborations could have the following results on our operations, financial position and liquidity:

we would not receive any further milestone payments or any royalty revenue from the collaborations; and

while we do not rely on any particular external development collaboration to produce marketable products (and, ultimately, royalty revenues), the failure of all of our external development collaborations would increase the likelihood that we would need to obtain additional financing for our internal research and development efforts.

### **Deferred Stock Compensation**

We have recorded deferred stock compensation expense in connection with the grant of stock options to employees and consultants. Deferred stock compensation for options granted to employees is the difference between the fair value for financial reporting purposes of our common stock on the date such options were granted and their exercise price. Deferred stock compensation for options granted to consultants has been determined in accordance with Statement of Financial Accounting Standards No. 123, "Accounting for Stock Based Compensation," as the fair value of the equity instruments issued. Deferred stock compensation for options granted to consultants is periodically remeasured as the underlying options vest in accordance with Emerging Issues Task Force No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services."

We recorded deferred stock compensation (net of cancellations) of \$(114,000), \$(294,000) and \$4.4 million for the years ended December 31, 2002, 2001 and 2000, respectively. These amounts were recorded as a component of stockholders' equity and are being amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred stock compensation of \$2.3 million, \$5.0 million and \$7.7 million for the years ended December 31, 2002, 2001 and 2000, respectively.

### **Results of Operations**

*Years ended December 31, 2002, 2001 and 2000*

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*Revenues* were \$6.3 million, \$6.4 million and \$5.9 million in 2002, 2001 and 2000, respectively. Revenues consisted of \$3.6 million, \$3.7 million and \$3.1 million of collaborative research and development, contract services and licensing fees from Pharmacia in 2002, 2001 and 2000, respectively, and \$2.7 million, \$2.7 million and \$2.8 million of collaborative research and development fees and milestone payments from Novartis in 2002, 2001 and 2000, respectively. The slight decrease in revenues in 2002 is due to a decrease in revenue from the Pharmacia upfront license and contract research fees that were recognized as revenue over the initial three-year contract term through March 31, 2002. The increase in revenues in 2001 was due to the increase in collaborative research and development funding from both Pharmacia and Novartis.

*Research and development expenses* were \$48.2 million, \$32.6 million and \$15.5 million in 2002, 2001 and 2000, respectively. Research and development expenses consist of salaries and related costs of research and development personnel, as well as the costs of consultants, parts and supplies and clinical trials associated with research and development projects. During 2002, 2001 and 2000, we recorded \$791,000, \$2.4 million and \$2.1 million of amortization of non-cash stock compensation, respectively.

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Excluding these charges, research and development expenses were \$47.4 million, \$30.2 million and \$13.4 million in 2002, 2001 and 2000, respectively. The increase in research and development expenditure in both 2002 and 2001 is primarily due to the increase in clinical expenditure for the development of our product candidates. Our lead product candidate, anidulafungin, moved into Phase III clinical trials in the first half of 2001 and our second product candidate, dalbavancin, moved into Phase II clinical trials in the second quarter of 2001 and Phase III clinical trials in December 2002. We have also increased the size of our development administration team from one person in February 2001 to 28 at December 31, 2002. In addition, we have expanded our collaborative and internal research programs.

*General and administrative expenses* were \$8.2 million, \$9.6 million and \$8.9 million in 2002, 2001 and 2000, respectively. General and administrative expenses consist of salaries and related costs for executive and other administrative personnel, as well as the costs of facilities, insurance, legal fees and administrative service fees paid to Sepracor prior to our initial public offering in August 2000. General and administrative costs included amortization of non-cash stock compensation expense of \$1.5 million, \$2.6 million and \$5.6 million in 2002, 2001 and 2000, respectively. Excluding the amortization of non-cash stock compensation charges, general and administrative expenses were \$6.7 million, \$7.0 million and \$3.3 million in 2002, 2001 and 2000, respectively. Our general and administrative expenses decreased slightly in 2002 mainly due to a reduction in business development activity from 2001. The increase in general and administrative expenses in 2001 over 2000 is due to the increase in personnel, legal, insurance and other expenses associated with being a public company, the expansion of our research and development operations and business development activities.

