VERSICOR INC /CA
Form 10-K
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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, 2001**

**COMMISSION FILE NUMBER 000-31145**

# VERSICOR INC.

(Exact Name of Registrant as Specified in its Charter)

| **Delaware** | **04-3278032** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **34790 Ardentech Court Fremont, CA** | **94555** |
| (Address of Principal Executive Offices) | (Zip Code) |

(Registrant's Telephone Number, Including Area Code): **(510) 739 3000**

Securities Registered Pursuant to Section 12(b) of the Act:

| **Title of Each Class** | **Name of Exchange on Which Registered** |
|---|---|
| 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 ý No o

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. o

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sale price of the common stock on March 4, 2002 as reported on the NASDAQ National Market, was approximately $265.9 million. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 4, 2002, there were outstanding 23,252,333 shares of Common Stock of Versicor Inc.

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.

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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. Out 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 Versicor Inc.*

**Overview**

We are a biopharmaceutical company focused on the discovery, development and marketing of pharmaceutical products for the treatment of bacterial and fungal infections. The market for antibacterial and antifungal products is large and growing, reporting approximately $24 billion in worldwide sales in 1998. We focus on antibiotics and antifungals which we believe have certain 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 in other major therapeutic categories to market.

We have a distinct, two-fold approach to product development and marketing. Our primary strategy is to focus on the development of proprietary products, concentrating on injectable antibiotic and antifungal products for the hospital market. The hospital market accounted for approximately $6.5 billion in worldwide sales in 1998. 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 substantial markets where there is significant 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 the products are commercialized.

Our discovery platform combines our proprietary expertise in the critical areas of functional genomics, mechanism-based rational drug design 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 intravenous products, and for our pharmaceutical collaborations, in the case of oral products.

**Our Proprietary Products**

Our lead antifungal product candidate, anidulafungin, is an antifungal 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 safety profile to date. We began a pivotal Phase III trial with anidulafungin for the treatment of esophageal candidiasis in the first quarter of 2001. Assuming successful completion of this trial, we intend to file an NDA in the fourth quarter of 2002. We began a Phase II trial in invasive candidiasis and candidemia in the second quarter of 2001 and a Phase III trial in aspergillosis in the fourth quarter of 2001.

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 either daily or weekly, which is a significant competitive advantage over other products. We have initiated a Phase II trial with dalbavancin for the treatment of skin and soft tissue infections and in the first quarter of 2002, a Phase II trial in catheter-related bloodstream infections. Assuming successful completion of the Phase II trial for skin and soft tissue infections, we intend to commence our first Phase III clinical trial with dalbavancin in the second half of 2002.

**Our Research Programs**

*Research Collaborations*

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 FDA approval, 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 preclinical *in vivo* studies when administered orally. In October 2000, Pharmacia increased its research support payments to us by 30%, and in June 2001, we received a milestone payment from Pharmacia when they initiated a Phase I clinical trial with a novel oxazolidinone discovered as part of this collaboration.

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 present in bacteria but absent in human cells, and thus represents a good target for the discovery of 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 important respiratory pathogens such as *S. pneumoniae*, *H. influenzae* and *M. catarrhalis*. Several lead compounds have demonstrated activity in preclinical *in vivo* studies when administered orally, representing a rare example of *de novo* design of an active antibacterial agent. Additionally, in August 2001 and January 2002, we received a 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.

Our third collaboration is with Biosearch Italia, an infectious disease company with expertise in discovering natural products with antibacterial activity. We call this collaboration BIOCOR. Biosearch



scientists have already been responsible for the discovery of an important antibiotic, teicoplanin. Natural product antibiotics frequently require chemical modification to convert them into a usable drug. Biosearch makes such naturally occurring lead molecules available to us, and we employ our expertise in combinatorial and medicinal chemistry to optimize the leads and produce clinical candidates. Early progress has validated our ability to apply combinatorial chemistry to these frequently large and complex molecules.

*Internal Discovery Research*

In addition to our external research collaborations, we have an internal research program. The objective of internal research is to discover novel antimicrobials for hospital use for development by us. This effort combines our internal expertise in functional genomics-based target selection, novel assay development, mechanism-based rational drug design, combinatorial chemistry and medicinal chemistry. We are currently investigating several interesting *in vivo* active leads.

**The Anti-Infective Market Opportunity**

According to the most recent data provided by the United States Centers for Disease Control and Prevention, for the period 1980 to 1992, approximately 2 million hospital-acquired infections occurred annually in the United States, accounting for more than 8 million days of extended hospital stay and causing more than $4 billion in additional health care costs for each of those years. While overall per capita mortality rates declined in the United States from 1980 to 1992, the per capita mortality rate due to infectious diseases increased 58% over this period, making infectious diseases the third leading cause of death in the United States during that period.

In the United States, the great majority of serious infectious diseases, with the exception of AIDS, are caused by bacteria and fungi. Additionally, the vast majority of major AIDS-related complications are also due to fungi and bacteria. The nature of disease has changed over the past two decades as a result of changing patient populations, organisms and treatment paradigms. Some of the most important and life-threatening pathogens, Gram-positive bacteria such as *Staphylococcus aureus* and certain *streptococci*, have always posed serious threats to humans. However, particularly in hospitals, *S. aureus* has been increasing, both in the proportion of infections it causes and in its resistance to multiple classes of antibiotics. Additionally, certain strains of Gram-positive bacteria once considered non-pathogenic, such as coagulase-negative *Staphylococci* and *Enterococci*, are now significant causes of infections in hospitalized patients. These bacteria are generally highly resistant to a number of antibiotics. The risk of infection is particularly acute among very ill patients in intensive care units, those with indwelling catheters and those with impaired immune systems due to age, chemotherapy for cancer, immune suppression for bone marrow or organ transplantation, and AIDS.

These factors have also contributed to the emergence of fungi as a serious threat in these patients. For example, *Candida* now causes a significant number of bloodstream infections, and sometimes serious infections of mucosal surfaces such as in the mouth and esophagus. *Aspergillus* infection has emerged as a very serious complication in transplant patients. The number of different antibiotic classes available to treat fungal infections is very limited and resistance to existing therapies has already become a problem.

There are a number of challenging unmet medical needs in the antibacterial and antifungal area. Whereas resistance has been a driver of the discovery effort, at least for antibacterial agents, there is a need for more potent antibiotics with bactericidal activity rather than mere suppression of microbial growth, improved safety and tolerability, simplified dosage regimens and ease of administration.

We believe the anti-infective product market presents a highly attractive opportunity for three major reasons:

*Large market.* The market for antibiotics and antifungal products represents the third largest worldwide pharmaceutical drug market, with 1998 sales of nearly $24 billion. The hospital anti-infective product market, where we target our proprietary products, totaled $6.5 billion worldwide in 1998.

*Continued need for improved drugs.* The number of patients with impaired immune systems has been increasing dramatically, due to the aging population, growing use of therapies such as chemotherapy, bone marrow transplants and organ transplantation, and the growing prevalence of AIDS. These factors have created a growing need for new and improved therapies.

*Efficient and well-defined drug development process*. *In vitro* and early *in vivo* testing of anti-infective drugs has been shown to be more predictive of clinical trial results than other therapeutic categories. Moreover, anti-infective products that successfully complete Phase I clinical testing are more likely to prove efficacious and to receive regulatory approval.

**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 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 pronged 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 proprietary 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.

**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 |
|---|---|---|---|
| | **Proprietary** | | |
| Anidulafungin | *Esophogeal Candidiasis* | Fungicidal | Phase III |
| | *Aspergillosis* | Fungicidal | Phase III |
| | *Candidemia* | Fungicidal | Phase II |
| Dalbavancin | *Skin and Soft Tissue Infections* | Bactericidal | Phase II |
| | *Bacteremia* | Bactericidal | Phase I |
| VRC 3950 Series | *Bacterial Infections* | Bactericidal | Pre-clinical *in vivo* |
| | **Collaborations** | | |
| Oxazolidinones (Pharmacia) | *Bacterial Infections* | Bacteriostatic | Phase I |
| Deformylase Inhibitors (Novartis) | *Bacterial Infections* | Bacteriostatic | Pre-clinical *in vivo* |

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

*The Antifungals Market.* The number of patients suffering from serious fungal infections is increasing. Individuals with impaired immune systems are the most susceptible and suffer from significant rates of morbidity and mortality. These patients include people receiving chemotherapy, those on immunosuppressive regimens for organ and bone marrow transplantation, and those with AIDS. In 1998, 2.5 million of these patients were hospitalized in the United States and approximately 25% of them developed serious fungal infections, with mortality rates as high as 38% for *Candida* infections and over 80% for *Aspergillus* infections.

Currently, only two classes of antifungal drugs are widely used to treat these infections: the polyenes, which include amphotericin B; and the azoles, which include fluconazole and itraconazole. Novel approaches are needed because polyene treatment is associated with severe side effects and azoles only inhibit growth, rather than kill the fungi, and because of an increasing resistance problem. Despite these limitations, these two drug classes generated over $1 billion in United States sales in 1998.

Because of these limitations, some companies, including ourselves, have begun developing a new class of antifungal drugs, the echinocandins. We are developing anidulafungin, an echinocandin antifungal, to take advantage of its fungicidal activity combined with an excellent safety and tolerability profile, based on results from our Phase I and Phase II clinical trials. Recently, another echinocandin product, Cancidas , received the first FDA approval in its class for salvage therapy of aspergillosis. Anidulafungin, which belongs to the same chemical class, has shown superior *in vitro* potency against *Aspergillus* and *Candida* compared to Cancidas .



*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 figure below, at both dosing regiments, over 80% of evaluable patients were cured or improved, as measured by an endoscope, an instrument permitting visual examination of the esophagus. Anidulafungin was well-tolerated at both of the doses studied.

| **Anidulafungin Dosage (Loading/Maintenance)** | **Endoscopic Response** |
|---|---|
| 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 was well tolerated by volunteers. Based upon the proportion of complete and partial responders observed in the Phase II trials and the safety data obtained from the maximum tolerable 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 its safety and tolerability profile.

A pivotal Phase III trial of anidulafungin for the treatment of esophageal candidiasis, which we began in the first quarter of 2001, is currently underway. In this randomized, double-blind, double-dummy trial, which is expected to enroll at least 450 patients, anidulafungin at a loading dose of 100 mg and daily maintenance doses of 50 mg is being compared with 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. As in the Phase II trial, endoscopic response will be the primary endpoint, with both clinical responses and eradication of fungi as secondary endpoints. Assuming successful completion of the Phase III trial, we anticipate filing an NDA in the fourth quarter of 2002.

We began a Phase II trial in candidemia and invasive *Candida* infections in the second quarter of 2001. In this randomized, open-label clinical trial, we are comparing the efficacy of different anidulafungin dosages: a loading dose of 200 mg and daily maintenance doses of 100 mg, a loading dose of 150 mg and daily maintenance doses of 75 mg, and a loading dose of 100 mg and daily maintenance doses of 50 mg. The trial is expected to enroll at least 120 patients at centers in the United States. Assuming successful completion of the Phase II trial, we expect to initiate a Phase III trial in candidemia in the fourth quarter of 2002.

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 of a 200 mg loading dose followed by daily maintenance doses of 100 mg directly into our Phase III trials. This open-label, non-comparative study will enroll at least 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. Secondary endpoints are survival measured at 28 days, at the conclusion of therapy and at four weeks following therapy in addition to clinical, radiographic and mycologic responses at the end of therapy and at four weeks following 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, pulmonary infections and esophagitis, or severe infections of the esophagus. The most serious fungal infections generally occur in individuals who have impaired immune systems. In clinical trials, anidulafungin not only inhibits but kills both yeasts, such as *Candida*, and filamentous fungi or molds, such as *Aspergillus*, that cause these infections. Anidulafungin is active against strains resistant to azoles and polyenes, the two most widely used classes of antifungal drugs.

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 $MIC_{90}$, or the concentration of drug that inhibits the growth of 90% of the fungal strains. 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.

The following figure illustrates the *in vitro* potency of anidulafungin against *Aspergillus fumigatus*, as measured by the mean MIC of the drug. The figure demonstrates that to inhibit growth of *Aspergillus fumigatus*, far less anidulafungin is needed as compared with existing agents, caspofungin and amphotericin B.

