VICURON PHARMACEUTICALS INC
Form 10-K
March 15, 2004
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO

SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

x Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2003

¨ Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from to .

Commission file number: 000-31145.

VICURON PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3278032**
(State or Other Jurisdiction of Incorporation)	**(I.R.S. Employer Identification Number)**
455 South Gulph Road, Suite 305	
King of Prussia, PA 19406	**(610) 491-2200**
(Address of principal executive offices) (Zip Code)	**(Telephone number)**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, $0.001 par value	**Nasdaq National Market and Nuovo Mercato**

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

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 x No ¨

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

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

On June 30, 2003, which was the last business day of our most recently completed second fiscal quarter, our public market value was approximately $623.8 million (based on 43,931,387 shares of our common stock then held by non-affiliates and a closing price that day of $14.20 per share of our common stock on the Nasdaq National Market). These public market value calculations exclude shares held on the stated dates by our officers, directors and 5% or greater stockholders. (Exclusion from these public market value calculations does not imply affiliate status for any other purpose).

On March 4, 2004, we had 54,004,723 shares of our common stock outstanding.

Documents Incorporated By Reference: Certain exhibits to our prior reports on Forms 10-K, 10-Q, 8-K, Registration Statement on Form S-1 (no. 333-33022), Registration Statements on Forms S-3 (nos. 333-105921 and 333-112847), Registration Statement on Form S-4 (no. 333-98935), and Registration Statement on Form S-8 (no. 333-103082), each as amended, are incorporated by reference in Part IV hereof. The Exhibit Index begins at page Ex-1.

Table of Contents

TABLE OF CONTENTS

		Page
PART I		
ITEM 1.	Business	1
ITEM 2.	Properties	23
ITEM 3.	Legal Proceedings	24
ITEM 4.	Submission of Matters to a Vote of Security Holders	24
PART II		
ITEM 5.	Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	25
ITEM 6.	Selected Financial Data	26
ITEM 7.	Management s Discussion and Analysis of Financial Condition and Results of Operations	27
ITEM 7.A.	Quantitative and Qualitative Disclosures About Market Risk	53
ITEM 8.	Financial Statements and Supplementary Data	54
ITEM 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	54
ITEM 9.A.	Controls and Procedures	54
PART III		
ITEM 10.	Directors and Executive Officers of the Registrant	55
ITEM 11.	Executive Compensation	58
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	66
ITEM 13.	Certain Relationships and Related Transactions	69
ITEM 14.	Principal Accountant Fees and Services	70
PART IV		
ITEM 15.	Exhibits, Financial Statement Schedules and Reports on Form 8-K	71

Cautionary Note Regarding Forward-Looking Statements

In addition to historical information, this Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts included in this Annual Report on Form 10-K, regarding our strategy, future operations, financial position, projected costs, prospects, plans and objectives of management are forward-looking statements. As contained herein, the words expects, anticipates, believes, intends, will, and similar types of expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are based on information that is currently available to us, speak only as of the date hereof, and are subject to certain risks and uncertainties. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations with regard thereto or to reflect any change in events, conditions, or circumstances on which any such forward-looking statement is based, in whole or in part. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to, those discussed in the sections in this Annual Report on Form 10-K entitled Risk Factors. Readers should carefully review the risk factors described in other documents the Company files from time to time with the Securities and Exchange Commission, including the Quarterly Reports on Form 10-Q that we will file in 2004.

All references to dollars or $ in this Annual Report on Form 10-K are references to United States dollars; all references to euros or are references to European Union, or EU, euros. On March 5, 2004, the median 4 p.m. Greenwich Mean Time spot rate for the euro expressed in dollars per euro was $1.24 to 1.00.

Table of Contents

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 expects, believes, intends, will, anticipates, and similar expressions as they relate to us are included to identify forward-looking statements. Our actual results could differ materially from the results discussed in the forward-looking statements as a result of certain of the risk factors set forth below and in the documents incorporated herein by reference, and those factors described under Risk Factors. In this Annual Report on Form 10-K, references to Vicuron, we, us and our refer to the combined company and its subsidiaries following the merger of Versicor Inc. and Biosearch Italia S.p.A., or Biosearch, which was completed on February 28, 2003. This Annual Report contains trademarks and trade names of other entities.

Overview

We are a transatlantic biopharmaceutical company focused on the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of seriously ill patients. We focus on seeking to develop antibiotics and antifungals that may have competitive advantages over existing products, such as greater potency, improved effectiveness against difficult-to-treat strains and reduced toxicity. Because the development process for anti-infective products is relatively efficient and well-defined, we believe the costs and time required to bring new anti-infective products to market can be significantly less than the time required to bring products to market in other major therapeutic categories. In April 2003, we filed a new drug application, or NDA, for our lead antifungal product candidate, anidulafungin, with the U.S. Food and Drug Administration, or FDA, which has accepted the application for review. Anidulafungin belongs to the first new class of antifungal agents, called echinocandins, introduced in more than 40 years. In January 2004, we announced that we received notification from the FDA that the agency anticipates completing its review of our anidulafungin NDA on May 25, 2004. We continue to expect the launch of anidulafungin in the first half of 2004 as planned, although our plans are dependent on receiving FDA approval. In addition, in December 2003, we announced the filing of our marketing authorization application for anidulafungin for the treatment of esophageal candidiasis with the European Medicines Evaluation Agency, or EMEA. Our marketing application to the EMEA will be reviewed under the European Community centralized licensing procedure, which is the procedure used to authorize human therapeutic products in all member states of the European Community.

On February 28, 2003, we merged with Biosearch Italia S.p.A., a publicly listed company in Italy. Biosearch used natural product sourcing for the discovery of novel anti-infective drugs and pursued their development and production with a primary commercial emphasis on Europe. We expect that the merger will enhance our capabilities with respect to discovery, pre-clinical, development and manufacturing, as well as our European market presence and effectiveness. As a combined company, we have a greater presence in two of the three major pharmaceutical markets (North America and Europe) as well as an enhanced product portfolio for collaborations in Asia. We had previously licensed the North American rights to our lead antibiotic product candidate, dalbavancin, from Biosearch, and by acquiring the global rights we eliminate potential royalties and manufacturing fees in North America, acquire the full potential of dalbavancin in Europe and the rest of the world, and enhance our ability to commercialize our lead antifungal drug, anidulafungin. As a result, we believe all of these benefits will increase our margin and profitability prospects for dalbavancin and anidulafungin upon regulatory approval in North America and Europe. We also believe that we will be able to file for European regulatory approval of dalbavancin and anidulafungin with only a modest increase in the clinical development expenses already planned for our North American filings. On June 30, 2003, we contributed the former assets, liabilities and business of Biosearch to our wholly-owned subsidiary in Italy, Vicuron Pharmaceuticals Italy S.r.l.

We have a two-fold approach to product discovery, development and marketing. Our primary strategy is to focus on the discovery and development of proprietary products, concentrating on injectable antibiotic and

1

Table of Contents

antifungal products for the hospital market. We expect to market these products to hospitals in North America and selected European markets through the direct sales force that we are currently developing, which we believe we can accomplish through a targeted and cost-effective sales and marketing infrastructure. Our product candidates target disease indications that represent markets where there is demand for new therapies. Anidulafungin and dalbavancin are examples of product candidates that we believe will fuel this strategy.

Our secondary strategy is to collaborate with major pharmaceutical companies to discover and develop orally administered antibiotic and antifungal products for the community market. Major pharmaceutical companies are generally better suited to market these products, as these products require substantial expenditures for sales and marketing to reach their full market potential. Under our typical collaboration agreements, we are responsible for discovering the compounds and our collaborators are responsible for developing and marketing them. We expect to receive a combination of research funding, milestone payments and equity investments from our collaborators, as well as royalty fees if any products are commercialized. We currently have collaborations with Pfizer and Novartis.

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

Our Proprietary Products

Anidulafungin

Our lead antifungal product candidate, anidulafungin, is intended for the intravenous treatment of serious 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 different mechanism of action, it is active against strains resistant to other agents, such as fluconazole. We believe anidulafungin will have competitive advantages over existing therapies because it combines potent fungicidal activity with a good resistance profile to date. In early 2003, we completed a Phase III clinical trial with anidulafungin for the treatment of esophageal candidiasis. Based in part on the results of that trial, in April 2003 we filed an NDA for anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In January 2004, we announced that we received notification from the FDA that it now anticipates completing its review of our anidulafungin NDA on May 25, 2004, which represents a 90-day extension of the original action date. The extension was triggered by the FDA s request for additional pharmacokinetic data. We continue to expect the launch of anidulafungin in the first half of 2004 as planned, although our plans are dependent on receiving FDA approval. In December 2003, we also announced the filing of our marketing authorization application for anidulafungin for the treatment of esophageal candidiasis with the EMEA, which will be reviewed under the European Community centralized licensing procedure, which is the procedure used to authorize human therapeutic products in all member states of the European Community.