*Net interest income (expense)* was \$1.2 million, \$3.0 million and \$3.2 million in 2002, 2001 and 2000, respectively. Net interest income (expense) consists of interest income on cash and cash equivalents and marketable securities and interest expense on our term loans and equipment notes. The decrease in net interest income in 2002 and 2001 is due to the significant reduction in interest rates during these two years.

*Income taxes.* As of December 31, 2002, we had federal and state net operating loss carryforwards of approximately \$99.2 million and \$64.4 million, respectively. As of December 31, 2002, we have recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We also have federal research credit carryforwards of \$3.5 million. The federal net operating loss and credit carryforwards may be limited by the change in ownership provisions contained in Section 382 of the Internal Revenue Code.

### **Liquidity and Capital Resources**

We have funded our operations principally with the proceeds of \$78.5 million from a series of six preferred stock offerings over the period 1995 through 1999, and net proceeds of \$52.7 million from our initial public offering received in August and September 2000. In addition, on April 9, 2002, we completed a private placement of 2,993,800 shares of common stock to selected institutional investors at a purchase price of \$15 per share, from which we received net proceeds of approximately \$41.9 million.

As of December 31, 2002, we have also received approximately \$27.9 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, \$2.0 million constitutes deferred revenue as of December 31, 2002.

We have also increased our cash and cash equivalents and marketable securities as a result of our recently completed merger with Biosearch. At December 31, 2002, Biosearch had unrestricted cash and cash equivalents and marketable securities of approximately \$100.6 million.

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In addition, we have a \$6.0 million term loan and \$2.0 million equipment note with a commercial bank. The term loan accrues interest at the prime rate plus 0.50% (the prime rate was 4.25% at December 31, 2002) and the equipment note's interest rate is based on the LIBOR rate plus an applicable margin (the applicable LIBOR rate for our note was 1.77% at December 31, 2002). As of December 31, 2002, there was an outstanding loan balance of \$2.8 million and an outstanding note balance of \$1.4 million. Proceeds from the loan were used to repay Sepracor for leasehold improvements to our facilities and for general corporate purposes. Proceeds from drawdowns on the equipment note were used to finance capital expenditure. The terms of the term loan were renegotiated in January 2003 and the balance of \$2.8 million is now repayable in eight equal quarterly installments beginning on March 31, 2003 with the final payment due on December 31, 2004. The final note balance is also payable on December 31, 2004. Also, in January 2003 the term loan was amended to include a three-year equipment note for \$1.5 million that we are able to draw down on through December 31, 2003. The note bears interest at the prime rate unless we exercise an option to have the interest on all or any portion of the principal amount based on the LIBOR rate plus an applicable margin. The interest on the note is payable in quarterly installments during the draw down period. The principal of the note is payable in equal installments beginning on March 31, 2004 with the final payment due on December 31, 2005.

**Years ended December 31, 2002, 2001 and 2000**

*Cash used in operations* was \$42.0 million, \$21.4 million and \$215,000 in 2002, 2001 and 2000, respectively. The net loss of \$48.8 million for 2002 was offset by non-cash charges for the amortization of non-cash stock compensation and depreciation of \$3.5 million and an increase in accounts payable and accrued liabilities of \$4.3 million less an increase in prepaid expenses and other current assets of \$3.8 million. The net loss of \$32.8 million for 2001 was partially offset by non-cash charges for the amortization of non-cash stock compensation and depreciation of \$6.0 million and an increase in accounts payable and accrued liabilities of \$6.0 million. In both 2002 and 2001, the increase in accounts payable and accrued liabilities is a direct result of the increase in our operating costs principally relating to the increase in clinical trial expenditure for the development of our product candidates. In 2002, the increase in prepaid expenses and other current assets primarily relates to prepaid acquisition costs relating to the merger of Biosearch with and into Versicor. In 2000, the net loss of \$15.3 million was partially offset by non-cash charges for the amortization of non-cash stock compensation and depreciation of \$8.6 million and also the release of \$5.0 million of restricted cash that was no longer required to be maintained under our term loan agreement with Fleet National Bank. The decrease in non-cash stock compensation in 2002 and 2001 is due to the fact that the majority of the compensation relates to options issued prior to our initial public offering in August 2000 and is being amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28.