Source:
J. Clin. Microbiol. (1998), 36:2950
J. Clin. Microbiol. (1997), 36:198

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 important characteristic stems from its novel mechanism of action, because it affects the integrity of the protective cell wall of fungi. This is 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.

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 11 separate Phase I, II and III clinical trials, over 200 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.

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

*The Antibacterials Market.* In 1995, there were 1.9 million nosocomial, or hospital-acquired infections, which resulted in 88,000 deaths. The majority of these infections are caused by bacteria. Bacteria are classified in two major groups, Gram-positive and Gram-negative. This grouping enables bacteria to be quickly categorized to guide initial therapies. Clinically important Gram-positive bacteria include *Staphylococci*, *Streptococci* and *Enterococci*. These organisms, particularly *Staphylococci*, are responsible for a considerable portion of nosocomial infections, including 44% of bloodstream infections. The overall mortality rate from staphylococcal infections is estimated at 25%. The two species responsible for most nosocomial *Staphylococcus* infections are *Staphylococcus aureus* and *Staphylococcus epidermidis*. Of great concern is the increasing prevalence of multidrug resistant strains



of these two organisms. In particular, methicillin-resistant strains, which are referred to as MRSA and MRSE, occur at high frequencies in hospitals and are usually resistant to multiple antibiotics.

Due to the prevalence of antibiotic resistance, particularly in the hospital setting, vancomycin is the most widely-used drug to treat serious MRSA and MRSE infections. It requires at least twice daily intravenous administration, and is administered over an extended period of time. Although a new class of antibiotic, represented by Zyvox , was recently introduced for this indication, this antibiotic is bacteriostatic rather than bactericidal.

Our aim in developing dalbavancin is to take advantage of its potent anti-staphylococcal activity, its safety profile to date and its long duration of action to improve and simplify the treatment of serious bacterial infections. We are not targeting enterococcal infections, which account for only a small portion of vancomycin use.

*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 preclinical, preliminary Phase I and modeling studies. The safety and tolerability profile was very good, with no dose-limiting toxicities encountered. On the basis of these results, we initiated and are currently conducting a Phase II clinical trial in skin and soft tissue infections. We also started a Phase II trial in catheter-related bloodstream infections in the first quarter of 2002. Both Phase II trials 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 unique pharmacokinetic profile and its safety and tolerability profile to date. We initiated a Phase II clinical trial of dalbavancin for the treatment of skin and soft tissue infections in the second quarter of 2001 and we are currently planning to initiate a II trial in catheter-related bloodstream infections in the first quarter of 2002. Following successful completion of the Phase II trial, we plan to commence our first Phase III trial in the second half of 2002.

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 by the $MIC_{90}$.

Source:
JAC (1999), 44:179

This data illustrates that dalbavancin is more potent than available 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 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 oral antibiotics and other reduced costs.

*Well-tolerated in humans.* We recently successfully completed our Phase I dose-escalation clinical trial, which demonstrated that dalbavancin is well tolerated even at very high doses and that its pharmacokinetics are predictable.

**Research Programs**

**Research Collaborations**

*Oxazolidinones*

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 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. As a result of our relatively rapid progress in this area, Pharmacia, the leader in this field, 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, vancomycin-resistant *Enterococci* and penicillin-resistant *Streptococcus pneumoniae*. Several compounds have also demonstrated good activity in preclinical *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. In October 2000, Pharmacia increased its research funding to us by 30%. In June 2001, Pharmacia paid us a milestone payment as a result of the initiation of a Phase I clinical trial with a collaboration compound.

*Deformylase Inhibitors*

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 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 preclinical 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. In addition to the work on deformylase inhibitors, 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 January 2002, Novartis paid us our fourth and fifth milestone payment, respectively, for this collaboration.

*BIOCOR Collaboration*

In February 1998, we established an exclusive lead optimization collaboration with Biosearch called BIOCOR. Through this collaboration, Biosearch contributes natural product leads, and we contribute our combinatorial and medicinal chemistry expertise to optimize these leads and identify product candidates. The advantage of working with these leads is that they have already been shown to inhibit the growth of intact bacterial cells. Penetrating an intact cell is frequently a major obstacle to the successful development of an active drug. Biosearch is the management spin-off of an infectious disease research center that was formerly part of Hoechst Marion Roussel, now called Aventis. Biosearch scientists have been screening microbial fermentations for over 20 years. BIOCOR provides us with access to the attractive area of natural product leads without the expensive infrastructure necessary to generate such leads independently. In December 2000, we expanded this collaboration by sponsoring additional chemists in Italy and by providing novel proprietary screening assays and targets to BIOCOR. Biosearch has increased the number of natural product libraries that they are contributing to BIOCOR.

**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 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 preclinical 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.



*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 four additional metalloenzyme targets to build on this success in our novel molecules programs.

**Licensing and Collaborative 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 over a three-year period 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 development and commercialization rights to oral formulations 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. We will also have the right to exclusively co-promote the oral product with Eli Lilly in the hospital market.

*Biosearch Italia*

In February 1998, we entered into a license agreement and a collaboration 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 preclinical studies, we paid a license fee and issued shares of our common stock to Biosearch. We are obligated to make additional payments upon the achievement of specified milestones. We are also required to pay Biosearch royalties in respect of sales of any product that results from the compound. Subject to its establishment of an FDA-approved facility capable of manufacturing dalbavancin within an agreed-upon time frame, Biosearch has a right of first refusal to manufacture and supply us with our requirements for dalbavancin. The license agreement terminates on a country-by-country basis upon the expiration of all product patents in the country.



Under the collaborative agreement with Biosearch and a related addendum entered into in January 2001, we established a lead optimization joint venture called BIOCOR. Biosearch contributes leads, while we contribute our combinatorial and medicinal chemistry expertise to optimize the leads. Under the terms of the collaboration agreement, we agreed to pay Biosearch for each lead compound that is successfully optimized and developed through Phase I clinical trials. Biosearch has the exclusive license in Europe to commercialize intravenous products resulting from this collaboration and will retain all income derived from commercialization in Europe. We have the exclusive license in the United States and Canada for the commercialization of intravenous products and will retain all income resulting from commercialization in the United States and Canada. We will share with Biosearch all revenue from the commercialization of intravenous drugs in all countries other than the United States and Canada and outside of Europe, as well as from any oral products that are developed. Subject to its establishment of an FDA-approved facility within an agreed-upon time frame, Biosearch has a right of first refusal to manufacture and supply us with our requirements for products that result from this collaboration. The collaboration agreement terminates upon the expiration of all licensed patents resulting from the collaboration. In January 2001, we expanded this collaboration by sponsoring additional chemists in Italy and making certain proprietary screening assays available to Biosearch through BIOCOR. Biosearch has increased the number of natural product libraries they are contributing to BIOCOR.

*Pharmacia Corporation*

In March 1999, we entered into a collaboration agreement with Pharmacia 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 initial equity investment in us and paid research support and license fee payments to us. Under the terms of this agreement and as consideration for our research obligations, we are entitled to receive from Pharmacia funding to support certain of our full-time researchers. If specified milestones are achieved, Pharmacia must pay us additional payments per compound. In October 2000, pursuant to an agreement between Pharmacia and us, Pharmacia increased its funding for this collaboration by 30%. We have assigned to Pharmacia one United States patent application and a corresponding Patent Corporation Treaty patent application relating to this collaboration. Both applications involve the methodology of preparing oxazolidinones, libraries and pharmaceutical compositions. Pharmacia has agreed to conduct the development, manufacture and sale of products resulting from the collaboration. We are entitled to receive royalties on the sales of any products developed and commercialized. Pharmacia is allowed to offset some of its royalty payments with 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.

*Novartis Pharma AG*

In March 1999, we entered into a collaboration agreement with Novartis pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis has made an equity investment in us and has made milestone payments to us. 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. 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. We are entitled to receive payments upon Novartis' achievement of certain research milestones. For each product that Novartis develops and launches in a major country, we are entitled to receive royalties on 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 with 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. This agreement terminates on a country-by-country basis with respect to a product developed under the collaboration upon the longer 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.

**Sales and Marketing**

We intend to market and sell our proprietary products through a direct sales force in the United States and Canada. 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 outside hospitals in the United States and Canada, and in overseas markets.

**Manufacturing**

We have no manufacturing facilities and have used contract manufacturers to produce our drugs. Eli Lilly has supplied us with sufficient product to finish clinical trials of anidulafungin. In June 2001, we entered into a manufacturing, development and supply agreement with Abbott pursuant to which Abbott will manufacture final formulation of anidulafungin. Additionally, pursuant to the terms of the agreement with Abbott and in consideration of Abbott's obligations to us, we have agreed to pay Abbott (i) a non-refundable research and development fee, and (ii) subject to certain conditions, an additional research and development fee. At such time as we begin commercial sales of a product containing anidulafungin and to the extent that Abbott is able to meet our manufacturing and commercial supply requirements, and once we have agreed upon a satisfactory price with Abbott, we have agreed to purchase a substantial portion of our commercial supplies of anidulafungin from Abbott. Our agreement with Abbott may be terminated by either party upon 12-months prior notice at the end of the fourth year following the date on which the first product containing anidulafungin is made by us. Biosearch is our supplier of bulk drug substance dalbavancin.

**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.

We have two issued United States patents and seven United States 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 12 United States patents, 12 United States patent applications, 37 foreign patents and 132 foreign patent applications. Our license agreement with Biosearch with respect to dalbavancin includes three issued United States patents, two issued Canadian patents and several pending United States and Canadian patent applications. Our collaborative agreement with Pharmacia with respect to the development of oxazolidinones includes one United States patent and five United States patent



applications. Our collaborative agreement with Novartis includes three United States 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, Schering, Aventis, Fujisawa, Janssen, a division of Johnson & Johnson, J.B. Roerig, a division of Pfizer, Merck, Cubist, Gilead 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 preclinical 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.

The process for new drug approval has many steps, including:

*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 preclinical phase.

*Preclinical testing.* During the preclinical 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 preclinical 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, comprised of physicians 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 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, 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 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. The FDA may request additional studies (Phase IV) to evaluate long-term effects.

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

We have limited experience in conducting and managing clinical trials, and currently have only twelve full-time clinical 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. We also have a clinical advisory board that meets periodically with our staff and management to discuss present and future clinical testing activities.

**Employees**

As of December 31, 2001, we employed 63 persons, 29 of whom hold Ph.D or M.D. degrees. Approximately 54 employees were engaged in research and development, and nine supported administration, finance, management information systems and human resources. We believe that we maintain good relations with our employees.

**Risk Factors that may Affect Future Results**

The following is a summary of the many risks we face in our business. You should carefully review these risk factors in evaluating our business.



**Risks Related to Our Business**

**If we are unable to develop and successfully commercialize our product candidates, we may never generate significant revenues or become profitable.**

You must evaluate us in light of the uncertainties and complexities present in a biopharmaceutical company. Most of our product candidates are in the early stages of development, and two are in clinical trials. We do not know whether any of our clinical trials will result in marketable products. Preclinical testing and clinical trials are long, expensive and uncertain processes. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful.

To date we have not commercialized any products or recognized any revenue from product sales. To do so will require significant additional investment in research and development, preclinical testing and clinical trials, regulatory approval, and sales and marketing activities. Furthermore, our potential drug candidates will be subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies. These risks include:

- the possibilities that any or all of our drug candidates will be found to be unsafe, ineffective or toxic, or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- that these drug candidates, if safe and effective, will be difficult to develop into commercially viable drugs or to manufacture on a large scale or will be uneconomical to market commercially;
- that third party proprietary rights will preclude us from marketing such drugs; or
- that third parties will market superior or equivalent drugs.

Finally, even if our product candidates are successfully developed, they may not generate sufficient or sustainable revenues to enable us to become profitable.

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

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 approximately $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 and $32.8 million in 2001. As of December 31, 2001, our accumulated deficit was approximately $103.8 million. Our losses to date have resulted principally from:

- research and development costs relating to the development of our product candidates;
- costs of acquiring product candidates; and

general and administrative costs relating to our operations.