We are also currently studying anidulafungin in a Phase III clinical trial for invasive candidiasis/candidemia in up to 300 patients and additionally, we have completed enrollment in a 30 patient Phase III clinical trial for aspergillosis in combination with a liposomal amphotericin formulation.

Dalbavancin

Our lead antibiotic product candidate, dalbavancin, is a next-generation antibiotic belonging to the same class as vancomycin, one of the most widely-used injectable antibiotics for Staphylococcal infections. Dalbavancin is intended for the treatment of serious infections, particularly those caused by *Staphylococci*.

Table of Contents

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 merely inhibiting their growth, as shown in both the laboratory and in infected animals. Because of its unique pharmacokinetic properties and the tolerability profile seen to date, dalbavancin has the potential to be dosed weekly, which may be a significant competitive advantage over other products. Once weekly dalbavancin is in Phase III clinical trials for both complicated and uncomplicated skin and soft tissue infections, each clinical trial with at least 550 patients. In addition, in early October 2003, we initiated a Phase III clinical trial which will include up to 150 patients to evaluate the safety and efficacy of dalbavancin relative to vancomycin, one of the current standards of care for the treatment of skin and soft tissue infections. We expect to complete these Phase III trials in the first half of 2004, and plan to file an NDA for dalbavancin in the second half of 2004. In January 2004, we also announced results of a Phase II clinical trial for catheter-related bloodstream infections which demonstrated that once weekly dalbavancin showed superior efficacy to twice daily vancomycin, a current standard of care for the treatment of Gram-positive catheter-related bloodstream infections (CR-BSI). CR-BSIs are one of the most common hospital-acquired infections.

Ramoplanin

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

VIC-Acne

Our fourth product candidate, VIC-Acne, is a novel antibiotic which we are developing as a topical cream. VIC-Acne has a new mechanism of action and shows selective activity against *Propionibacterium acnes*, a bacteria associated with acne, including drug resistant strains, while it shows only modest activity against normal skin flora. As a result, it might have the potential to selectively eliminate the *Propionibacterium acnes* without significantly affecting the natural skin flora. We completed a Phase I clinical trial with VIC-Acne in the second quarter of 2003 which showed that the drug was safe and well-tolerated. We plan to out-license this product candidate to a company with a dermatology business who will agree to develop and commercialize the product candidate. We would expect to receive milestone payments and a royalty on our contemplated licensee s sales.

Research Collaborations

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

Table of Contents

original agreement in order to extend the research term an additional year and to provide that Novartis will make an additional payment upon our achievement of a new milestone. In February 2003, we amended the original agreement in order to extend the research term through March 31, 2005. In September 2003, we announced achievement of a late-stage pre-clinical milestone for which we received a milestone payment from Novartis and in December 2003, we announced that we received a further milestone payment associated with the entry into Phase I of a drug candidate stemming from the ongoing research collaboration with Novartis.

Our second most advanced collaboration is with Pfizer Inc. and is aimed at discovering second and third generation oxazolidinones. The oxazolidinones represent one of the first new major classes of antibacterial products to enter the market in over 30 years. In test tubes, our collaboration compounds are active against a broad range of bacteria, including multi-drug resistant *Staphylococci*, *Streptococci* and *Enterococci*. Pfizer received approval from the FDA, independent of us, for the first generation oxazolidinone called Zyvox. We have identified several structurally novel second generation oxazolidinone candidates, certain of which have either a broader spectrum of activity or improved potency as compared to Zyvox. Some of these compounds also show good activity in pre-clinical *in vivo* studies when administered orally. This collaboration began in April 1999 with Pharmacia Corporation, and continued when Pharmacia was acquired by Pfizer. In October 2000, Pfizer increased its research support payments to us by 30% and, in June 2002, we amended our agreement with Pfizer to extend the research term for an additional three years. In May 2003, we announced an agreement to continue this collaboration with Pfizer after their acquisition of Pharmacia, our original collaborator.

Another collaboration program is called VITACHEM and is designed to investigate the pharmaceutical and non-pharmaceutical utility of our collection of microbial chemicals in markets outside of the anti-infectives market. We offer two types of collaborations under the VITACHEM program: fee-for-service collaborations, under which our collaborators pay us research fees, plus milestone payments and royalties calculated as a percentage of net sales; and equal collaborations, based on cost-sharing and reward-sharing. Currently, we have one equal collaboration with Myriad Genetics Inc. on oncology, cardiovascular and viral targets.

Internal Discovery Research

In addition to our external research collaborations, we have internal research programs both in the United States and in Italy. The objective of internal research is primarily 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, high-throughput screening of our diversified library of microbial extracts and medicinal chemistry. We are currently investigating several *in vivo* active leads.

Our Strategy

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

Focus our discovery and development efforts on products to treat bacterial and fungal infections. We believe that anti-infective products have significant development advantages over products in other therapeutic categories. These advantages include lower costs and shorter development cycles. In addition, product candidates in this area have a greater probability of clinical success due to the higher predictive value of clinical trials in this area. Finally, there is a growing demand for new anti-infective products. We believe that 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.

4

Table of Contents

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 twofold approach to product development. We have a twofold approach to product development and marketing. Our primary strategy is to internally develop anti-infective products with utility in a hospital setting and then to market these products to hospitals using our own focused sales force. For oral anti-infective products, which have utility in a broader community setting, we intend to collaborate in our development and marketing efforts with large pharmaceutical companies. This twofold approach allows us to pursue, on a proprietary basis, internal development and marketing of those products for which we feel the development and marketing requirements are manageable, such as injectable anti-infectives, and to out-license products, such as orally administered anti-infectives, that require greater marketing resources than we are willing to commit.

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	*Esophageal Candidiasis*	Fungicidal	Phase III[(1)]
	Invasive Candidiasis/ Candidemia	Fungicidal	Phase III
Dalbavancin	*Skin and Soft Tissue Infections*	Bactericidal	Three Phase III
	Blood Stream Infections	Bactericidal	Phase II[(1)]
Ramoplanin			Phase III*
	Prevention of Blood Stream Infections caused by VRE	Bactericidal	Phase II*
	Clostridium difficile Bactericidal - associated Diarrhea	Bactericidal	
VIC-Acne	*Acne*	Topical	Phase I[(1)]
Internal Research Programs	*Bacterial Infections*		Pre-clinical *in vivo*
	Collaborations		
Oxazolidinones (Pfizer)	*Bacterial Infections*	Bacteriostatic	Pre-clinical *in vivo*
Deformylase Inhibitors (Novartis)	*Bacterial Infections*	Bactericidal/Bacteriostatic	Pre-clinical *in vivo*

(1) Clinical trial complete.

(2) Patient enrollment complete.
* Clinical trials of our licensee in North America, Genome Therapeutics.

Table of Contents

Anidulafungin A Novel Antifungal for the Treatment of Serious Infections

Clinical Efficacy of Anidulafungin

On the basis of Phase I dose ranging studies and a successful Phase II study, we began a pivotal Phase III trial of anidulafungin for the treatment of esophageal candidiasis in the first quarter of 2001 and completed enrollment in October 2002. In this randomized, double-blind, double-dummy trial involving 600 patients, we compared anidulafungin at a loading dose of 100 mg and daily maintenance doses of 50 mg with oral fluconazole. Treatment continued for between 14 and 21 days, with the primary assessment of response made at the end of therapy. Additional evaluations were made at a follow-up visit approximately two weeks later. Endoscopic response was the primary endpoint, with both clinical responses and eradication of fungi as secondary endpoints. In early 2003, we completed this clinical trial. The primary endpoint showed:

	Anidulafungin (N=249)	Fluconazole (N-255)	Delta (95% CI)
Success Rate	97.2%	98.8%	Minus 4.1%*

* Lower bound of 95% CI.

This met the requirement on non-inferiority to oral fluconazole at the primary endpoint. Based in part on the results of this Phase III trial, in April 2003 we filed an NDA for anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In January 2004, we announced that we received notification from the FDA that the agency now anticipates completing its review of our anidulafungin NDA on May 25, 2004, which represents a 90-day extension of the original action date. We continue to expect the launch of anidulafungin in the first half of 2004 as planned, although our plans are dependent on receiving FDA approval, which may be delayed or denied. In December 2003, we also announced the filing of our marketing authorization application for anidulafungin for the treatment of esophageal candidiasis with the EMEA, which will be reviewed under the European Community centralized licensing procedure, which is the procedure used to authorize human therapeutic products in all member states of the European Community.