*Investing activities* used \$2.6 million, \$16.3 million and \$18.4 million of cash during 2002, 2001 and 2000, respectively. In 2002, the net change in marketable securities was \$1.6 million as proceeds from our private placement in April 2002 funded the majority of our operating loss for the year. In 2001, cash was primarily used for the net purchases of marketable securities of \$14.4 million due to a change in investment portfolio managers and in 2000, cash was primarily used for the net purchases of marketable securities with the net proceeds of our initial public offering. Capital expenditure was \$945,000, \$2.0 million and \$447,000 in 2002, 2001 and 2000, respectively. Higher capital expenditure in 2001 related to leasehold improvements at our California facility.

*Financing activities* provided \$41.6 million, \$1.0 million and \$52.0 million of cash in 2002, 2001 and 2000, respectively. In 2002, our principal source of cash resulted from net proceeds of \$41.9 million received from the private placement of 2,993,800 shares of common stock to certain institutional investors in April 2002. Repayments on our term loans increased in 2002 due to the equipment note that we entered into in the second half of 2001. In 2001, the draw down on our equipment loan of

\$1.5 million was partially offset by repayments of our term loan of \$862,000. In 2000, we received net proceeds of \$52.7 million from our initial public offering in August 2000.

Future payments under debt and lease obligations at December 31, 2002 are as follows (in thousands):

	<b>Term Loan and Equipment Notes</b>	<b>Operating Leases</b>	<b>Total</b>
2003	\$ 3,500	\$ 1,646	\$ 5,146
2004	698	1,699	2,397

	Term Loan and Equipment Notes	Operating Leases	Total
2005		1,752	1,752
2006		1,805	1,805
2007		1,663	1,663
Thereafter		2,066	2,066
	\$ 4,198	\$ 10,631	\$ 14,829

We expect to have negative cash flow from operations for the foreseeable future. We expect to incur increasing research and development, and general and administrative expenses, including expenses relating to clinical development, additions to personnel, production and commercialization efforts and the integration of our operations with those of Biosearch. Our future capital requirements will depend on a number of factors, including our success in developing markets for our products, payments received or made under collaboration agreements, the timing and outcome of regulatory approvals, the need to acquire licenses to new products or compounds, the status of competitive products and the availability of other financing. We believe our existing cash and cash equivalents and marketable securities, in addition to the cash and cash equivalents, trading securities and available-for-sale securities acquired in the merger, will be sufficient to fund our operating expenses, debt repayments and capital requirements for at least 24 months.

### Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 145, "Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections". This standard will require gains and losses from extinguishment of debt to be classified as extraordinary items only if they meet the criteria of unusual and infrequent in Opinion 30, "Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions." Any gain or loss on extinguishment will be recorded in the most appropriate line item to which it relates within net income before extraordinary items. SFAS No.145 is effective for fiscal years beginning after May 15, 2002; however, certain sections are effective for transactions occurring after May 15, 2002. We do not expect the adoption of this standard to have a material effect on its financial statements.

In July 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities". This standard will require us to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. The standard replaces the existing guidance provided by Emerging Issues Task Force ("EITF") Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The standard is effective for fiscal years beginning after December 31, 2002. We do not expect the adoption of this standard to have a material effect on its financial statements.

In November 2002, the EITF reached a consensus on Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We believe that the adoption of this standard will have no material impact on our financial statements.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation, Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. We believe that the adoption of this standard will have no material impact on our financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 ("FIN 46"), "Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51." FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its



activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We believe that the adoption of this standard will have no material impact on our financial statements.

### Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical experience and other various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

Our critical accounting policies are as follows:

#### *Revenue Recognition*

We recognize revenues as they are earned. Revenue from license fees and contract services are recognized over the initial license or contract service term as the related work is performed, which generally is on a straight-line basis. Nonrefundable milestone payments received are recognized when they are earned, which is when the specific events which coincide with the achievement of substantive elements in the related collaboration agreements are achieved. Milestone payments received that are creditable against future royalty payments are deferred and recognized as revenue when the royalties are earned or when the payment is no longer creditable against future payments. Collaborative research and development payments are recognized as the related work is performed.