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 preclinical testing and clinical trials, and charges related to purchases of technology or other assets. We expect that the amount of operating losses will fluctuate significantly from quarter to quarter as a result of increases or decreases in our research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, or other factors. Our chances for achieving profitability will depend on numerous factors, including success in:

developing and testing new product candidates;

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 ever become profitable.

**Our revenues will be subject to significant fluctuations, which will make it difficult to compare our operating results to prior periods.**

We expect that substantially all of our revenues for the foreseeable future will result from payments under collaborative arrangements. To date, these payments have been in the form of up-front payments, reimbursement for research and development expenses and milestone payments. We may not be able to generate additional revenues under existing or future collaborative agreements. Furthermore, payments to us under our existing and any future collaborative arrangements will be subject to significant fluctuation in both timing and amount, and may never be achieved or payable. In addition, we may not be able to generate revenues from future product sales. Our revenues may not be indicative of our future performance or of our ability to continue to achieve additional milestones. Our revenues and results of operations for any period may also not be comparable to the revenues or results of operations for any other period.

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

An important component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Competition for promising compounds can be intense. If we are not able to identify future licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

**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 certain product candidates. These collaborations are 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. Only a limited number of product candidates have been generated pursuant to our collaborations. We cannot assure you that any of these product candidates will result in commercially successful products. Current or future collaborative arrangements may not be successful. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may 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 may devote to the product

candidates or their prioritization of the product candidates, and our collaborators may choose to pursue alternative products. Our collaborators may also not perform their obligations as expected. Business combinations or significant changes in a collaborator's business strategy may 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 certain circumstances. If any collaborator was to terminate or breach our agreement with it, 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 products 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 develop, we must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting preclinical testing and clinical trials is a lengthy, time-consuming and expensive process. Completion of clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

slower than expected rate of hospital and patient recruitment;

inability to manufacture sufficient quantities of materials for use in clinical trials;

unforeseen safety issues;

lack of efficacy during the clinical trials;

inability to adequately follow patients after treatment; or

governmental or regulatory delays.

The results from preclinical 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 clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Data obtained from preclinical and clinical activities are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, regulatory delays or rejections may 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, 2001, two of our product candidates, anidulafungin and dalbavancin, were in clinical trials. 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 may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin and dalbavancin or any other potential product candidates. This failure may delay development of other product candidates and hinder our ability to conduct related preclinical testing and clinical trials. Regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates. Our other product candidates are in preclinical development, and we have not submitted investigational new drug applications, or INDs, to commence clinical trials involving these compounds. Our preclinical development efforts may not be successfully completed and we may not file further INDs. Any delays in, or termination of, our clinical trials will harm our development and commercialization timelines, which would cause our stock price to decline. Any of these events would also seriously impede our ability to obtain additional financing.

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

We have limited experience in conducting and managing clinical trials, and currently have only fourteen full-time clinical development employees. We 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 may be delayed or unsuccessful. Furthermore, the FDA may inspect some of our clinical investigational sites, our collaborators' records and our facility and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that the trials were not in compliance, we may 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, they may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any pharmaceutical product that we 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

effectiveness of our marketing and distribution capabilities.

Physicians will not recommend therapies using our 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 our products is established, physicians may elect not to recommend the therapies for a number of other reasons, including whether the mode of administration of our products is effective for certain indications. For example, many antibiotic or antifungal products are typically administered by infusion or injection, which requires substantial cost and inconvenience to patients. Our product candidates, if successfully developed, will compete with a number of drugs and therapies manufactured and marketed by major pharmaceutical and other biotechnology companies. Our products may also compete with new products currently under development or developed by others in the future. Physicians, patients, third-party payors and the medical community may not accept and utilize any product candidates that we or our collaborators develop. If our products do not achieve significant market acceptance, we are not likely to generate significant revenues or become profitable.

**If we are unable to attract and retain key employees and consultants, we will be unable to develop and commercialize our products.**

We are highly dependent on the principal members of our scientific and management staff. In addition, we have depended to date on third parties to perform significant management functions. In order to pursue our product development, marketing and commercialization plans, we may need to hire additional personnel with experience in clinical testing, government regulation, manufacturing, marketing and finance. We may 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 scientific and management staff does not have employment contracts. If we lose any of these persons, or are unable to attract and retain qualified personnel, our business, financial condition and results of operations may be harmed. We do not have key person life insurance on any of our key personnel.

In addition, we rely on members of our scientific and clinical advisory boards and other consultants to assist us in formulating our research and development strategy. All of our consultants and the members of our scientific and clinical advisory boards are employed by other entities, and they may have commitments to, or advisory or consulting agreements with, other entities that may limit their

availability to us. If we lose the services of these advisors, the achievement of our development objectives may be impeded, and our business, financial condition and results of operations may be harmed. In addition, 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 cannot assure you that we will be able to obtain such licenses on favorable terms or at all.

**If our third-party manufacturers fail to deliver our product candidates, clinical trials and commercialization of our product candidates could be delayed.**

We do not have our own manufacturing facilities to produce our product candidates and anticipate that we will continue to rely on third parties to manufacture our product candidates and our products. Our contract manufacturers have a limited number of facilities in which our product candidates can be produced. These manufacturers have limited experience in manufacturing anidulafungin and dalbavancin in quantities sufficient for conducting clinical trials or for commercialization.

Contract manufacturers often encounter difficulties in scaling up production, 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. Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our product candidates. If our contract manufacturers fail to perform satisfactorily under our agreements with them, including 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 fail to 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 fail to establish successful marketing and sales capabilities or fail to enter into successful marketing arrangements with third parties, we would not be able to commercialize our products and we would not become profitable.**

We intend to sell a portion of our products through our own sales force. We currently have no sales and marketing infrastructure and have no 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 to our customers. We may 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 may 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 compete with other companies that have experienced and well-funded marketing and sales operations.

**If circumstances require us to obtain additional funding, we may 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. Our requirements for additional capital may be substantial and will depend on many factors, some of which are beyond our control, including:

payments received or made under possible future collaborative agreements;

continued progress in the research and development of our products;



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

development of marketing and sales capabilities; or

market acceptance of our products.

To the extent our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds to continue the development of our product candidates. Other than with respect to our existing lines of credit for equipment financing, we have no committed sources of additional capital. We cannot assure you that funds will be available to us on favorable terms, if at all. To the extent that additional capital is raised 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 may 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, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or otherwise significantly curtail operations, 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. Our inability to raise capital would harm our business, financial condition and results of operations.

**Disruption in our operations and United States commercial activities generally following the September 2001 terrorist attacks on the United States may adversely impact our results of operations, our ability to raise capital or our future growth.**

Although we have not suffered directly as a result of the September 2001 terrorist attacks on the United States and recent related events, our operations may be harmed indirectly. For example, we may experience an increase in certain operating costs, such as costs for transportation, courier services, insurance and security, or delays in receiving payments from parties that have been affected by the attacks, which, in turn, would harm our business. We may also be affected either directly or indirectly by possible future terrorist attacks. Moreover, any further terrorist activities, or the effect of the United States' political, economic or military response to such activities, could result in the further deterioration of the United States and world economy. This economic downturn could harm our results of operations, impair our ability to raise capital or impede our ability to continue growing our business.

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

If appropriate opportunities become available, we may attempt to acquire products, product candidates or businesses that we believe are a strategic fit with our business. We currently have no agreements to consummate any material acquisitions. If we pursue any transaction of this sort, the process of negotiating the acquisition and integrating an acquired product, product candidate or business may result in operating difficulties and expenditures and may 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 may 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 amortization expenses related to goodwill and other intangible assets, which could harm our business, financial condition and results of operations.



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

Our research and manufacturing activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources.

## Risks Related to Operating in Our Industry

**If we experience delays in obtaining regulatory approvals, or are unable to obtain them at all, we could be delayed in or precluded from commercializing our products.**

Our product candidates under development are subject to extensive and rigorous domestic government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments. We must provide the FDA and foreign regulatory authorities with clinical data that demonstrate our products' safety and efficacy in humans before they can be approved for commercial sale. 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 hope to develop. The regulatory review and approval process takes many years, is dependent upon the type, complexity and novelty of the product, requires the expenditure of substantial resources, involves post-marketing surveillance, and may involve ongoing requirements for

post-marketing studies. Delays in obtaining regulatory approvals may:

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

impose costly procedures on us or our collaborators;

diminish any competitive advantages that we or our collaborators may attain; and

adversely affect our receipt of revenues or royalties.

Any required approvals, once granted, may be withdrawn. Further, if we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

delays in clinical trials or commercialization;

refusal of the FDA to review pending market approval applications or supplements to approval applications;

product recalls or seizures;

suspension of production;

withdrawals of previously approved marketing applications; and

fines, civil penalties and criminal prosecutions.

We expect to file INDs and generally direct the regulatory approval process for proprietary products we develop, and we expect to rely on our collaborators to generally direct the regulatory approval process for our collaboration products. Our collaborators may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates. In addition, we may encounter delays or rejections based upon additional government regulation resulting from future legislation or administrative action or changes in FDA policy or interpretation during the period of product development, clinical trials and FDA regulatory review. If



we fail to obtain required governmental approvals, we or our collaborators will experience delays in or be precluded from marketing products developed through our research. In addition, the commercial use of our products will be limited.

If regulatory clearance for a 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 efficacious. We cannot ensure that any compound developed by us, alone or with others, will prove to be safe and efficacious in clinical trials and will meet all of the applicable regulatory requirements needed to receive marketing clearance.

We and our contract manufacturers also are required to comply with the applicable FDA current Good Manufacturing Practice regulations. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well as the corresponding 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. We or our contract manufacturers may not be able to comply with the applicable Good Manufacturing Practice requirements and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions, or be precluded from marketing our products.

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 may include additional risks.

**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 firms and universities and other research institutions. We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibiotic and antifungal products. These companies have commenced clinical trials or have successfully commercialized their products. Many of these companies are addressing the same diseases and disease indications as we, or our collaborators, are addressing.

Many of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development staffs 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.

Developments by others may render our product candidates or technologies obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies for establishing relationships with academic and research institutions, and for licenses of proprietary technology. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are more effective, less expensive, have fewer side effects or are easier to administer than ours. In addition, some of our competitors have greater experience than us in conducting preclinical and human clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than us. Companies that complete clinical trials, obtain required regulatory agency approvals



and commence commercial sales of their drugs before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that would delay our ability to market certain products. There can be no assurance that drugs resulting from our research and development efforts, or from joint efforts with our collaborators, will obtain regulatory approval in the United States or elsewhere or will be able to compete successfully with our competitors' existing products or products under development.

**If our intellectual property rights do not adequately protect our product candidates, 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 proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether they will be enforceable. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against

competitors with similar technologies. The laws of certain foreign countries do not protect our 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 may 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 proprietary 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 products.**

Research has been conducted for many years in the areas in which we have focused 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 depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Our technologies may infringe the patents or violate other proprietary rights of third parties. In the event an infringement claim is brought against us, we may be required to pay legal and other expenses to defend such claim and, if we are unsuccessful, we and our collaborators may be prevented from pursuing product development and commercialization and may 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 suits, United States 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 may 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 proprietary 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 may subject us to loss of our proprietary position or to significant liabilities, or require us to seek licenses that may not be available from third parties. We may be restricted or prevented from manufacturing and selling our 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 may be substantial and may include ongoing royalties. Furthermore, we may 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 product candidates, our revenues and prospects for profitability will be harmed.**

In both domestic and foreign markets, sales of our product candidates 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 may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial and other resources. Our product candidates may not ultimately be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our 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 may 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, may expose us to product liability claims. We have obtained limited product liability insurance coverage for our clinical trials. Our insurance coverage limits are $10 million per occurrence and $10 million in the aggregate. Such insurance coverage may not protect us against all of the claims to which we may become subject. We may 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 may 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 may be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm our business.