We completed a Phase II trial in invasive candidiasis/candidemia in the fourth quarter of 2002. This randomized, open-label trial enrolled approximately 120 patients in the United States with documented diagnosis of invasive candidiasis/candidemia. Patients were treated with a daily intravenous (IV) infusion of anidulafungin at three different dose levels for 15 to 42 days. Patients were examined for clinical and microbiological responses at the conclusion of therapy and two weeks following therapy. End-of-therapy outcomes in evaluable patients demonstrated an 89% global response rate (25/28 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 90% (27/30 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 84% (21/25 patients) with 100 mg followed by 50 mg. Outcomes in evaluable patients at the two-week, test-of-cure visit demonstrated an 83% global response rate (20/24 patients) with a loading dose of 200 mg followed by a 100 mg maintenance dose per day. The response rate was 85% (22/26 patients) with an analogous anidulafungin regimen of 150 mg followed by 75 mg per day, and 72% (13/18 patients) with 100 mg followed by 50 mg. Anidulafungin was well-tolerated and adverse events attributable to the study drug were similar for each dose. Global response rates reported in previous clinical trials with other agents, such as fluconazole, amphotericin B and caspofungin range from 56% to 81% in patients with invasive candidiasis/candidemia.

We began a Phase III trial of anidulafungin for invasive candidiasis/candidemia in December 2002. In this double-blind, randomized trial we will enroll up to 300 patients in the United States, Canada and Europe to study the safety and efficacy of a 200 mg loading dose followed by a

100 mg daily maintenance dose of anidulafungin versus fluconazole. Patients will receive daily IV infusions of either anidulafungin or fluconazole for 10 to 42 days. The primary endpoint is global assessment of clinical and microbiological responses at the end of IV therapy.

We began a Phase III trial of anidulafungin for the treatment of aspergillosis in the fourth quarter of 2001. Aspergillosis has a very high rate of mortality, therefore, new therapies are urgently needed. 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

Table of Contents

directly into our Phase III trial. This open-label, non-comparative study enrolled 30 hospitalized patients with a diagnosis of invasive aspergillosis. A single daily intravenous infusion of anidulafungin and a single daily intravenous infusion of a lipid-complexed formulation of amphotericin B will be administered to patients for up to 90 days. The primary endpoint is combined global response, *i.e.,* clinical and radiographic responses, at the conclusion of therapy.

Characteristics of Anidulafungin

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

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

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

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

Potent broad spectrum. Anidulafungin has shown highly potent *in vitro* activity against diverse groups of fungi, both yeasts and molds, that cause life-threatening infections. Anidulafungin is particularly potent against *Candida,* including fluconazole-resistant strains, and *Aspergillus,* the two most common types of fungi causing serious human infections. Anidulafungin also shows activity against *non-albicans species of Candida*, which are important causative agents for systemic infections and show higher rates of resistance to fluconazole. 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, on a logarithmic scale. The figure demonstrates that to inhibit the growth of *Candida albicans,* less anidulafungin is needed as compared with existing agents caspofungin, amphotericin B and fluconazole.

Table of Contents

Source:

NIAID MSG 33-34

Survey

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

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

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

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

Table of Contents

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

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

Clinical Experience with Dalbavancin

Phase I dose-ranging trials in normal volunteers have been concluded. High single doses, up to 1120 mg, and multiple doses, consisting of a loading dose of 1000 mg and repeat daily doses up to 100 mg for six days, were evaluated in these trials. The pharmacokinetics of dalbavancin with these dosage regimens were reproducible and followed the predictions made on the basis of preliminary Phase I and modeling studies. The safety and tolerability profile was very good, with no dose-limiting toxicities encountered. We have successfully completed a Phase II trial with dalbavancin for the treatment of skin and soft tissue infections and in December 2002, announced the start of two Phase III trials for this indication. In addition, in early October 2003 we initiated another Phase III clinical trial, which will include up to 150 patients to evaluate the safety and efficacy of dalbavancin relative to vancomycin, one of the current standards of care for the treatment of skin and soft tissue infections. We have also completed a Phase II trial in catheter-related bloodstream infections in 2004. Both the Phase III skin and soft tissue infections trials and the Phase II catheter-related bloodstream infections trial evaluate the efficacy and safety of weekly administration of dalbavancin. In January 2004, we announced the results of the Phase II clinical trial for catheter-related bloodstream infections which demonstrated that dalbavancin dosed once weekly showed superior efficacy to vancomycin, dosed twice daily the current standard of care for the treatment of Gram-positive catheter-related bloodstream infections (CR-BSI). CR-BSIs are one of the most common hospital-acquired infections.

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*

Table of Contents

include skin and soft tissue infections, bloodstream infections and osteomyelitis. An additional advantage of dalbavancin is its ease of administration, because of its once weekly dosing regimen and its safety and tolerability profile to date.

In the second quarter of 2002 we completed a Phase II clinical trial of dalbavancin for the treatment of skin and soft tissue infections. This randomized, controlled study showed that dalbavancin given once a week for two weeks had numerically higher clinical and microbiological response rates than a variety of standard of care regimens, including vancomycin, given for a mean duration of 15 days for the treatment of skin and soft tissue infections. As in all other clinical studies to date, dalbavancin was also shown to be very well tolerated. The trial enrolled 62 hospitalized patients with skin and soft tissue infections involving deep skin structures or requiring surgical intervention, such as abscesses, infected ulcers, burns and cellulitis. Patients were treated with one of two dalbavancin-dosing regimens or a standard of care agent, which was specified by the investigator prior to randomization. Patients were examined for clinical and microbiological responses at the conclusion of therapy and two weeks following therapy. The primary endpoint was clinical response at follow-up in evaluable patients. Outcomes in evaluable patients demonstrated a 94.1% clinical success rate (16/17 patients) with two doses of dalbavancin given one week apart (at day one and day eight), compared with 76.2% (16/21 patients) for the standard care arm (given daily for 7-21 days, mean = 15 days) and 61.5% (8/13 patients) for the single dose dalbavancin arm (given day one). Microbiological success was 72.7% (8/11 evaluable patients) with two weekly doses of dalbavancin compared with 64.3% (9/14 patients) for standard of care and 27.3% (3/11 patients) for the single dose dalbavancin arm. Dalbavancin was well-tolerated and adverse events were infrequent and similar across the study arms. There were no trends in any laboratory abnormalities in patients receiving dalbavancin.

We also initiated a Phase II trial in catheter-related bloodstream infections in the first quarter of 2002. In January 2004, we announced the results of this Phase II clinical trial for catheter-related bloodstream infections which demonstrated that dalbavancin showed superior efficacy to vancomycin, the current standard of care for the treatment of Gram-positive catheter-related bloodstream infections (CR-BSI). The Phase II CR-BSI enrolled 67 patients who were randomized to receive either dalbavancin (one gram on day one, 500mg on day eight) or 14 days at twice daily vancomycin. At the primary endpoint, follow-up in evaluable patients, dalbavancin had an overall success (clinical and microbiological) of 86.9% (20/23) versus vancomycin 50.0% (14/28). CR-BSIs are one of the most common hospital-acquired infections.

In December 2002 we started two Phase III trials with dalbavancin for the treatment of skin and soft tissue infections. These randomized, double-blind trials will each enroll at least 550 hospitalized patients who will be examined for overall clinical and microbiological responses at the conclusion of therapy. In the first trial, patients with complicated skin and soft tissue infections will receive either a one gram intravenous dose of dalbavancin on study day one followed by a 500 mg dose on study day eight or approved doses of linezolid for 14 days. In the second study, patients with uncomplicated skin and soft tissue infections will receive either a one gram intravenous dose of dalbavancin on study day one, with the option of adding a 500 mg does on study day eight, or intravenous cefazolin, followed by oral cephalexin. On day eight, the investigator will decide the duration of the study comparator medication therapy (seven or fourteen days) based on the clinical status of the patient.

In addition, in early October 2003 we initiated another Phase III clinical trial, which will include up to 150 patients to evaluate the safety and efficacy of dalbavancin, relative to vancomycin, one of the current standards of care for the treatment of skin and soft tissue infections. Patients will receive either dalbavancin, one gram intravenous dose on day one plus 500 mg on day eight, or approved daily doses of vancomycin for 14 days.

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

Table of Contents

MRSA and MRSE. The figure demonstrates that to inhibit the growth of MRSA and MRSE, less dalbavancin is needed as compared with existing agents vancomycin, teicoplanin and the investigational agent, oritavancin. Activity is expressed as the MIC_{90}.

Source:

JAC (1999), 44:179

This data illustrates that dalbavancin is more potent than other glycopeptide therapies. Dalbavancin also demonstrated impressive potency in a number of animal model infections, caused by a variety of Gram-positive bacteria, including those resistant to methicillin. Dalbavancin was efficacious against *Staphylococcal endocarditis* in animal models, as well as against *Streptococcus pneumoniae* pulmonary infection in normal and immunosuppressed animal models. Pharmacodynamic studies in animal models demonstrated bactericidal activity in the animals coupled with good tissue penetration and distribution of dalbavancin.