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#### *Valuation Allowance*

We have established a valuation allowance to reduce our deferred tax asset to an amount that is more likely than not to be realized. We account for income taxes under the provisions of Statement of Financial Accounting Standards No. 109 "Accounting for Income Taxes". Under this method, deferred tax assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income.

### ITEM 7.A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

#### Interest rates

Our exposure to interest rate risk relates to our cash and cash equivalents and marketable securities as well as our term loan and equipment notes with a commercial bank. Our marketable securities are subject to interest rate risk and could decline in value if interest rates fluctuate. However, due to the conservative and short-term nature of these investments, such exposure is limited. Borrowings under our term loan and equipment loan are also exposed to interest rate risk as they are subject to interest rates based on the bank's base rate or LIBOR.

The table below presents principal amounts and related weighted average interest rates by year of maturity for our cash and cash equivalents and marketable securities at December 31, 2002 (in thousands):

	<b>2002</b>
Cash and cash equivalents	\$ 28,271
Average interest rate	1.32%
Marketable securities	\$ 33,969
Average interest rate	1.95%

The estimated fair value of our cash and cash equivalents and marketable securities approximate the principal amounts reflected above based on the short-term maturities of these financial instruments.

The estimated fair value of our debt obligations approximates the principal amounts due based on the interest rates currently available to us for debt with similar terms and remaining maturities.

#### **Inflation**

We do not believe that inflation has had a material adverse impact on our business or operating results during the years presented.

#### **Currency Risk**

As a result of our recently completed merger with Biosearch, we are exposed to risks associated with foreign currency transactions insofar as we might desire to use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuates, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Although our reporting currency remains the U.S. dollar, a significant portion of our consolidated revenues and costs now arise in euros, which we restate in U.S. dollars for purposes of financial reporting, based on exchange rates prevailing at the end of the applicable reporting period. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Accordingly, changes in the value of the U.S. dollar relative to the euro might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period.

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### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information required by this item is included in Item 15 of Part IV of this report on Form 10-K and is incorporated by reference.

### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

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## **PART III**

### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Pursuant to General Instructions G(3) to Form 10-K, the information required by this item is incorporated by reference to such information contained in the Company's definitive Proxy Statement for the Annual Meeting of Shareholders, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

### **ITEM 11. EXECUTIVE COMPENSATION**

Pursuant to General Instructions G(3) to Form 10-K, the information required by this item is incorporated by reference to such information contained in the Company's definitive Proxy Statement for the Annual Meeting of Shareholders, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

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Pursuant to General Instructions G(3) to Form 10-K, the information required by this item is incorporated by reference to such information contained in the Company's definitive Proxy Statement for the Annual Meeting of Shareholders, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	3,688,538 \$	7.61	6,538,435
Equity compensation plans not approved by security holders			422,500
Total	3,688,538 \$	7.61	6,960,935

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Pursuant to General Instructions G(3) to Form 10-K, the information required by this item is incorporated by reference to such information contained in the Company's definitive Proxy Statement for the Annual Meeting of Shareholders, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

### ITEM 14. CONTROLS AND PROCEDURES

#### Disclosure Controls

Within the 90 days preceding the filing of this report, an evaluation was performed of the effectiveness of the design and operation of the Company's disclosure controls and procedures. The evaluation was conducted under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer of the Company. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer of the Company concluded that the Company's disclosure controls and procedures were effective as of the date of the evaluation. There have been no significant changes in the Company's internal controls subsequent to September 30, 2002.

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## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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<b>Item 15(a)2. Financial Statement Schedules</b>	

All schedules have been omitted because the information either has been shown in the financial statements or notes thereto, or is not applicable or required under the instructions.

**Item 15(a)3. Exhibits**

The exhibits listed on the Exhibit Index (following the Signatures and Certifications sections of this report) are included, or incorporated by reference, in this annual report.

**Item 15(b). Reports on Form 8-K**

None.

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