**ITEM 2. PROPERTIES**

Our facilities currently consist of approximately 55,400 square feet of office and laboratory facilities located in Fremont, California, which is leased to us until November 2009, and an aggregate of approximately 9,500 square feet of office facilities in King of Prussia, Pennsylvania, which is leased to us until September 2007. 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**

No matters were submitted to a vote of shareholders during the last quarter of our fiscal year ended December 31, 2001.



**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 August 8, 2000, the date of our initial public offering, through March 4, 2002, the high and low closing prices, as reported on the NASDAQ composite trading system, for the periods shown:

| | Sales Prices | |
|---|---|---|
| | **High** | **Low** |

| | Sales Prices | |
|---|---|---|
| **2000** | | |
| Third Quarter, commencing on August 8, 2000 through September 30, 2000 | $ 16.31 | $ 9.38 |
| Fourth Quarter | $ 14.06 | $ 5.75 |
| **2001** | | |
| First Quarter | $ 9.44 | $ 7.06 |
| Second Quarter | $ 13.87 | $ 6.63 |
| Third Quarter | $ 15.67 | $ 11.95 |
| Fourth Quarter | $ 20.99 | $ 13.66 |
| **2002** | | |
| First Quarter through March 4, 2002 | $ 24.16 | $ 17.34 |

As of March 4, 2002, there were approximately 86 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**

From January 1, 1999 through December 31, 2001, we sold and issued the following unregistered securities:

In March 1999, we sold 625,000 shares of Series D-1 Preferred Stock to a strategic investor for $3.8 million.

In March 1999, we sold 625,000 shares of Series E-1 Preferred Stock to another strategic investor for $3.0 million.

In October 1999, we sold 8,513,388 shares of Series F Preferred Stock to private investors; 1,204,072 shares upon conversion of $5.5 million of bridge loans issued in June 1999, plus accrued interest, and 7,309,316 shares for cash of $35.0 million.

The above securities were offered and sold by us in reliance upon exemptions from registration pursuant to Section 4(2) of the Securities Act of 1933 as transactions not involving any public offering or Rule 701 promulgated under the Securities Act of 1933. The recipients of the above-described securities represented their intention to acquire the securities for investment only and not with a view to distribution thereof. Appropriate legends were affixed to the stock certificates issued in such transactions. All recipients had adequate access to information about the Registrant.



**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. To date we have not used any of the net offering proceeds from the offering. We expect to use the net proceeds in the future primarily for the clinical development and commercialization of our drug candidates as well as for general corporate purposes, including working capital and research expenses.

**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, 2001, 2000, 1999, 1998 and 1997 is derived from our audited financial statements.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | (in thousands, except per share amounts) | | | | |
| **Statement of Operations Data:** | | | | | |
| **Revenues:** | | | | | |
| Collaborative research and development and contract services | $ 6,145 | $ 5,338 | $ 3,750 | $ | $ |
| License fees and milestones | 283 | 533 | 525 | | |
| Total revenues | 6,428 | 5,871 | 4,275 | | |
| Operating expenses: | | | | | |
| Research and development non-cash stock compensation expense | 2,359 | 2,073 | 3,315 | 536 | |
| Research and development other | 30,253 | 13,458 | 22,157 | 10,893 | 5,403 |
| Total research and development | 32,612 | 15,531 | 25,472 | 11,429 | 5,403 |
| General and administrative non-cash stock compensation expense | 2,599 | 5,631 | 1,081 | 1 | |
| General and administrative other | 7,001 | 3,260 | 1,505 | 1,385 | 807 |
| Total general and administrative | 9,600 | 8,891 | 2,586 | 1,386 | 807 |
| Total operating expenses | 42,212 | 24,422 | 28,058 | 12,815 | 6,210 |
| Loss from operations | (35,784) | (18,551) | (23,783) | (12,815) | (6,210) |
| Other income (expense): | | | | | |
| Interest income | 3,313 | 3,712 | 749 | 770 | 104 |
| Interest expense | (316) | (482) | (6,171) | (540) | (178) |
| Other | (60) | 18 | (14) | | |
| Net loss | (32,847) | (15,303) | (29,219) | (12,585) | (6,284) |
| Deemed dividends related to beneficial conversion feature of preferred stock | | | (35,112) | | |
| Accretion of dividends on preferred stock | | (3,486) | (3,063) | (2,527) | (422) |
| Net loss available to common stockholders | $ (32,847) | $ (18,789) | $ (67,394) | $ (15,112) | $ (6,706) |
| Net loss per share: | | | | | |
| Basic and diluted | $ (1.42) | $ (1.95) | $ 127.28 | $ (47.11) | $ (24.31) |
| Weighted average shares | 23,090 | 9,638 | 530 | 321 | 276 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2001 | 2000 | 1999 | 1998 | 1997 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | (in thousands) | | | | |
| **Balance sheet data:** | | | | | |
| Cash and cash equivalents and marketable securities | $ 63,768 | $ 85,934 | $ 34,619 | $ 4,507 | $ 14,491 |
| Total assets | 70,697 | 91,596 | 45,233 | 15,865 | 26,258 |
| Term loan payable, less current portion | 1,004 | 3,448 | 4,310 | 5,172 | 6,034 |
| Convertible and redeemable preferred stock | | | 83,843 | 33,984 | 31,472 |
| Accumulated deficit | (103,823) | (70,976) | (55,673) | (26,454) | (12,536) |
| Total stockholders' equity (deficit) | 52,894 | 80,287 | (48,796) | (27,076) | (12,551) |



## 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 the 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 these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the discovery, development and marketing of pharmaceutical products for the treatment of bacterial and fungal infections. Since our inception on May 2, 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 and on August 8, 2000, we sold 4,600,000 shares of our common stock at $11 per share in an initial public offering and on September 7, 2000, the underwriters exercised an over-allotment option and purchased an additional 690,000 shares of common stock at $11 per share. We received total net proceeds from the initial public offering and the over-allotment of approximately $52.7 million.

Since we began our operations in May 1995, we have not generated any revenues from product sales. Our lead product candidate, anidulafungin, is in Phase III clinical trials and our second product candidate, dalbavancin, is in Phase II clinical trials. We also have several lead compounds in preclinical studies and in June 2001, Pharmacia Corporation started clinical development of one of the compounds in our oxazolidinone program for which we have received a milestone payment.

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 certain milestones. If our development efforts result in clinical success, regulatory approval and successful commercialization of our products, we will generate revenues from sales of our products and from receipt of royalties on sales of licensed products.

Our expenses have consisted primarily of costs incurred 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. We also expect that our general and administrative expenses will increase as we add personnel and continue to expand our research and development operations. In addition, 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, 2001, we had an accumulated deficit of $103.8 million. We anticipate incurring additional losses, which may increase, for the foreseeable future, including at least through December 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.

**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 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.

We recorded deferred stock compensation (net of cancellations) of approximately $(294,000), $4.4 million and $15.9 million for the years ended December 31, 2001, 2000 and 1999, respectively. These amounts were recorded as a component of stockholders' equity (deficit) and are being amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred stock compensation of approximately $5.0 million, $7.7 million and $4.4 million for the years ended December 31, 2001, 2000 and 1999, respectively.

**Results of Operations**

*Years ended December 31, 2001, 2000 and 1999*

*Revenues.* Revenues were $6.4 million, $5.9 million and $4.3 million in 2001, 2000 and 1999, respectively. Revenues consisted of $3.7 million, $3.1 million and $2.1 million of collaborative research and development, contract services and licensing fees from Pharmacia in 2001, 2000 and 1999, respectively, and $2.7 million, $2.8 million and $2.2 million of collaborative research and development fees and milestone payments from Novartis in 2001, 2000 and 1999, respectively. The increase in revenues in both 2001 and 2000 is due to the increase in collaborative research and development funding from both Pharmacia and Novartis.

*Research and development expenses.* Research and development expenses were $32.6 million, $15.5 million and $25.5 million in 2001, 2000 and 1999, 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 2001 and 2000, we recorded $2.4 million and $2.1 million of amortization of non-cash stock compensation, respectively. During 1999, we recorded $14.0 million of expense related to license fees and product inventory paid to Eli Lilly and amortization of non-cash stock compensation of $3.3 million. Excluding these payments to Eli Lilly and the non-cash stock compensation expenses, research and development expenses were $30.3 million, $13.5 million and $7.3 million in 2001, 2000 and 1999, respectively. The increase in research and development expenditure in both 2001 and 2000 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. In addition, we have expanded our collaborative and internal research programs.

*General and administrative expenses.* General and administrative expenses were $9.6 million, $8.9 million and $2.6 million in 2001, 2000 and 1999, 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. General and administrative costs included amortization of non-cash stock compensation expense of $2.6 million, $5.6 million and $1.1 million in 2001, 2000 and 1999, respectively. Excluding the amortization of non-



cash stock compensation charges, general and administrative expenses were $7.0 million, $3.3 million and $1.5 million in 2001, 2000 and 1999, respectively. The increase in general and administrative expenses in 2001 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. The increase in general and administrative expenses in 2000 is due to the increase in personnel, legal, insurance and other expenses associated with being a public company.

*Net interest income (expense).* Net interest income (expense) was $3.0 million, $3.2 million and $(5.4) million in 2001, 2000 and 1999, respectively. Net interest income (expense) consists of interest income on cash and cash equivalents and marketable securities and interest expense on term loans payable, and in 1999, on a bridge financing. The decrease in interest income in 2001 is due to the reduction in interest rates during 2001. The increase in interest income in 2000 is due to the higher average cash and investment balances we maintained as a result of our initial public offering in August 2000. In 1999, interest expense includes non-cash interest expense of $5.5 million related to the beneficial conversion feature and the fair value of warrants issued in connection with a bridge loan financing.

*Income taxes.* As of December 31, 2001, we had federal and state net operating loss carryforwards of approximately $49.9 million and $17.3 million, respectively. As of December 31, 2001, 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 $1.0 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**

Since our inception through 1999, we 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. In addition, on August 8, 2000, we sold 4.6 million shares of our common stock at $11 per share in an initial public offering. On September 7, 2000, the underwriters executed an overallotment option and purchased an additional 690,000 shares of common stock at $11 per share. We received total net proceeds of approximately $52.7 million from the initial public offering and the overallotment after payment of underwriting discounts and commissions and other expenses. The net proceeds have been invested in highly liquid, interest bearing, investment grade securities. Upon the closing of the initial public offering, all of our preferred stock automatically converted into shares of common stock.

As of December 31, 2001, we have also received $21.6 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborative partners, including Sepracor. Of these payments, $2.1 million constitutes deferred revenue as of December 31, 2001.

In addition we have a $6.0 million term loan agreement with a commercial bank. This loan bears interest at a rate of prime plus 0.50% and is payable in 15 equal quarterly installments of $216,000, with the balance due on December 31, 2002. The net proceeds of this loan were used to repay Sepracor for leasehold improvements to our facilities and for general corporate purposes. As of December 31, 2001, there was an outstanding loan balance of $3.4 million. In October 2001, the loan agreement was amended to include a four-year equipment note for $2.0 million that we are able to draw down on through June 30, 2002 for specified purposes. The loan 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 loan is payable in quarterly installments commencing on March 31, 2002. The principal of the note is payable in equal installments beginning on March 31, 2002 with the final payment due on December 31, 2004. As of December 31, 2001, there was an outstanding note balance of $1.5 million.



Cash used in operations was $21.4 million, $215,000 and $15.4 million in 2001, 2000 and 1999, respectively. 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 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. In 1999, the net loss of $29.2 million was offset by non-cash charges for non-cash stock compensation, depreciation and interest expense on bridge loans of $10.8 million.

Investing activities used $16.3 million, $18.4 million and $264,000 of cash during 2001, 2000 and 1999, respectively. In 2001, cash was primarily used for the net purchases of marketable securities of $14.4 million and the purchase of property and equipment of $2.0 million. In 2000, cash was primarily used for the net purchases of marketable securities with the net proceeds of our initial public offering, and in 1999 cash was used for the purchase of property and equipment.

Financing activities provided $1.0 million, $52.0 million and $45.8 million of cash in 2001, 2000 and 1999, respectively. 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, and in 1999 we received net proceeds of $41.1 million from the issuance of preferred stock.