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

Unique, flexible and infrequent dosing regimen. Human pharmacokinetic data and studies in animal models demonstrated that dalbavancin has a long duration of action after administration and shows promise to become the first available once-weekly injectable antibiotic for the treatment of Staphylococcal and other serious Gram-positive hospital infections. Once-weekly dosing may allow some patients to have IV lines discontinued, which translates into fewer opportunities for local infection and blood stream infections. This may also provide pharmacoeconomic benefits, such as shorter hospital stays, less need for follow-up home IV or oral antibiotics and other reduced costs.

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

Ramoplanin

Ramoplanin is a novel antibiotic with excellent *in vitro* potency against Gram-positive bacteria including VRE. It is currently in a Phase III study being conducted by our North American licensee, Genome Therapeutics,

Table of Contents

for the prevention of VRE bloodstream infections in patients at risk. Our licensee is also conducting a Phase II dose response and vancomycin comparator trial to evaluate the safety and efficacy of ramoplanin for the treatment of *Clostridium difficile*-associated diarrhea.

VIC-Acne

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

Research Collaborations

Deformylase Inhibitors collaboration with Novartis

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

Based on our scientists experience in the captopril field, we initiated a highly focused chemistry effort targeting the rational design and synthesis of deformylase inhibitors. We designed a set of pharmacophoric libraries specifically suited for metalloenzyme targets and also developed new synthetic methodologies for the preparation of these libraries. Screening these libraries against deformylase led to the identification of several molecules with excellent enzymatic and whole-cell inhibitory activity. Our proprietary Gene to Screen technology helped identify those leads that inhibited bacterial growth by specifically inhibiting deformylase. Through proper integration of combinatorial chemistry with medicinal chemistry, more specific lead series were further optimized with excellent selectivity, as well as activity against clinically significant multi-drug resistant bacteria. Novartis has filed patent applications on the novel structures that we have synthesized. Many of these compounds have demonstrated good *in vivo* activity in pre-clinical studies when administered orally. The lead compound in this collaboration entered Phase I clinical trials by Novartis in the fourth quarter of 2003. We are currently in the process of evaluating additional deformylase inhibitors.

We entered into our collaboration agreement with Novartis in March 1999. Pursuant to this agreement, we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of $3.0 million and provides us with funding to support some of our full-time researchers. Under the terms of this agreement, we have established with Novartis a joint research committee and we are responsible for performing the three-year research plan developed by the committee. In return, Novartis has agreed to pay us a fee. We are also entitled to receive payments of up to $13.0 million for our compounds or up to $7.25 million for Novartis compounds upon Novartis achievement of certain research milestones. In addition, we granted Novartis, and Novartis granted us, reciprocal research licenses. We also granted Novartis an exclusive worldwide commercial license, pursuant to which it may develop, manufacture and sell products resulting from this collaboration. For each product that Novartis develops and launches in specified countries, we are entitled to receive royalties on worldwide sales of the product and additional payments if the product contains one of our compounds and a lesser sum if the product contains a Novartis compound. Novartis may offset some of its royalty payments by the amount of previous milestone payments made to us. We have the option to co-promote with Novartis in hospitals in the United States and Canada any product that contains one of our

compounds as an active ingredient, but we will not be entitled to royalties from sales of the product in that

Table of Contents

territory if we exercise our co-promotion option. This agreement terminates on a country-by-country basis with respect to a product developed under the collaboration upon the later of 10 years from the date of the first commercial sale of the product in the country or the time at which the product is no longer covered by a pending or issued patent in the country. In addition to the work on deformylase inhibitors, we have been delivering to Novartis under the agreement a series of screening assays based on novel anti-bacterial targets. For each screen that Novartis accepts as validated, we receive a milestone payment. In August 2001 and January 2002, Novartis paid us our fourth and fifth milestone payments, respectively, as a result of our delivery of our fourth and fifth target-based screens, which we expect will be used in Novartis high-throughput screening laboratory to identify new anti-infectives. In March 2002, the collaboration agreement was amended to extend the research term by an additional year, through March 2003, and to provide that Novartis shall make an additional payment to us upon our achievement of a new milestone. In February 2003, the collaboration agreement was amended to extend the research term by an additional two years, through March 2005. In September 2003, we announced achievement of a late-stage pre-clinical milestone for which we received a milestone payment from Novartis, and in December 2003 we announced that we received an additional milestone payment from Novartis as a result of entering into Phase I work on our research collaboration with Novartis. Through December 31, 2003, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of $15.5 million. We do not depend upon continued milestone payments from Novartis to any significant extent because we have funded, and intend to fund, our drug development programs primarily with the proceeds of equity offerings. Although we currently depend upon our collaborations, in-licensing opportunities and in-house research, in the aggregate, for a sustained pipeline of product candidates, we do not depend to any significant extent on any individual collaboration.

Oxazolidinones collaboration with Pfizer

We are collaborating with Pfizer 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. Pfizer has received FDA approval, independent of us, for a new drug called Zyvox, the most advanced molecule in this class. Based on historical precedents for antibiotics, it is likely that the development of subsequent generations of oxazolidinones with improved potency and a broader spectrum of activity will create a major market opportunity. Oxazolidinones are active against a broad spectrum of Gram-positive pathogens, including multidrug resistant *Staphylococci, Streptococci* and *Enterococci.* They have a novel mechanism of action involving inhibition of an early step in protein biosynthesis. 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. Pfizer signed a collaboration agreement with us in March 1999, which we continued when Pharmacia was acquired by Pfizer. We have identified several novel molecules with an enhanced spectrum of activity, including activity against the pathogen *H. influenzae,* improved potency against multidrug resistant bacteria including MRSA, MRSE, VRE and penicillin-resistant *Streptococcus pneumoniae.* Several compounds have also demonstrated good activity in pre-clinical *in vivo* studies when administered orally and are therefore undergoing advanced *in vivo* testing. Advanced *in vivo* testing includes testing the efficacy of the compounds with increased dosages, the absorption of the compound in the blood, the differences between the oral formulation and the intravenous formulation and the toxicity of the compound.

We entered into our collaboration agreement with Pharmacia Corporation, now Pfizer, in March 1999. Pursuant to this agreement, we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. We supply research, product leads and other specified intellectual property to the collaboration. Pfizer has the right to conduct the development of any product candidates and the manufacture and sale of any products resulting from the collaboration. In connection with the collaboration, Pfizer made an equity investment in us of $3.8 million and paid us research support and license fee payments. We have assigned

Table of Contents

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

Through December 31, 2003, Pfizer has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $16.6 million. We do not depend upon continued milestone payments from Pfizer to any significant extent because we have funded, and intend to fund, our drug development programs primarily with the proceeds of equity offerings. Although we currently depend upon our collaborations, in-licensing opportunities and internal research, in the aggregate, to seek to obtain a pipeline of product candidates, we do not depend to any significant extent on any individual collaboration.

VITACHEM Program

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

- microbial chemical libraries;
- high-throughput screening;
- product fractioning; and
- laboratory-scale fermentation.

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

There are two types of collaborations under the VITACHEM program:

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

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

Currently, we have one equal collaboration with Myriad Genetics Inc. on oncology, cardiovascular and viral targets.

Table of Contents

Consortium Italbiotec (the former Consortium Roberto Lepetit for Biotechnologies)

In February 1998, we established in conjunction with the University of Bologna (now Alma Mater Studiorum University of Bologna) and the University of the Studies of Palermo, the Roberto Lepetit Consortium for Biotechnologies , a non-profit organization aimed at the promotion of the development of biotechnologies through advanced research activities in collaboration with academic institutions with a view to utilizing new technologies and products for industrial purposes.

In November 2002, Newron Pharmaceuticals S.p.A. joined the Consortium and in February 2003, the University of Calabria also entered as a member.

In November 2003 the Consortium changed its name in Consortium Italbiotec . The headquarters of the Consortium is located at our offices in Italy.

Internal Discovery Research

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

Lead Optimization

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

Functional Genomics and Mechanism-Based Rational Drug Design

The complete genetic blueprints, or genomes, of the majority of clinically relevant bacteria are now accessible through the Internet. We take a highly focused and practical approach to using this genomic information by carefully selecting targets that have a mechanism suited to rational drug design. To facilitate efficient integration of mechanism-based drug discovery with combinatorial chemistry, we select mechanism-based families of targets such as metalloenzymes. We search genomes for characteristic genetic signatures and compare different genomes to identify targets that are present in a clinically relevant spectrum of bacteria. We use genetic techniques to establish that any target selected is essential for growth, and confirm this in several relevant bacterial species. Once we have carefully selected the target, we begin a highly focused chemistry effort using mechanism-based drug design. We then apply our Gene to Screen technology that allows us to increase or decrease the amount of target gene product, which is usually an enzyme, inside a cell by use of a special genetic regulator. Our ability to vary the concentration of a target enzyme inside a cell has proved an important support tool for our chemists, as they can then confirm whether a potent enzyme inhibitor stops the growth of

Table of Contents

bacteria by inhibiting the same enzyme. Our Gene to Screen technology allows our chemists to select leads that have the correct mechanism, without the inhibition of other enzymes that could result in toxicity. This integrated approach has been validated by our metalloenzyme program with Novartis to develop deformylase inhibitors. We are currently working with one additional metalloenzyme target to build on this success in our novel molecules programs.

Diversified Library of Microbial Extracts

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

generating a large number of structurally diverse natural product libraries;

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

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

The natural products we study are made by microbes found in the soil and other sources. Our scientists have internationally recognized expertise in isolating rare and unusual genetically diverse soil microbes and have now accumulated a unique collection of about 50,000 microbes. Each of these microbes is capable of producing a unique mixture of natural products when grown in liquid media. Depending on the media that they grow in, microbes can produce different mixtures of molecules. Concentrated extracts of these fermented media represent an invaluable source of chemical structural diversity. Thus, a library containing about over 170,000 of these extracts has been created. New microbes and extracts are continually being added to this collection.

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

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

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

Our research center in Italy has a long and rich history in the development of important antibiotics having been responsible for the discovery of rifampin, teicoplanin, dalbavancin, ramoplanin and VIC-Acne. Although natural products have found their widest use as antibiotics, it is clear

that they also represent a tremendous source of structural diversity for other therapeutic uses as well. We are currently involved in exploiting this opportunity through collaborations with other companies.

Licensing Agreements

Eli Lilly

In May 1999, we entered into a license agreement with Eli Lilly to obtain an exclusive worldwide license for the development and commercialization of anidulafungin. The license agreement provides for a number of payments from us to Eli Lilly, as follows: (i) an up-front payment for the license; (ii) periodic milestone

Table of Contents

payments bearing on achieving certain goals related to intravenous and oral formulations; (iii) payments during the period 2000 through 2002 for product inventory; and (iv) royalty payments based upon the net sales of the applicable products. We have also granted to Eli Lilly an option to license the exclusive worldwide rights to any oral formulation of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, Eli Lilly will pay us an up-front fee and royalties based on net product sales, and will reimburse us for any milestone payments paid plus the value, on a cost-plus basis, of all prior development expenses attributed to the development and commercialization of the oral formulation of anidulafungin. We are not currently working on an oral formulation program.

Genome Therapeutics

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

Sales and Marketing

We intend to market and sell our proprietary products through a direct sales force in the United States and Canada and the UK, Germany, Italy, France and Spain, also known as the five major European markets . Because we are targeting the hospital market, we have commenced the development of a relatively small focused sales force which will be sufficient to provide coverage. Our management has experience in building specialty pharmaceutical sales forces and we are in the process of developing a sales and marketing infrastructure, and have already hired a senior vice-president, sales and a senior vice-president, marketing. We expect to collaborate with other pharmaceutical companies to market our collaboration products in non-hospital markets in the United States and Canada and the five major European markets, and in overseas markets.

Manufacturing

In June 2001, we entered into a manufacturing, development and supply agreement with Abbott pursuant to which Abbott would manufacture the final formulation of anidulafungin. In August 2002, we agreed with Abbott to terminate this agreement. Eli Lilly has supplied us with sufficient anidulafungin echinocandin-B nucleus to finish clinical trials and market the drug for several years. We currently obtain some active ingredients from ChemSym Laboratories, a department of Eagle-Picher Technologies, L.L.C. We currently do not have manufacturing facilities capable of manufacturing products in quantities necessary for large-scale trials or marketing. The Aventis plant in Brindisi, Italy, and the Chemsyn Laboratories plant in the United States will be our initial manufacturing sites for dalbavancin and anidulafungin, respectively. Subsequently, we intend to manufacture products in our own manufacturing plant in Pisticci, Italy, which is currently under construction.

Intellectual Property

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

Table of Contents

Based on available information as of December 31, 2003, we have rights relating to 29 issued U.S. patents, 12U.S. patent applications, 453 foreign patents and 51 foreign patent applications. Of these patents and patent applications:

- our non-Biosearch patent portfolio as of December 31, 2003 includes no U.S. patents, 10 U.S. patent applications and 11 foreign patent applications; and

- our Biosearch patent portfolio, as of December 31, 2003, includes an additional 29 U.S. patents, two U.S. patent applications, 453 foreign patents and 40 foreign patent applications (of which, dalbavancin-related rights include four issued U.S. patents, 113 foreign patents and one foreign patent application).

Our collaborations involve the following patents:

- our license agreement with Eli Lilly with respect to anidulafungin covers 17 U.S. patents, nine U.S. patent applications, 117 foreign patents and 106 foreign patent applications;

- our collaborative agreement with Novartis covers two U.S. patent applications; and

- our collaborative agreement with Pfizer (as successor to Pharmacia) with respect to the development of oxazolidinones covers four U.S. patents, six U.S. patent applications, two Canadian patent applications and one foreign patent application.

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

Competition

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

Governmental Regulation and Product Approval

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

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

Table of Contents

Pre-Clinical Stages

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

Drug discovery.

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

Pre-clinical testing.

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

Investigational new drug application.

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

Some limited human clinical testing may be done under a physician s IND in support of an IND application and prior to receiving an IND. A physician s IND is an IND application that allows a single individual to conduct a clinical trial. A physician s IND does not replace the more formal IND process, but can provide a preliminary indication as to whether further clinical trials are warranted, and can, on occasion, facilitate the more formal IND process.

Clinical Trials

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

Table of Contents

Phase I clinical trials.

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

Phase II clinical trials.

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

Phase III clinical trials.

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

New drug application

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

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

Marketing approval

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

Phase IV clinical trials and post marketing studies

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

Table of Contents

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.

As of December 31, 2003, we had 37 full-time development employees. Like many other biotechnology companies in our stage of development, we rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials.

Governmental Support of Medical Research and Training

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

Italian Investment Programs

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

In order to be awarded grants or subsidies, eligible companies must submit a detailed request to MIUR and/or MAP, as applicable, describing their business and specifying the proposed project. MIUR and/or MAP, as applicable, will then evaluate the request and decide whether to make an award. Each grant and subsidy which is awarded will be paid, depending on the actual progress of the project (a portion of the grants may, however, be disbursed by MIUR and/or MAP, as applicable). The companies receiving the grants must comply with certain conditions relating

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

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

- oncology project (research activities);
- genomics project (training and research activities); and
- antibiotics project (training and research activities).

Table of Contents

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

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

- notice of any structural and organizational changes affecting us (including the change of our directors) and/or our business (including the award of further grants or subsidies) must be provided in advance to the authorized bank;
- consent to any merger, de-merger or transformation of us must be received in advance from the authorized bank; and
- any default by us under any of the agreements can cause the termination of all the agreements concerning the payment of grants and subsidies and our obligation to repay some or all of the amounts received by us with interest.

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

Regional Investment Programs

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

European Union Investment Programs

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

- Eurocellwall project;

Megatop project;

Actapharm project; and

Ribosome project.

Table of Contents

The agreements relevant to these grants, which are governed by European Union rules, provide that the grants may be awarded only to EU legal entities or entities of an Associated State that has entered into a convention with the EU. The United States has not entered into such a convention.

On June 30, 2003, we contributed the assets of the former Biosearch to our subsidiary, Vicuron Pharmaceuticals Italy S.r.l. In connection with such contribution, we submitted a request to the EU Commission to transfer the EU grants formerly of Biosearch to our Italian subsidiary. In the name of our subsidiary, we may from time to time in the future, apply to MIUR and the EU Commission for additional grants and subsidies. However, there can be no assurance that our subsidiary will in the future qualify or be approved for any grants or subsidies that may be applicable to it.

General

We were incorporated in Delaware as a wholly-owned subsidiary of Sepracor Inc. in 1995 and we have been operating as an independent company since 1996. In March 2003, we changed our name from Versicor Inc. to Vicuron Pharmaceuticals Inc. Our principal executive offices are located at 455 South Gulph Road, Suite 305, King of Prussia, Pennsylvania 19406. Our telephone number is (610) 205-2300. Our website is *http://www.vicuron.com*. The information found on our website and on websites linked to it are not incorporated into or a part of this Annual Report on Form 10-K.

The name Vicuron and our logo are trademarks of Vicuron Pharmaceuticals Inc. Other trademarks and trade names appearing in this Annual Report on Form 10-K are the property of their holders.