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 related to additions to personnel and production and commercialization efforts. 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 collaborative agreements, continued research and development of our product candidates, 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 will be sufficient to fund our operating expenses, debt repayments and capital equipment requirements for approximately two years.

Except for the term loan and equipment loan, we have no credit facility or other committed sources of capital. To the extent our capital resources are insufficient to meet future capital requirements, we will need to raise additional capital or incur indebtedness to fund our operations. We cannot guarantee that additional debt or equity financing will be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate research and development programs, reduce our commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates or lead compounds that we might otherwise seek to develop or commercialize. Any future funding may dilute the ownership of our equity investors.

**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*

The Company recognizes 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 as specified in the related collaboration agreements. Collaborative research and development payments are recognized as the related work is performed.

*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.

**Recent Accounting Pronouncements**

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method  the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortized to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortization of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. Versicor is required to adopt SFAS 142 in the first quarter of fiscal year 2002. We believe that the adoption of these standards will have no impact on our financial statements.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect

the adoption of SFAS 144 to have a material impact on the Company's financial position or results of operations.

**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 loan 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 (in thousands):

| | 2002 |
|---|---|
| Cash and cash equivalents | $ 31,349 |
| Average interest rate | 2.01% |
| Marketable securities | $ 32,321 |
| Average interest rate | 2.98% |

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.

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

The information required by this item is included in Item 14 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.



**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 to be held on June 6, 2002, 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 to be held on June 6, 2002, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

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

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 to be held on June 6, 2002, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.

**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 to be held on June 6, 2002, filed with the Securities and Exchange Commission pursuant to Regulation 14-A.



**PART IV**

**ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

**Item 14(a)1. Financial Statements**

**INDEX TO FINANCIAL STATEMENTS**



**Item 14(a)2. Financial Statement Schedules**

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 14(a)3. Exhibits**

**Description**

| Exhibit Number | |
|---|---|
| 3.1 | Restated Certificate of Incorporation of Versicor Inc.(1) |
| 3.2 | Amended and Restated Bylaws of Versicor Inc.(1) |
| 4.1 | Form of Common Stock Certificate(1) |
| 4.2 | Warrant for the Purchase of Shares of Common Stock dated as of March 10, 1997 by and between Genome Therapeutics, Inc. and Versicor Inc.(1) |
| 4.3 | Form of Warrant for the Purchase of Shares of Series C Preferred Stock dated as of December 9, 1997(1) |
| 4.4 | Form of Warrant for the Purchase of Shares of Series F Preferred Stock dated as of June 25, 1999(1) |
| 4.5 | Second Amended and Restated Investor Rights Agreement(1) |
| 10.1* | 1995 Stock Option Plan(1) |
| 10.2* | Form of 1995 Incentive Stock Option Agreement(1) |
| 10.3* | Form of 1995 Non-Statutory Stock Option Agreement(1) |
| 10.4* | 1997 Equity Incentive Plan(1) |
| 10.5* | Form of 1997 Stock Option Award Agreement(1) |
| 10.6* | 2000 Employee Stock Purchase Plan(1) |
| 10.7 | License Agreement dated as of February 12, 1998 by and between Biosearch Italia, S.p.A. and Versicor Inc.(1) |
| 10.8 | License Agreement dated as of May 17, 1999 by and between Eli Lilly and Versicor Inc.(1) |
| 10.9 | Collaboration and License Agreement dated as of March 31, 1999 by and between Novartis Pharma AG and Versicor Inc.(1) |



| | |
|---|---|
| 10.10 | Collaboration and License Agreement dated as of March 31, 1999 by and between Pharmacia Corporation and Versicor Inc.(1) |
| 10.11 | Collaboration Agreement dated as of February 12, 1998 by and between Biosearch Italia, S.p.A. and Versicor Inc.(1) |
| 10.11.1 | Addendum No. 1 to Collaboration Agreement dated as of January 2001 by and between Versicor Inc. and Biosearch Italia, S.p.A.(2) |
| 10.12 | Administrative Services Agreement dated as of December 1997 by and between Sepracor Inc. and Versicor Inc.(1) |
| 10.13* | Employment Agreement dated as of July 28, 2000 by and between George F. Horner III and Versicor Inc.(1) |
| 10.14* | Employment Agreement dated as of July 28, 2000 by and between Richard J. White and Versicor Inc.(1) |
| 10.15* | Employment Agreement dated as of July 28, 2000 by and between Dinesh V. Patel and Versicor Inc.(1) |
| 10.16* | Employment Agreement dated as of July 28, 2000 by and between Paul F. Truex and Versicor Inc.(1) |
| 10.17* | Promissory Note dated as of May 15, 1997 by and between Richard J. White and Versicor Inc.(1) |
| 10.18* | Promissory Note dated as of April 24, 1996 by and between Dinesh V. Patel and Versicor Inc.(1) |
| 10.19* | Consulting Agreement dated as of March 11, 1998 by and between Dr. Christopher Walsh and Versicor Inc.(1) |
| 10.20* | Consulting Agreement dated as of January 1, 1997 by and between Dr. David Milligan and Versicor Inc.(1) |
| 10.21 | Term Loan Agreement dated as of December 30, 1997 by and between Fleet National Bank and Versicor Inc.(1) |
| 10.22 | Industrial Lease dated as of November 18, 1996 by and between Arcadia-Tavistock, L.C. and Versicor Inc.(1) |
| 10.23 | Indemnity Agreement dated as of October 29, 1999 by and between Thomas C. McConnell and Versicor Inc.(1) |
| 10.24 | Indemnity Agreement dated as of October 29, 1999 by and between Mark Leschly and Versicor Inc.(1) |
| 10.25 | Indemnity Agreement dated as of October 29, 1999 by and between George F. Horner III and Versicor Inc.(1) |
| 10.26 | Indemnity Agreement dated as of October 29, 1999 by and between James H. Cavanaugh and Versicor Inc.(1) |
| 10.27 | |

| | |
|---|---|
| | Indemnity Agreement dated as of October 29, 1999 by and between Christopher T. Walsh and Versicor Inc.(1) |
| 10.28 | Indemnity Agreement dated as of October 29, 1999 by and between Richard J. White and Versicor Inc.(1) |
| 10.29 | Indemnity Agreement dated as of October 29, 1999 by and between David V. Milligan and Versicor Inc.(1) |



| | |
|---|---|
| 10.30 | Indemnity Agreement dated as of October 29, 1999 by and between Lori Rafield and Versicor Inc.(1) |
| 10.31 | Indemnity Agreement dated as of October 29, 1999 by and between Timothy J. Barberich and Versicor Inc.(1) |
| 10.32* | Employment Agreement dated as of July 28, 2000 by and between Dov A. Goldstein and Versicor Inc.(1) |
| 10.33* | Employment Agreement dated as of July 28, 2000 by and between Mikhail F. Gordeev and Versicor Inc.(1) |
| 10.34* | Employment Agreement dated as of July 28, 2000 by and between Joaquim Trias and Versicor Inc.(1) |
| 10.35* | Employment Agreement dated as of July 28, 2000 by and between Zhengyu Yuan and Versicor Inc.(1) |
| 10.36* | Employment Agreement, dated as of December 18, 2000, by and between Versicor Inc. and Tim Henkel(2) |
| 10.37* | Amended and Restated Promissory Note dated as of December 28, 2000 by and between Paul F. Truex and Versicor Inc.(2) |
| 10.38 | Versicor Manufacturing Development and Supply Agreement between Versicor Inc. and Abbott Laboratories dated June 25, 2001(3) |
| 10.39* | 2001 Stock Option Plan(4) |
| 10.40 | Second Amendment to Term Loan Agreement dated October 22, 2001, by and between Fleet National Bank and Versicor Inc.(5) |
| 23.1 | Consent of PricewaterhouseCoopers, LLP, Independent Accountants(5) |

* Denotes management contract or compensatory plan.

(1) Previously filed as an exhibit to the Company's registration statement on Form S-1, effective August 2, 2000, and incorporated here by reference.

(2) Previously filed as an exhibit to the Company's report on Form 10-K for the year ended December 31, 2000, and incorporated here by reference.

(3) Incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the period ended June 30, 2001.

(4) Incorporated by reference to Exhibit 10.1 of the Company's report on Form 10-Q for the period ended September 30, 2001.

(5) Filed herewith.

**Item 14(b). Reports on Form 8-K**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, Versicor Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**VERSICOR INC.**
*(Registrant)*

BY: /s/ GEORGE F. HORNER III

Dated: March 12, 2002

George F. Horner III
*Chief Executive Officer and President*

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each of the persons whose names appear below appoint and constitute George F. Horner, III and Dov A. Goldstein, M.D., and each one of them, acting individually and without the other, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to execute any and all amendments to this Report on Form 10-K and to file the same, together with all exhibits thereto, with the Securities and Exchange Commission, and such other agencies, offices and persons as may be required by applicable law, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each said attorney-in-fact and agent may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Report on Form 10-K has been signed by the following persons in the capacities and on the dates indicated:

| Signature | Title | Date |
|---|---|---|
| /s/ DAVID V. MILLIGAN, PH.D.<br>David V. Milligan, Ph.D. | Chairman of the Board | March 12, 2002 |
| /s/ GEORGE F. HORNER III<br>George F. Horner III | President and Chief Executive Officer (and principal executive officer) | March 12, 2002 |
| /s/ DOV A. GOLDSTEIN, M.D.<br>Dov A. Goldstein, M.D. | Chief Financial Officer<br>(and principal accounting officer) | March 12, 2002 |
| /s/ TIMOTHY J. BARBERICH<br>Timothy J. Barberich | Director | March 12, 2002 |
| /s/ JAMES H. CAVANAUGH, PH.D.<br>James H. Cavanaugh, Ph.D. | Director | March 12, 2002 |

| | | |
|---|---|---|
| /s/ MARK LESCHLY<br>Mark Leschly | Director | March 12, 2002 |
| /s/ LORI F. RAFIELD, PH.D.<br>Lori F. Rafield, Ph.D. | Director | March 12, 2002 |
| /s/ CHRISTOPHER T. WALSH, PH.D.<br>Christopher T. Walsh, Ph.D. | Director | March 12, 2002 |
| /s/ RICHARD J. WHITE, PH.D.<br>Richard J. White, Ph.D. | Director | March 12, 2002 |



**REPORT OF INDEPENDENT ACCOUNTANTS**

To the Board of Directors and Stockholders of
Versicor Inc.