Website Access to Our Periodic SEC Reports

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

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

Employees

As of December 31, 2003, we employed 242 persons, 66 of whom hold Ph.D. or M.D. degrees. One hundred and forty-eight employees are engaged in research, 37 in clinical, 27 in manufacturing, five in marketing and business development and 25 support administration, finance, management information systems and human resources. We believe that we maintain good relations with our employees.

ITEM 2. PROPERTIES

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

We own offices and laboratory facilities consisting of approximately 170,000 square feet located in Gerenzano, Italy. We use approximately 70% of the square footage of these buildings and have leased a number of the offices and laboratories we are not currently using to Areta International. We also own land consisting of

Table of Contents

approximately 87,000 square meters in the Pisticci technical area in southern Italy through our subsidiary, Biosearch Manufacturing S.r.l., which land we contributed to our Italian subsidiary, Vicuron Pharmaceuticals Italy S.r.l., in June 2003. We also lease 200 square meters in Milan.

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 a party to any material legal proceedings.

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

None.

Table of Contents

PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Price Range of Common Stock

Our common stock is listed for trading on both the NASDAQ and the Nuovo Mercato in Italy under the symbol MICU . The following table sets forth for the period from January 1, 2002 through March 10, 2004, the high and low intra-day sales prices, as reported on the NASDAQ composite trading system, for the periods shown:

	Sales Prices	
	High	**Low**
2002		
First Quarter	$ 24.26	$ 15.70
Second Quarter	$ 19.00	$ 9.26
Third Quarter	$ 13.20	$ 7.78
Fourth Quarter	$ 12.29	$ 7.65
2003		
First Quarter	$ 13.08	$ 10.05
Second Quarter	$ 15.62	$ 10.54
Third Quarter	$ 18.00	$ 11.68
Fourth Quarter	$ 19.46	$ 16.76
2004		
First Quarter through March 10, 2004	$ 24.54	$ 18.79

As of March 8, 2004, there were approximately 84 registered holders of our common stock.

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

Recent Sales of Unregistered Securities

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

25

Table of Contents

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. Our merger with Biosearch in February 2003 materially affects the comparability of the selected financial data for our year ended December 31, 2003 with the selected financial data for our prior year ends. As a result, you should read the discussions regarding these matters in our audit financial statements and the notes thereto and the Management s Discussion and Analysis of Financial Condition and Results of Operations section. The selected financial data for the years ended December 31, 2003, 2002, 2001, 2000 and 1999 are derived from our audited financial statements.

	2003	2002	2001	2000	1999
Statement of Operations Data:					
Revenues					
Collaborative research and development and contract services	$ 7,929	$ 6,083	$ 6,145	$ 5,338	$ 3,750
License fees and milestones	1,679	258	283	533	525
Total revenues	9,608	6,341	6,428	5,871	4,275
Operating expenses:					
Research and development	77,893	48,189	32,612	15,531	25,472
General and administrative	13,531	8,184	9,600	8,891	2,586
Acquired in-process research and development	94,532				
Total operating expenses	185,956	56,373	42,212	24,422	28,058
Loss from operations	(176,348)	(50,032)	(35,784)	(18,551)	(23,783)
Other income (expense):					
Interest income	2,749	1,483	3,313	3,712	749
Interest expense	(506)	(247)	(316)	(482)	(6,171)
Other			(60)	18	(14)
Net loss	(174,105)	(48,796)	(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	$ (174,105)	$ (48,796)	$ (32,847)	$ (18,789)	$ (67,394)
Net loss per share:					
Basic and diluted	$ (3.69)	$ (1.91)	$ (1.42)	$ (1.95)	$ (127.28)
Weighted average shares	47,162	25,516	23,090	9,638	530

December 31,				
2003	2002	2001	2000	1999

	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents and marketable securities	$ 166,157	$ 62,305	$ 63,768	$ 85,934	$ 34,619
Total assets	258,498	72,736	70,697	91,596	45,233
Term loan payable, less current portion	2,360	698	1,004	3,448	4,310
Convertible and redeemable preferred stock					83,843
Accumulated deficit	(326,723)	(152,619)	(103,823)	(70,976)	(55,673)
Total stockholders equity (deficit)	213,783	48,666	52,894	80,287	(48,796)

Table of Contents

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

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

Overview

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

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

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

On February 28, 2003, we acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. We have issued 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares.

On June 30, 2003, we contributed the former assets, liabilities and business of Biosearch to our wholly-owned subsidiary in Italy, Vicuron Pharmaceuticals Italy S.r.1.

On July 17, 2003, we sold 6,000,000 shares of common stock at $13.85 per share in a public offering. We received net proceeds of approximately $77.8 million.

In February 2004, we filed a universal shelf registration statement on Form S-3, which we expect either has been or will be declared effective on the date of this filing. If the SEC declares the shelf registration effective, we will be able to offer up to $200 million of our securities from time to time in one or more public offerings of our common stock, preferred stock, warrants and/or debt securities.

Since we began our operations in 1995, we have not generated any revenues from product sales. In early 2003, we completed a Phase III clinical trial with anidulafungin, our lead antifungal product candidate, for the treatment of esophageal candidiasis. Based in part on the results of that trial, in April 2003 we filed an NDA for anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In January 2004, we announced that we received notification from the FDA that the agency now anticipates completing its review of our anidulafungin NDA on May 25, 2004, which represents a 90-day extension of the original action date. The extension was triggered by the FDA s request for additional bioanalytical data. We continue to expect the launch of anidulafungin in the first half of 2004 as planned, although our plans are dependent on receiving FDA approval. In December 2003, we also announced the filing of our marketing authorization application for anidulafungin for the treatment of esophageal candidiasis with the European Agency for the Evaluation of Medicinal Products (EMEA), which will be reviewed under the European Community centralized licensing procedure, which is the procedure used to determine the scope of marketing authorization for human therapeutic products in all member states of the European Community. Our lead antibiotic product candidate, dalbavancin entered into Phase III clinical trials in December 2002. We also completed a Phase I clinical trial of VIC-Acne in 2003. We also have several lead compounds in pre-clinical studies.

Table of Contents

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

Our expenses have consisted primarily of costs incurred when in-licensing existing product candidates, research and development of new product candidates and in connection with our collaboration agreements, and from general and administrative costs associated with our operations. We expect licensing costs to increase as certain milestones are achieved, and our research and development expenses to increase as we continue to develop our product candidates. As a result of our merger with Biosearch in the first-quarter of 2003, we also expect our general and administrative expenses to increase as we continue to add personnel, integrate our operations and expand our research and development operations. We expect to incur sales and marketing expenses in the future when we establish our sales and marketing organization.

Since our inception, we have incurred significant losses. As of December 31, 2003, we had an accumulated deficit of $326.7 million. We anticipate incurring additional losses, which may increase for the foreseeable future, including at least through December 31, 2004.

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

Major Research and Development Projects

Our ongoing clinical trials of anidulafungin and dalbavancin are our two most significant research and development projects, generating 29% and 21%, respectively, of our total research and development expenses since our inception.

Anidulafungin

Anidulafungin is our lead antifungal product candidate. We in-licensed anidulafungin from Eli Lilly pursuant to the May 1999 agreement described below. We completed a Phase III clinical trial for the treatment of esophageal candidiasis. As of December 31, 2003, the intravenous formulation of anidulafungin is in a:

- Phase III clinical trial for the treatment of invasive candidiasis/candidemia; and
- Phase III clinical trial for the treatment of aspergillosis, patient enrollment completed.

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of anidulafungin. We paid $11.0 million for the license and an additional $3.0 million for product inventory (which we have received). As a result, we recognized $14.0 million of research and development costs in 1999. If specified milestones are achieved on the intravenous formulation of anidulafungin in the

United States and Canada, we will be obligated to make additional payments of up to $8.0 million to Eli Lilly. We are also obligated to make additional payments of up to $8.0 million to Eli Lilly if specified milestones on the intravenous formulation of anidulafungin are achieved in Europe, and additional payments of up to $8.0 million if specified milestones on the intravenous formulation of anidulafungin are achieved in Japan. We are obligated to make additional payments to Eli Lilly of up to $21.0 million if sales of an intravenous formulation of anidulafungin exceed specified targets in the United States and Canada, Europe and Japan. In addition, we are obligated to make royalty payments in respect of sales of any product resulting from the compound. We also made a $6 million milestone payment to Eli Lilly in 2003, which was triggered by our filing of the NDA with the FDA.