In our opinion, the financial statements listed in the index appearing under Item 14(a) 1 on page 41 present fairly, in all material respects, the financial position of Versicor Inc. at December 31, 2001 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP
San Jose, California
February 11, 2002



**VERSICOR INC.**
**BALANCE SHEETS**
**(in thousands, except per share amounts)**

| | December 31, | |
|---|---|---|
| | **2001** | **2000** |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 31,349 | $ 67,989 |
| Marketable securities | 32,419 | 17,945 |
| Employee notes receivable | 13 | 357 |

| | December 31, | |
|---|---|---|
| Prepaid expenses and other current assets | 1,624 | 591 |
| Total current assets | 65,405 | 86,882 |
| Property and equipment, net | 5,197 | 4,384 |
| Employee notes receivable | | 188 |
| Other assets | 95 | 142 |
| Total assets | $ 70,697 | $ 91,596 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 4,335 | $ 1,421 |
| Accrued liabilities | 6,278 | 3,225 |
| Related party payable | | 12 |
| Current portion of term loan payable | 3,950 | 862 |
| Deferred revenue | 1,561 | 1,233 |
| Total current liabilities | 16,124 | 6,753 |
| Term loan payable | 1,004 | 3,448 |
| Deferred revenue | 500 | 108 |
| Other long-term liabilities | 175 | 1,000 |
| Total liabilities | 17,803 | 11,309 |
| Commitments (Notes 7 and 12) | | |
| Stockholders' equity: | | |
| Preferred Stock, $0.001 par value; 5,000 shares authorized at December 31, 2001 and 2000; no shares issued and outstanding | | |
| Common stock, $0.001 par value, 100,000 shares authorized at December 31, 2001 and 2000; 23,242 and 23,042 shares issued and outstanding at December 31, 2001 and 2000, respectively | 23 | 23 |
| Additional paid-in capital | 160,163 | 160,059 |
| Deferred stock compensation | (3,567) | (8,819) |
| Accumulated other comprehensive income | 98 | |
| Accumulated deficit | (103,823) | (70,976) |
| Total stockholders' equity | 52,894 | 80,287 |
| Total liabilities and stockholders' equity | $ 70,697 | $ 91,596 |

The accompanying notes are an integral part of these financial statements



**VERSICOR INC.**
**STATEMENTS OF OPERATIONS**
**(in thousands, except per share amounts)**

**Year Ended December 31,**

| | 2001 | 2000 | 1999 |
|---|---|---|---|
| Revenues: | | | |
| Collaborative research and development and contract services | $ 6,145 | $ 5,338 | $ 3,750 |
| License fees and milestones | 283 | 533 | 525 |
| Total revenues | 6,428 | 5,871 | 4,275 |
| Operating expenses: | | | |
| Research and development non-cash stock compensation expense | 2,359 | 2,073 | 3,315 |
| Research and development other | 30,253 | 13,458 | 22,157 |
| Total research and development | 32,612 | 15,531 | 25,472 |
| General and administrative non-cash stock compensation expense | 2,599 | 5,631 | 1,081 |
| General and administrative other | 7,001 | 3,260 | 1,505 |
| Total general and administrative | 9,600 | 8,891 | 2,586 |
| Total operating expenses | 42,212 | 24,422 | 28,058 |
| Loss from operations | (35,784) | (18,551) | (23,783) |
| Other income (expense): | | | |
| Interest income | 3,313 | 3,712 | 749 |
| Interest expense | (316) | (482) | (6,171) |
| Other | (60) | 18 | (14) |
| Net loss | (32,847) | (15,303) | (29,219) |
| Deemed dividends related to beneficial conversion feature of preferred stock | | | (35,112) |
| Accretion of dividends on preferred stock | | (3,486) | (3,063) |
| Net loss available to common stockholders | $ (32,847) | $ (18,789) | $ (67,394) |
| Net loss per share: | | | |
| Basic and diluted | $ (1.42) | $ (1.95) | $ (127.28) |
| Weighted average shares | 23,090 | 9,638 | 530 |

The accompanying notes are an integral part of these financial statements



**VERSICOR INC.**
**STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**

**(in thousands)**

| | Common Stock | | | | | | |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | Additional Paid In Capital | Deferred Stock Compensation | Accumulated Other Comprehensive Income | Accumulated Deficit | Total |
| Balances, December 31, 1998 | 386 | $ | $ | $ (622) | $ | $ (26,454) | $ (27,076) |
| Exercise of common stock options | 47 | | 19 | | | | 19 |
| Issuance of common stock under license agreement | 250 | 1 | 646 | | | | 647 |
| Exercise of warrants | | | 623 | | | | 623 |
| Issuance of bridge loans with beneficial conversion feature | | | 4,877 | | | | 4,877 |
| Deferred stock compensation | | | 15,882 | (15,882) | | | |
| Amortization of deferred stock compensation | | | | 4,396 | | | 4,396 |
| Accretion of dividends on preferred stock | | | (3,063) | | | | (3,063) |
| Issuance of preferred stock with beneficial conversion feature | | | 35,112 | | | | 35,112 |
| Deemed dividends on preferred stock | | | (35,112) | | | | (35,112) |
| Net loss | | | | | | (29,219) | (29,219) |
| Balances, December 31, 1999 | 683 | 1 | 18,984 | (12,108) | | (55,673) | (48,796) |
| Exercise of common stock options | 392 | | 151 | | | | 151 |
| Conversion of preferred stock to common stock | 16,677 | 17 | 87,312 | | | | 87,329 |
| Issuance of common stock in initial public offering, net of issuance costs | 5,290 | 5 | 52,683 | | | | 52,688 |
| Deferred stock compensation | | | 4,415 | (4,415) | | | |
| Amortization of deferred stock compensation | | | | 7,704 | | | 7,704 |
| Accretion of dividends on preferred stock | | | (3,486) | | | | (3,486) |
| Net loss | | | | | | (15,303) | (15,303) |
| Balances, December 31, 2000 | 23,042 | 23 | 160,059 | (8,819) | | (70,976) | 80,287 |
| Exercise of common stock options | 175 | | 369 | | | | 369 |
| Exercise of common stock warrants | 22 | | | | | | |
| Issuance of common stock under Employee Stock Purchase Plan | 3 | | 29 | | | | 29 |
| Deferred stock compensation | | | (294) | 294 | | | |
| Amortization of deferred stock compensation | | | | 4,958 | | | 4,958 |
| Change in unrealized gain on investments | | | | | 98 | | 98 |
| Net loss | | | | | | (32,847) | (32,847) |
| Balances, December 31, 2001 | 23,242 | $ 23 | $ 160,163 | $ (3,567) | $ 98 | $ (103,823) | $ 52,894 |

The accompanying notes are an integral part of these financial statements



**VERSICOR INC.**
**STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |

| | Year Ended December 31, | | |
|---|---|---|---|
| **Cash flows from operating activities:** | | | |
| Net loss | $ (32,847) | $ (15,303) | $ (29,219) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 1,026 | 880 | 944 |
| Loss on disposal of property and equipment | 60 | | |
| Non-cash stock compensation expense | 4,958 | 7,704 | 4,396 |
| Accrued interest on convertible note | | | 182 |
| Non-cash interest expense on bridge loans | | | 5,500 |
| Changes in operating assets and liabilities: | | | |
| Employee notes receivable | 532 | 48 | (24) |
| Prepaid expenses and other current assets | (1,033) | (547) | 104 |
| Restricted cash | | 5,000 | |
| Other assets | 47 | 18 | (15) |
| Accounts payable | 2,914 | 1,335 | (119) |
| Accrued liabilities | 3,053 | 1,293 | (93) |
| Related party payable | (12) | (9) | (26) |
| Deferred revenue | 720 | 366 | 975 |
| Other long-term liabilities | (825) | (1,000) | 2,000 |
| Net cash used in operating activities | (21,407) | (215) | (15,395) |
| **Cash flows from investing activities:** | | | |
| Purchases of marketable securities | (54,714) | (41,153) | |
| Sales/maturities of marketable securities | 40,338 | 23,208 | |
| Additions to property and equipment | (1,956) | (447) | (264) |
| Disposals of property and equipment | 57 | | |
| Net cash used in investing activities | (16,275) | (18,392) | (264) |
| **Cash flows from financing activities:** | | | |
| Proceeds from bridge loans and warrants | | | 5,500 |
| Proceeds from initial public offering, net | | 52,688 | |
| Proceeds from issuance of common stock, net | 398 | 151 | 19 |
| Proceeds from issuance of preferred stock, net | | | 41,113 |
| Proceeds from long-term debt | 1,506 | | |
| Repayments of long-term debt | (862) | (862) | (862) |
| Other | | | 1 |
| Net cash provided by financing activities | 1,042 | 51,977 | 45,771 |
| Net change in cash and cash equivalents | (36,640) | 33,370 | 30,112 |
| Cash and cash equivalents at beginning of year | 67,989 | 34,619 | 4,507 |
| Cash and cash equivalents at end of year | $ 31,349 | $ 67,989 | $ 34,619 |
| **Noncash transactions:** | | | |
| Conversion of convertible subordinated notes and accumulated interest into Series F Preferred Stock | $ | $ | $ 5,683 |

| | Year Ended December 31, | | |
|---|---|---|---|
| Issuance of common stock under license agreement | $ | $ | $ 647 |
| Conversion of preferred stock to common stock | $ | $ 87,329 | $ |
| **Supplemental cash flow information:** | | | |
| Cash paid during the year for interest | $ 302 | $ 440 | $ 651 |

The accompanying notes are an integral part of these financial statements



**VERSICOR INC.**

**NOTES TO FINANCIAL STATEMENTS**

## NOTE 1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

***The Company***

Versicor Inc. ("Versicor" or the "Company") is a biopharmaceutical company focused on the discovery, development and marketing of drugs for the treatment of serious bacterial and fungal infections, primarily in the hospital setting. Since our inception on May 2, 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 and on August 8, 2000, we sold 4,600,000 shares of our common stock at $11 per share in an initial public offering, and on September 7, 2000 the underwriters exercised an over-allotment option and purchased an additional 690,000 shares of common stock at $11 per share. We received total net proceeds from the initial public offering and the over-allotment of approximately $52.7 million.

At December 31, 2001, Sepracor's ownership of the Company is approximately 7.8%. Through December 31, 2000, Sepracor provided certain facilities, support and administrative services under an administrative services agreement. Although this agreement expired on June 30, 1998, the companies continued to operate under the agreement until December 2000. The Company paid $143,000 and $78,000 to Sepracor under this agreement in 2000 and 1999, respectively. As a result of this agreement, the financial statements for 2000 and 1999 may not be indicative of the results that would have been achieved had the Company operated as a nonaffiliated entity. General and administrative costs on a stand-alone basis would not have been materially different from those recorded in the Company's statements of operations.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management 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. Actual results could differ from those estimates.

***Certain Risks and Uncertainties***

The Company is subject to risks common to companies in its industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, product liability, the need to obtain financing and such other matters more particularly set forth in "Risk Factors".

***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Included in cash equivalents are commercial paper instruments aggregating $14.5 million and $56.1 million at December 31, 2001 and 2000, respectively.



***Marketable Securities***

The Company has classified its marketable securities as available for sale in accordance with Statement of Financial Accounting Standard No. 115, "Accounting for Certain Investments in Debt and Equity Securities". The marketable securities are reported at fair value with unrealized gains and losses recorded as a separate component of stockholders' equity.

***Fair Value of Financial Instruments***

The carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents and accounts payable approximate fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans with similar terms, the carrying value of its debt obligations approximates fair value.

***Property and Equipment***

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the assets, including ten years for leasehold improvements and fixtures and furniture, seven years for laboratory equipment and three years for computers, software and office equipment, or the lease term of the respective assets, if shorter. Gains and losses upon asset disposal are reflected in operations in the year of disposal.

***Long-Lived Assets***

The Company periodically reviews the value of long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the future undiscounted cash flows arising from the assets with the carrying value of the asset. If impairment is indicated, the asset is written down to its estimated fair value on a discounted cash flow basis.

***Revenue Recognition***

The Company recognizes 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 as specified in the related collaboration agreements. Collaborative research and development payments are recognized as the related work is performed. Deferred revenue is comprised of cash received in advance of the related revenue being recognized. All revenues recognized to date under research and development collaborations are not refundable if the relevant research effort is not successful.

***Research and Development***

Research and development costs are charged to operations as incurred. Certain research and development projects are funded by research and development contracts, and the expenses related to these activities are included in research and development costs.



***Business Segments***

The Company operates as a single business segment in the United States of America as defined in SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information."

***Stock-Based Compensation***

The Company accounts for its stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25 ("APB 25"), "Accounting for Stock Issued to Employees" and complies with the disclosure provisions of SFAS No. 123, "Accounting for Stock Based Compensation". Under APB 25, unearned compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company's stock and the exercise price. Unearned compensation is amortlzed and expensed in accordance with Financial Accounting Standards Board Interpretation No. 28. The Company accounts for stock issued to non-employees in accordance with the provisions of SFAS No. 123 and 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".

***Income Taxes***

The Company recognizes deferred tax liabilities and assets for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax liabilities and assets are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

***Net Loss Per Share***

Basic net loss per share is computed using the weighted average number of shares of common stock outstanding. Diluted net loss per share does not differ from basic net loss per share since potential common shares are antidilutive for all periods presented and therefore are excluded from the calculation of diluted net loss per share. The following potentially dilutive common shares were excluded from the computation of net loss per share because their effect was antidilutive:

| | December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| | (in thousands) | | |
| Convertible and redeemable convertible preferred stock | | | 16,677 |
| Stock options | 2,770 | 2,468 | 2,066 |
| Common stock warrants | 389 | 439 | 439 |
| Common stock subject to repurchase | 8 | 17 | 26 |
| | 3,167 | 2,924 | 19,208 |

The restricted shares subject to repurchase are excluded from the loss per share calculations until the restrictions lapse. The weighted average common shares outstanding has been adjusted by weighted average common stock subject to repurchase of 12,000, 21,000 and 30,000 in 2001, 2000 and 1999, respectively, to give the denominator for the basic and diluted loss per share calculations.



***Recent Accounting Pronouncements***

In July 2001, the Financial Accounting and Standards Board ("FASB") issued Statements of Financial Accounting Standards No. 141 ("SFAS 141"), "Business Combinations," and No. 142 ("SFAS 142"), "Goodwill and Other Intangible Assets." SFAS 141 requires that all business combinations initiated after June 30, 2001 be accounted for under a single method  the purchase method. Use of the pooling-of-interests method is no longer permitted. SFAS 142 requires that goodwill no longer be amortlzed to earnings, but instead be reviewed for impairment upon initial adoption of the Statement and on an annual basis going forward. The amortlzation of goodwill will cease upon adoption of SFAS 142. The provisions of SFAS 142 will be effective for fiscal years beginning after December 15, 2001. Versicor is required to adopt SFAS 142 in the first quarter of fiscal year 2002. We believe that the adoption of these standards will have no impact on our financial statements.

In October 2001, the FASB issued Statement of Financial Accounting Standards No. 144 ("SFAS 144"), "Accounting for the Impairment or Disposal of Long-Lived Assets," which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. This Statement supersedes FASB Statement No. 121and APB 30, however, this Statement retains the requirement of Opinion 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of (by sale, by abandonment, or in a distribution to owners) or is classified as held for sale. This Statement addresses financial accounting and reporting for the impairment of certain long-lived assets and for long-lived assets to be disposed of. Management does not expect

the adoption of SFAS 144 to have a material impact on the Company's financial position or results of operations.

**NOTE 2 MARKETABLE SECURITIES**

The following is a summary of marketable securities at December 31, 2001:

| | December 31, 2001 | | |
|---|---|---|---|
| | Amortized Cost | Unrealized Gains | Estimated Fair Value |
| | (in thousands) | | |
| Commercial paper | $ 9,914 | $ 45 | $ 9,959 |
| Government agency and corporate bonds | 22,407 | 53 | 22,460 |
| | $ 32,321 | $ 98 | $ 32,419 |

At December 31, 2001 and 2000, all marketable securities were classified as available-for-sale and were due in less than one year. At December 31, 2000, marketable securities comprised government agency and corporate bonds and were reported at cost, which due to the short-term maturities of the securities, approximated fair value. Realized gains and losses were immaterial for all periods presented.



**NOTE 3 PROPERTY AND EQUIPMENT**

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| | (in thousands) | |
| Leasehold improvements | $ 4,655 | $ 3,891 |
| Laboratory equipment | 2,763 | 2,593 |
| Computers, software and office equipment | 1,458 | 930 |
| Fixtures and furniture | 428 | 174 |
| | 9,304 | 7,588 |
| Less: accumulated depreciation | (4,107) | (3,204) |
| Property and equipment, net | $ 5,197 | $ 4,384 |

Depreciation expense was $1.0 million, $880,000 and $944,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

**NOTE 4 EMPLOYEE NOTES RECEIVABLE AND RELATED PARTY TRANSACTIONS**

In 1996, 1997 and 2000, the Company made an aggregate of $825,000 of loans to certain key employees and officers. The loans accrued interest at 5% per annum with the exception of two loans that are interest free and forgivable. The loans were collaterallzed by the stock options of the employees and/or deeds of trust on the employees' residences. During 2000 and 2001, three of the loans were repaid in full. The remaining loan balance of $13,000 at December 31, 2001 will be fully forgiven in April 2002.

In January 1997, the Company entered into a consulting agreement with a Director of the Company. Under this agreement, the Company pays the Director an annual fee of $100,000. The agreement terminated by its terms in December 1997, but has continued through mutual consent of the Company and the Director.

In March 1998, the Company entered into a scientific agreement with a Director. Under this agreement, the Company pays the Director an annual fee of $50,000. The agreement terminated in January 2001, however, the Company continues to operate under the terms of this agreement. In addition, we paid the Director an annual laboratory gift of $25,000 in 1999.

**NOTE 5 ACCRUED LIABILITIES**

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| | (in thousands) | |
| Research and development | $ 3,484 | $ 1,363 |
| Employee compensation | 1,081 | 1,055 |
| Legal | 1,197 | 219 |
| Other | 516 | 588 |
| | $ 6,278 | $ 3,225 |

**NOTE 6 BORROWINGS**

In December 1997, the Company and a commercial bank entered into a term loan, which is evidenced by two term notes in principal amounts of $2,000,000 and $4,034,000. The term loan is



payable quarterly in fifteen installments, with each installment equal to $216,000, plus accrued interest, commencing on March 31, 1999 with the final payment of the balance of $2,802,000 payable on December 31, 2002. The term notes bear interest at the prime rate plus 0.50% (5.25% at December 31, 2001). The term loan originally required that the Company keep $4.0 million on deposit with the lender and maintain an additional $1.0 million of cash and cash equivalents. These amounts were shown as restricted cash at December 31, 1999. Following the Company's initial public offering in August 2000, the terms of the loan were renegotiated and the Company is no longer required to maintain these balances. Starting with the fourth quarter of 2000, the Company is required to comply with certain financial covenants. As of December 31, 2001, the Company was in compliance with these covenants. The term loan is collaterallzed by certain assets of the Company. There was $3.5 million and $4.3 million outstanding under this term loan at December 31, 2001 and 2000, respectively.

In October 2001, the term loan was amended to include a four-year equipment note for $2.0 million that we are able to draw down on through June 30, 2002. 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 commencing on March 31, 2002. The principal of the note is payable in equal installments beginning on March 31, 2002 with the final payment due on December 31, 2004. As of December 31, 2001, there was an outstanding note balance of $1.5 million and we have exercised our option to pay interest on this portion of the loan at LIBOR (4.75% at December 31, 2001).

Future principal payments on the term loan and the equipment loan are as follows:

| Year Ending December 31, (in thousands) | |
|---|---|
| 2002 | $ 3,950 |
| 2003 | 502 |
| 2004 | 502 |

| Year Ending December 31, (in thousands) | |
|---|---|
| | $ 4,954 |

**NOTE 7 COMMITMENTS**

Future minimum lease payments under all noncancelable operating leases in effect at December 31, 2001 are as follows:

| Year Ending December 31, (in thousands) | |
|---|---|
| 2002 | $ 1,157 |
| 2003 | 1,199 |
| 2004 | 1,241 |
| 2005 | 1,283 |
| 2006 | 1,325 |
| Thereafter | 3,515 |
| | $ 9,720 |

Future minimum lease payments under operating leases primarily relate to the Company's office and laboratory space in California and Pennsylvania. Rental expense under these leases amounted to $1.2 million, $849,000 and $841,000 for the years ended December 31, 2001, 2000 and 1999, respectively.



**NOTE 8 STOCKHOLDERS' EQUITY**

In March 1999, the Company sold 625,000 shares of Series D-1 Preferred Stock to a strategic investor for $3.8 million and 625,000 shares of Series E-1 Preferred Stock to another strategic investor for $3.0 million. The issuance of the Series E-1 Preferred Stock resulted in a beneficial conversion feature of $750,000, calculated in accordance with Emerging Issues Task Force Topic D-60, "Accounting for the Issuance of Convertible Preferred Stock and Debt Securities with a Nondetachable Conversion Feature". The beneficial conversion feature was reflected as a deemed preferred stock dividend in the Statement of Operations for 1999.

In June 1999, the Company entered into a Note and Warrant Purchase Agreement with a group of investors, including Sepracor. Under the agreement, the investors agreed to lend the Company $11.0 million, of which $5.5 million was paid to Versicor in June 1999 at the first closing. The outstanding principal amount of the notes was due and payable to the investors by Versicor in June 2000. Interest on the notes accrued at 9.75% per annum and was payable annually. The issuance resulted in a beneficial conversion feature of $4.9 million, calculated in accordance with Emerging Issues Task Force No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features". The beneficial conversion feature was reflected as interest expense in the Statement of Operations for 1999. In October 1999, the holders converted the notes and accrued interest of $181,000 into the Company's Series F Preferred Stock. In connection with the financing, the investors were granted warrants to purchase 226,236 shares of Series F Preferred Stock at $4.00 per share.

In October 1999, the Company completed a private equity financing of approximately $40.0 million. The Company converted its $5.5 million of bridge loans, plus accrued interest, into 1,204,072 shares of Series F Preferred Stock and issued 7,309,316 shares of Series F Preferred Stock at $4.72 per share, for $35.0 million in cash. Issuance costs associated with the transaction were $137,000. The issuance resulted in a beneficial conversion feature of $34.4 million, calculated in accordance with Emerging Issues Task Force No. 98-5, "Accounting for Convertible Securities with Beneficial Conversion Features". The beneficial conversion feature was reflected as a deemed preferred stock dividend in the Statement of Operations for 1999.

On August 8, 2000, the Company sold 4,600,000 shares of its common stock at $11 per share in an initial public offering. On September 7, 2000, the underwriters executed an overallotment option and purchased an additional 690,000 shares of common stock at $11 per share. The Company received net proceeds of approximately $52.7 million from the initial public offering and the overallotment after payment of

underwriting discounts and commissions and other expenses. Immediately prior to the initial public offering, the Company split its common and preferred stock 5-for-4. Upon closing of the initial public offering, all of the Company's preferred stock automatically converted into 16,677,000 shares of common stock.

At December 31, 2001 and 2000, there were 7,500 and 16,500 shares of common stock, respectively, subject to repurchase. The common stock is subject to repurchase at the original issuance price of $0.001 per share.



**NOTE 9 STOCK OPTIONS AND WARRANTS**

***Stock options***

The 1995 Stock Option Plan ("1995 Plan") permits the Company to grant up to 315,000 shares of Common Stock as incentive stock options ("ISOs") and nonstatutory stock options ("NSOs"). The 1995 Plan was amended in 1997 to increase the maximum number of shares to be issued to 348,750. The 1995 Plan provides for the granting of ISOs to officers and key employees of the Company and NSOs to officers, key employees, consultants and directors of the Company. ISOs and NSOs granted under the 1995 Plan have a maximum term of ten years from the date of grant. Vesting provisions may vary but in each case will provide for vesting of at least 20% per year of the total number of shares subject to the option and have an exercise price not less than the fair value of the stock at the date of grant.

The 1997 Equity Incentive Plan ("1997 Plan") permits the Company to grant up to 1,401,250 shares of Common Stock as ISOs, NSOs, stock bonuses, rights to purchase restricted stock, and stock appreciation rights. In 1999, the 1997 Plan was amended to increase the maximum number of shares available to 2,638,030. In 2000, the 1997 Plan was amended again to increase the maximum number of shares available to 4,038,030. All options shall be separately designated ISOs to officers and key employees and NSOs to officers, key employees, consultants and directors. ISOs granted under the 1997 Plan have a maximum term of ten years from the date of grant and have an exercise price of not less than fair value of the stock at the date of grant, as determined by the Company's Board of Directors. NSOs granted under the 1997 Plan have a maximum term of ten years from the date of grant and have an exercise price of not less than 85% of fair market value of the stock at the date of the grant, as determined by the Company's Board of Directors. Vesting provisions of ISOs and NSOs may vary but in each case will provide for vesting of at least 20% per year of the total number of shares subject to the option.

The 2001 Stock Option Plan ("2001 Plan") permits the Company to grant up to 1,200,000 shares of Common Stock as incentive stock options ("ISOs") and nonstatutory stock options ("NSOs"). The 2001 Plan provides for the granting of ISOs to officers and key employees of the Company and NSOs to officers, key employees, consultants and directors of the Company. ISOs and NSOs granted under the 2001 Plan have a maximum term of ten years from the date of grant. Vesting provisions may vary but in each case will provide for vesting of at least 20% per year of the total number of shares subject to the option and have an exercise price not less than the fair value of the stock at the date of grant.