Table of Contents

We are not currently developing an oral formulation of anidulafungin and do not presently intend to do so in the future. However, under the license agreement with Eli Lilly, we are obligated to make additional payments to Eli Lilly of up to $25.0 million if, and only if, specified milestones are achieved on an oral formulation of anidulafungin in the United States, additional payments of up to $15.0 million if specified milestones are achieved on an oral formulation of anidulafungin in Europe, and additional payments of up to $15.0 million if specified milestones are achieved on an oral formulation of anidulafungin in Japan. In addition, we are obligated to make additional payments to Eli Lilly of up to $24.0 million if, and only if, sales of an oral formulation of anidulafungin exceed specified targets worldwide. Because an oral formulation of anidulafungin is not currently feasible, we believe that it is unlikely that we will be obligated to make any of these payments to Eli Lilly. We have also granted to Eli Lilly an option to license the exclusive worldwide rights to any oral formulation of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, Eli Lilly would pay us an up-front fee and royalties based on net product sales, and would reimburse us for any milestone payments paid plus the value, on a cost-plus basis, of all prior development expenses attributed to the development and commercialization of the oral formulation of anidulafungin. However, due to the speculative nature of the oral formulation of anidulafungin, we believe that it is unlikely that we will be entitled to receive fees or royalties and reimbursement of expenses from Eli Lilly.

Research and development expense allocated to our anidulafungin project, expressed as a percentage of total research and development expense for the period, was:

22% for the year 2003 compare to 42% for the year 2002 and 37% for the year 2001; and

29% in the aggregate from our inception through December 31, 2003.

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

The goal of our anidulafungin project is to obtain marketing approval from the U.S. Food and Drug Administration, or FDA, and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. Material cash inflows relating to our anidulafungin project will not commence until after marketing approvals are obtained, and then only if anidulafungin finds acceptance in the marketplace. To date, we have not received any revenues from product sales of anidulafungin. Because of the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our anidulafungin project will commence, if ever.

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

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

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

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

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

Table of Contents

Dalbavancin

Dalbavancin is our lead antibiotic product candidate. We in-licensed dalbavancin from Biosearch pursuant to the February 1998 agreement described below. As of December 31, 2003, dalbavancin is in:

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

a Phase II clinical trial for the treatment of catheter-related blood stream infections, which was completed and topline data released in January 2004.

In February 1998, we entered into a license agreement and a collaborative agreement with Biosearch. Under the license agreement, Biosearch granted us an exclusive license to develop and commercialize dalbavancin in the United States and Canada. In exchange for the license and upon the receipt of favorable results in pre-clinical studies, we paid an initial license fee of $2.0 million and issued 250,000 shares of our common stock to Biosearch. In May 2001 and December 2002, we paid Biosearch additional milestone payments for the start of Phase II and Phase III clinical trials, respectively. As a result of the Biosearch merger, we no longer owe any milestones or royalties on dalbavancin.

Research and development expense allocated to our dalbavancin project, expressed as a percentage of total research and development expense for the period, was:

30% for the year 2003 compared to 23% for the year 2002 and 23% for the year 2001; and

21% in the aggregate from our inception through December 31, 2003.

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

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

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

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

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

Table of Contents

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

Risks relating to our major research and development projects

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

Development Administration

Research and development expense comprising development administration overhead costs, expressed as a percentage of total research and development expense for the period, was:

12% for the year 2003, compared to 12% for the year 2002 and 7% for the year 2001; and

9% in the aggregate from our inception through December 31, 2003.

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

Other research and development projects

The remaining 41% of our total research and development expenses from our inception through December 31, 2003 were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pfizer and Novartis described below.

Oxazolidinones collaboration with Pfizer.

In March 1999, we entered into a collaboration agreement with Pharmacia Corporation, now Pfizer, pursuant to which we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pfizer made an equity investment in us of $3.8 million and paid us research support and license fee payments. Under the terms of the agreement and in consideration of our research obligations, we are entitled to receive funding from Pfizer to support certain of our full-time researchers. If specified milestones are achieved, Pfizer is obligated to pay us additional payments of up to $14.0 million for each compound, a portion of which may be credited against future royalty payments to which we are entitled on the worldwide sales of any drug developed and commercialized from the collaboration. In October 2000, Pfizer increased its funding for this collaboration by 30%, and in June 2001, we received a milestone payment for the initiation of clinical development of one of the compounds. In July 2002, we agreed with Pfizer by amendment to extend the collaboration for an additional three years through March 2005. Through December 31, 2003, Pfizer has made

aggregate payments to us under this collaboration agreement (excluding equity investments) of $16.6 million. In 2003, the Company received $2.7 million in payments and recognized $3.6 million in revenue.

Research and development expense allocated to our collaboration with Pfizer, expressed as a percentage of total research and development expense for the period, was:

5% for the year 2003, compared to 7% for the year 2002 and 11% for the year 2001; and

8% in the aggregate from January 1, 1999 through December 31, 2003.

The goal of our collaboration with Pfizer is to discover, synthesize and obtain marketing approval for second and third generation oxazolidinone product candidates. We supply research, product leads and other specified intellectual property to the collaboration. The collaboration also depends upon Pfizer to develop the product candidates, to obtain marketing approval from the FDA and analogous international agencies and to

Table of Contents

manufacture and sell any products resulting from the collaboration. Material cash inflows in the form of royalties relating to this collaboration will not commence until after marketing approvals are obtained, and then only if the product finds acceptance in the marketplace. One product candidate resulting from the collaboration has entered Phase I clinical trials. In order to obtain marketing approval, Pfizer will need to complete Phase I, II and III clinical trials with satisfactory results and submit an NDA to the FDA. Pfizer is under no obligation to continue the development of any product candidate resulting from this collaboration. Because of this, and the substantial risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our collaboration with Pfizer will commence, if ever. In May 2003, we announced an agreement to continue this collaboration.

Deformylase inhibitors collaboration with Novartis.

In March 1999, we entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of $3.0 million. We have also received a number of milestone payments from Novartis and are entitled to receive additional payments of up to $13.0 million for our compounds or up to $7.25 million for Novartis compounds upon the achievement of specified milestones. Novartis may deduct a portion of these milestone payments from the royalties it will be obligated to pay us on the worldwide sales of any drug developed and commercialized from this collaboration. In February 2003, we amended the original agreement in order to extend the research term through March 31, 2005. In September 2003, we announced achievement of a late-stage pre-clinical milestone for which we received a milestone payment from Novartis, and in December 2003 we announced that we received an additional milestone payment from Novartis as a result of entering into Phase I work on our research collaboration with Novartis. Through December 31, 2003, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of $15.5 million. In 2003, the Company received $4.5 million of which $3.9 million was recognized as revenue.

Research and development expense allocated to our collaboration with Novartis, expressed as a percentage of total research and development expense for the period, was:

3% for the year 2003, compared to 5% for the year 2002 and 8% for the year 2001; and

6% in the aggregate from January 1, 1999 through December 31, 2003.

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

In addition to the work on deformylase inhibitors, under the collaboration agreement we have been delivering to Novartis a series of screening assays based on novel anti-bacterial targets. For each screen that Novartis accepts as validated, we receive a milestone payment. In August 2001 and January 2002, Novartis paid us our fourth and fifth milestone payment, respectively, as a result of our delivery of our fourth and fifth target-based screens, which we expect will be used in Novartis high-throughput screening laboratory to identify new anti-infectives.

32

Table of Contents

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

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

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

Deferred Stock Compensation

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

We recorded deferred stock compensation (net of cancellations) of $702,000, $(114,000) and $(294,000) for the years ended December 31, 2003, 2002 and 2001, respectively. These amounts were recorded as a component of stockholders equity and are being amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred stock compensation of $1.4 million, $2.3 million and $5.0 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Results of Operations

Years ended December 31, 2003, 2002 and 2001

Revenues were $9.6 million, $6.3 million and $6.4 million in 2003, 2002 and 2001, respectively. Revenues consisted of $3.6 million, $3.6 million and $3.7 million of collaborative research and development, contract services and licensing fees from Pfizer in 2003, 2002 and 2001, respectively, and $2.6 million, $2.7 million and $2.7 million of collaborative research and development fees and milestone payments from Novartis in 2003, 2002 and 2001, respectively. The increase in revenues in 2003 is due to the achievement of additional milestones in the Novartis collaboration and recognition of Biosearch Italia grant revenues. The slight decrease in revenues in 2002 is due to a decrease in revenue from the Pfizer upfront license and contract research fees that were recognized as revenue over the initial three-year contract term through March 31, 2002. The increase in revenues in 2001 was due to the increase in collaborative research and development funding from both Pfizer and Novartis.

Research and development expenses were $77.9 million, $48.2 million and $32.6 million in 2003, 2002 and 2001, 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.

The increase in research and development expenditure in 2003 were due to increased spending on clinical trials associated with dalbavancin and our merger with Biosearch Italia. The increase in research and development expenditure in both 2002 and 2001 is primarily due to the increase in clinical expenditure for the development of our product candidates. Our lead product candidate, anidulafungin, moved into Phase III clinical

Table of Contents

trials in the first half of 2001 and our second product candidate, dalbavancin, moved into Phase II clinical trials in the second quarter of 2001 and Phase III clinical trials in December 2002. We have also increased the size of our development administration team from one person in February 2001 to 28 at December 31, 2002. In addition, we have expanded our collaborative and internal research programs.