Stock option activity under the plans for the years ended December 31, 2001, 2000 and 1999 is as follows:

| | 2001 | | 2000 | | 1999 | |
|---|---|---|---|---|---|---|
| | Number | Weighted Average Exercise Price Per Share | Number | Weighted Average Exercise Price Per Share | Number | Weighted Average Exercise Price Per Share |
| Balance at beginning of year | 2,468,312 | $ 2.18 | 2,066,466 | $ 0.43 | 1,282,013 | $ 0.39 |
| Granted | 573,200 | 12.08 | 888,313 | 5.28 | 932,626 | 0.47 |
| Exercised | (175,098) | 2.11 | (391,782) | 0.39 | (47,425) | 0.35 |
| Canceled | (95,948) | 4.80 | (94,685) | 0.48 | (100,748) | 0.37 |
| Balance at end of year | 2,770,466 | 4.09 | 2,468,312 | 2.18 | 2,066,466 | 0.43 |

The following table summarlzes information about stock options outstanding at December 31, 2001:

| | Options outstanding | | | Options exercisable | |
|---|---|---|---|---|---|
| Exercise Price Per Share | Number Outstanding | Remaining Contractual Life | Weighted Exercise Price Per Share | Number Exercisable | Weighted Exercise Price Per Share |
| $ 0.09 $ 0.48 | 1,524,729 | 7.08 | $ 0.44 | 1,053,564 | $ 0.43 |
| $ 4.72 $ 7.56 | 697,287 | 8.78 | 5.55 | 198,901 | 5.41 |
| $ 9.40 $12.50 | 400,800 | 9.54 | 11.64 | 2,082 | 10.56 |
| $13.87 $15.55 | 147,650 | 9.64 | 14.47 | | |
| | 2,770,466 | | 4.09 | 1,254,547 | 0.62 |

There were 261,045, 636,565 and 1,200,000 options available for future grant under the 1995 Plan, the1997 Plan and the 2001 Plan, respectively, as of December 31, 2001. The Company has reserved 5,257,523 shares of common stock for the exercise of stock options and warrants.

***Employee Stock Purchase Plan***

In April 2001, the Company instituted an employee stock purchase plan. Under the plan, eligible employees can purchase Versicor stock through payroll deductions in semi-annual offerings at a price equal to the lower of 85% of the stock price at the beginning of the offering period and 85% of the stock price at the end of the offering period. The Company has reserved 1,100,000 shares of stock for issuance under the plan.

***Fair value disclosures***

The Company applies the measurement principles of APB 25 in accounting for its employee stock options. Had compensation expense for options granted to employees been determined based on the fair value at the grant date as prescribed by SFAS No. 123, the Company's net loss and net loss per share would have been as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| | (in thousands, except per share data) | | |
| Net loss available to common stockholders: | | | |
| As reported | $ (32,847) | $ (18,789) | $ (67,394) |
| Proforma | $ (34,147) | $ 19,556) | $ (67,469) |
| Basic and diluted net loss per share: | | | |
| As reported | $ (1.42) | $ (1.95) | $ (127.28) |
| Proforma | $ (1.48) | $ (2.03) | $ (127.42) |



The value of each option grant was estimated on the date of grant using the minimum value method until August 8, 2000; thereafter options were valued using the Black-Scholes option pricing model with the following weighted assumptions:

*Stock Option Plans*

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Risk-free interest rate | 4.2% | 5.1% | 6.3% |
| Expected average life | 4 years | 4 years | 6 years |
| Volatility | 60% | 60% | |
| Expected dividends | | | |

*Employee Stock Purchase Plan*

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2001 | 2000 | 1999 |
| Risk-free interest rate | 3.7% | | |
| Expected average life | 0.5 years | | |
| Volatility | 60% | | |
| Expected dividends | | | |

The risk-free interest rate was calculated in accordance with the grant date and expected average life. The weighted average per share fair value of options granted during the years ended December 31, 2001, 2000 and 1999 was $18.43, $12.89 and $14.18, respectively.

***Deferred stock based compensation***

During the period from January 1997 through December 31, 2001, the Company recorded $21.2 million of deferred stock based compensation in accordance with APB 25, SFAS 123 and Emerging Issues Task Force 96-18, related to stock options granted to consultants and employees. For options granted to consultants, the Company determined the fair value of the options using the Black-Scholes option pricing model with the following assumptions: expected lives of four years; weighted average risk-free interest rate between 4.7% and 6.2%; expected dividend yield of zero percent; volatility between 60% and 75%, and values of common stock between $0.40 and $20.35 per share. Stock compensation expense is being recognized in accordance with FIN 28 over the vesting periods of the related options, generally four years. The Company recognized stock compensation expense of $5.0 million, $7.7 million and $4.4 million for the years ended December 31, 2001, 2000 and 1999, respectively.

***Warrants***

In 1997, the Company issued warrants to purchase 45,000 shares of common stock at $4.45 per share. These warrants were still outstanding at December 31, 2001 and expire on March 10, 2002. The fair value of these warrants was estimated using the Black Scholes pricing model and was not material.

In 1997, the Company issued warrants to purchase 168,125 shares of Series C Preferred Stock (which converted to warrants to purchase common stock upon the Company's initial public offering) at $4.00 per share. 149,375 of these warrants were still outstanding at December 31, 2001 and expire on



December 9, 2002. The fair value of these warrants was estimated using the Black Scholes pricing model and was not material.

In 1999, the Company issued warrants to purchase 226,236 shares of Series F Preferred Stock (which converted to warrants to purchase common stock upon the Company's initial public offering) at $4.72 per share in connection with a bridge loan financing. 195,072 of these warrants were still outstanding at December 31, 2001 and expire on August 7, 2005. The warrants were valued using the Black-Scholes pricing model. The allocated fair value of these warrants of $623,000 has been reflected as interest expense in the 1999 statement of operations.

**NOTE 10 INCOME TAXES**

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are

measured using enacted tax rates. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be reallzed. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset.

The statutory and effective tax rates were 34% and 0%, respectively, for all periods presented. The effective tax rate resulted from net operating losses and nonrecognition of any deferred tax asset At December 31, 2001, the Company had federal and state tax net operating loss carryforwards ("NOL") of approximately $49.9 million and $17.3 million, which will expire beginning in the year 2010 and 2003, respectively. Based upon the Internal Revenue Code and changes in the Company's ownership, utillzation of the NOL will be subject to an annual limitation. The Company had federal and state research and experimentation credit carryforwards of approximately $1.0 million and $800,000 at December 31, 2001, which will expire beginning in the year 2010.

The components of net deferred taxes were as follows:

| | December 31, | |
|---|---|---|
| | 2001 | 2000 |
| | (in thousands) | |
| **Assets:** | | |
| Net operating losses | $ 18,665 | $ 7,983 |
| Capitallzed R&D | 10,335 | 11,240 |
| Credits | 1,575 | 1,417 |
| Accrued expenses and other liabilities | 918 | 785 |
| Property and equipment | 646 | 4 |
| Less: valuation allowance | (32,139) | (21,429) |
| Net deferred taxes | $ | $ |

**NOTE 11 EMPLOYEE SAVINGS PLAN**

Up until October 31, 2000, the Company's employees were able to participate in Sepracor's 401(k) savings plan. From November 1, 2000, the Company's employees were able to participate in the Versicor 401(k) savings plan. Under the provisions of both plans, employees may voluntarily contribute up to 15% of their compensation up to the statutory limit. In addition, the Company can make a matching contribution at its discretion. The Company matches 50% of the first $3,000 up to a



maximum of $1,500 per employee per annum. The Company's contributions made during 2001, 2000 and 1999 were $62,000, $47,000 and $39,000, respectively.

**NOTE 12 AGREEMENTS**

In February 1998, we entered into a license agreement and a collaborative agreement with Biosearch Italia. Under the license agreement, Biosearch granted us an exclusive license to develop and commerciallze dalbavancin in the United States and Canada. In exchange for the license and upon receipt of favorable results in preclinical studies, we paid an initial license fee of $2.0 million and issued 250,000 shares of our common stock to Biosearch. The license fee payment and the fair value of the common stock of $647,000 were expensed as research and development in 1998. Under the agreement, we are also obligated to make up to $8.0 million in additional milestone payments to Biosearch upon the achievement of specified milestones and are also required to pay to Biosearch royalties in respect of sales of any product that result from the compound. Under the collaborative agreement, we have established a lead optimlzation collaboration called BIOCOR. Biosearch contributes natural product leads and we contribute our combinatorial and medicinal chemistry expertise to optimlze these leads and identify product candidates.

In March 1999, we entered into a collaboration agreement with Pharmacia Corporation pursuant to which we are collaborating to discover, syntheslze and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pharmacia Corporation made an initial equity investment in us of $3.75 million and paid us research support and license fee payments. Under the terms of this agreement and in consideration for 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 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 commerciallzed from the collaboration. In October 2001, 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 which is recorded as deferred revenue in the accompanying balance sheet.

In March 1999, we entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop 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 certain of our full-time researchers. We have also received a number of milestone payments from Novartis and are entitled to receive additional payments upon the achievement of specified milestones, 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 commerciallzed from the collaboration.

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commerciallzation of anidulafungin. We paid $11 million for the license and have agreed to pay an additional $3 million for product inventory, which we have received, over a three-year period. As a result, we recognized $14 million of research and development costs in 1999. We are obligated to make additional payments to Eli Lilly if certain milestones are achieved and royalty payments in respect of sales of any product resulting from the compound. Eli Lilly has an option to license the exclusive development and commerciallzation rights to oral formulations of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, we will have the right to receive royalty payments and reimbursement of prior development expenses and milestone payments. We will also have the right to co-promote the product with Eli Lilly.



In June 2001, we entered into a manufacturing, development and supply agreement with Abbott pursuant to which Abbott will manufacture final formulation of anidulafungin. Additionally, pursuant to this terms of the agreement with Abbott and in consideration of Abbott's obligations to us, we have agreed to pay Abbott (i) a non-refundable research and development fee, and (ii) subject to certain conditions, an additional research and development fee. At such time as we begin commercial sales of a product containing anidulafungin and to the extent that Abbott is able to meet our manufacturing and commercial supply requirements, and once we have agreed upon a satisfactory price with Abbott, we have agreed to purchase a substantial portion of our commercial supplies of anidulafungin from Abbott. Our agreement with Abbott may be terminated by either party upon 12-months prior notice at the end of the fourth year following the date on which the first product containing anidulafungin is made by us.

**NOTE 13 QUARTERLY FINANCIAL DATA (UNAUDITED)**

The following is selected unaudited quarterly financial data for the years ended December 31, 2001, 2000 and 1999. In the opinion of the Company's management, this quarterly information has been prepared on the same basis as the financial statements and included all adjustments necessary to present fairly the information for the periods presented.

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, 2001 | June 30, 2001 | September 30, 2001 | December 31, 2001 |
| | (in thousands, except per share amounts) | | | |
| Revenues | $ 1,494 | $ 1,813 | $ 1,563 | $ 1,558 |
| Net loss | $ (5,166) | $ (8,642) | $ (8,574) | $ 10,465) |
| Net loss available to common stockholders | $ (5,166) | $ (8,642) | $ (8,574) | $ (10,465) |
| Net loss per share, basic and diluted | $ (0.22) | $ (0.37) | $ (0.37) | $ (0.45) |
| Shares used in computing net loss per share, basic and diluted | 23,041 | 23,054 | 23,085 | 23,176 |

Quarter Ended

| | Quarter Ended | | | |
|---|---|---|---|---|
| | March 31, 2000 | June 30, 2000 | September 30, 2000 | December 31, 2000 |
| | (in thousands, except per share amounts) | | | |
| Revenues | $ 1,258 | $ 1,560 | $ 1,309 | $ 1,744 |
| Net loss | $ (3,558) | $ (2,734) | $ (3,916) | $ (5,095) |
| Net loss available to common stockholders | $ (4,993) | $ (4,170) | $ (4,531) | $ (5,095) |
| Net loss per share, basic and diluted | $ (7.09) | $ (4.57) | $ (0.33) | $ (0.22) |
| Shares used in computing net loss per share, basic and diluted | 705 | 913 | 13,690 | 23,021 |



QuickLinks