General and administrative expenses were $13.5 million, $8.2 million and $9.6 million in 2003, 2002 and 2001, 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 and legal fees. The increase in general and administrative expenses for 2003 was due to our merger with Biosearch Italia and costs incurred to develop a marketing infrastructure. Our general and administrative expenses decreased slightly in 2002 primarily due to a reduction in business development activity from 2001.

Interest income was $2.7, $1.5 and $3.3 million in 2003, 2002 and 2001, respectively. Interest income consists of interest income on cash and cash equivalents and marketable securities. The increase in interest income for 2003 is due to additional interest earning assets acquired in our merger with Biosearch Italia combined with the proceeds of our July 2003 stock offering. The decrease in interest income in 2002 and 2001 was due to a reduction in interest rates during these two years.

Interest expense was $0.5, $0.2 and $0.3 million in 2003, 2002 and 2001, respectively. Interest expense consists of interest on the Company s short term and long term debt. The increase in interest expense was due to the additional debt acquired in our merger with Biosearch Italia. The decrease in interest expense in 2002 was due to the decrease in related debt.

Income taxes.

As of December 31, 2003, we had federal, state and foreign net operating loss carryforwards of approximately $182.3 million, $104 and $61.1 million, respectively. As of December 31, 2003, we have recorded a full valuation allowance for our existing net deferred tax assets due to uncertainties regarding their realization. We also have federal and state research credit carryforwards of $5.7 million and $6.0 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

We have funded our operations principally with the proceeds of $78.5 million from a series of six preferred stock offerings over the period 1995 through 1999, and net proceeds of $52.7 million from our initial public offering received in August and September 2000. In addition, on April 9, 2002, we completed a private placement of 2,993,800 shares of common stock to selected institutional investors at a purchase price of $15 per share, from which we received net proceeds of approximately $41.9 million. On July 17, 2003, we sold 6,000,000 shares of common stock at $13.85 per share in a public offering. We received net proceeds of $77.8 million.

As of December 31, 2003, we have also received approximately $32.1 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, $1.8 million constitutes deferred revenue as of December 31, 2003.

We have also increased our cash and cash equivalents and marketable securities as a result of our 2003 merger with Biosearch.

Table of Contents

In addition, in February 2004, we filed a universal shelf registration statement on Form S-3, which we expect either has been or will be declared effective on the date of this filing. If the SEC declares the shelf registration statement effective, we will be able to offer up to $200 million of our securities from time to time in one or more public offerings of our common stock, preferred stock, warrants and/or debt securities.

In addition, we have a $6.0 million term loan and $2.0 million equipment note with a commercial bank. The term loan accrues interest at the prime rate plus 0.50% (the prime rate was 4.50% at December 31, 2003) and the equipment note s interest rate is based on the LIBOR rate plus an applicable margin (the applicable LIBOR rate for our note was 1.20% at December 31, 2003). The terms of the term loan were revised in January 2003 and the balance at that time of $2.8 million became now repayable in eight equal quarterly installments beginning on March 31, 2003 with the final payment due on December 31, 2004. The final note balance is also payable on December 31, 2004. Also, in January 2003 the term loan was amended to include a three-year equipment note for $1.5 million that we are able to draw down on through December 31, 2003. The note bears interest at the prime rate unless we exercise an option to have the interest on all or any portion of the principal amount based on the LIBOR rate plus an applicable margin. The interest on the note is payable in quarterly installments during the draw down period. The principal of the note is payable in equal installments beginning on March 31, 2004 with the final payment due on December 31, 2005. As of December 31, 2003 and 2002, there was an outstanding loan balance of $2.1 million and $4.2 million, respectively.

Years ended December 31, 2003, 2002 and 2001

Cash used in operations was $72.2 million, $42.0 million and $21.4 million in 2003, 2002 and 2001, respectively. The net loss of $174.1 million for 2003 includes a non-cash charges for the write off of acquired in-process research and development of $94.5 million and the amortization of non-cash stock compensation and depreciation of $6.3 million. The net loss of $48.8 million for 2002 was offset by non-cash charges for the amortization of non-cash stock compensation and depreciation of $3.5 million and an increase in accounts payable and accrued liabilities of $7.0 million less an increase in prepaid expenses and other current assets of $3.8 million. The net loss of $32.8 million for 2001 was partially offset by non-cash charges for the amortization of non-cash stock compensation and depreciation of $6.0 million and an increase in accounts payable and accrued liabilities of $6.0 million. In both 2002 and 2001, the increase in accounts payable and accrued liabilities is a direct result of the increase in our operating costs principally relating to the increase in clinical trial expenditure for the development of our product candidates. In 2002, the increase in prepaid expenses and other current assets primarily relates to prepaid acquisition costs relating to the merger of Biosearch with and into Versicor. The decrease in non-cash stock compensation in 2002 and 2001 is due to the fact that the majority of the compensation relates to options issued prior to our initial public offering in August 2000 and is being amortized on an accelerated basis in accordance with Financial Accounting Standards Board Interpretation No. 28.

Investing activities provided $69.2 million of cash and used $2.6 million and $16.3 million of cash during 2003, 2002 and 2001, respectively. The increase in cash provided was due to the sale and maturity of investment securities. In 2002, the net change in marketable securities was $1.6 million as proceeds from our private placement in April 2002 funded the majority of our operating loss for the year. In 2001, cash was primarily used for the net purchases of marketable securities of $14.4 million due to a change in investment portfolio managers. Capital expenditure was $11.7 million, $945,000 and $2.0 million 2003, 2002 and 2001, respectively. Higher capital expenditure in 2003 related to the construction of our manufacturing facility in Italy. The Company estimates that the facility will require $12.1 million to complete construction during the period from January 1, 2004 to June 30, 2004. Higher capital expenditure in 2001 related to leasehold improvements at our California facility.

Financing activities provided $82.6 million, $41.6 million and $1.0 million of cash in 2003, 2002 and 2001, respectively. In 2003, our principal source of cash resulted from the net proceeds of $77.8 million received from the sale of 6,000,000 shares of stock in a public offering. In 2002, our principal source of cash resulted from net

Table of Contents

proceeds of $41.9 million received from the private placement of 2,993,800 shares of common stock to certain institutional investors in April 2002. Repayments on our term loans increased in 2002 due to the equipment note that we entered into in the second half of 2001. In 2001, the draw down on our equipment loan of $1.5 million was partially offset by repayments of our term loan of $862,000.

We expect to have negative cash flow from operations for the foreseeable future. We expect to incur increasing research and development, and general and administrative expenses, including expenses relating to clinical development, additions to personnel, production and commercialization efforts and the integration of our operations with those of Biosearch. Our future capital requirements will depend on a number of factors, including our success in developing markets for our products, payments received or made under collaboration agreements, the timing and outcome of regulatory approvals, the need to acquire licenses to new products or compounds, the status of competitive products and the availability of other financing. We believe our existing cash and cash equivalents and marketable securities, in addition to the cash and cash equivalents, trading securities and available-for-sale securities acquired in the merger, will be sufficient to fund our operating expenses, debt repayments and capital requirements for at least 18 months.

Financial Condition

Assets

At December 31, 2003 our total assets were approximately $ 258.5 million compared to approximately $72.7 million at December 31, 2002. The reason for this increase is a result of the merger with Biosearch Italia.

Liabilities

At December 31, 2003 our total liabilities were approximately $ 44.7 million compared to approximately $24.0 million at December 31, 2002. The reason for this increase is a result of the merger with Biosearch Italia.

Contractual Obligations and Commitments.

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Long-Term Debt Obligations	7,663	170	1,703	1,871	3,919
Capital Lease Obligations	91	91			
Operating Lease Obligations	9,539	2,021	3,780	2,786	952
Purchase Obligations	3,242	3,242			

Total	20,535	5,524	5,483	4,657	4,871

Stockholders Equity

Stockholders equity at December 31, 2003 was approximately $ 213.8 million compared to approximately $48.7 million at December 31, 2002. The reason for this increase is attributed to common stock issued in connection with the merger with Biosearch Italia and the issuance of 6,000,000 shares of common stock in a public offering.

Off-Balance Sheet Arrangements

Since inception, we have not maintained any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. Further, we have not guaranteed any obligations of unconsolidated entities nor do we have any commitment or intent to provide additional funding to any such entities.

Table of Contents

Recent Accounting Pronouncements

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

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

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of this standard did not have a material impact on our financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ending after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. The adoption of this standard did not have a material impact on our financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46, or FIN 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of this standard did not have a material impact on our financial statements.

Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the

Table of Contents

date of the financial statements and the reported amounts of revenues and expenses during the reporting period. We base our estimates on historical experience and other various assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates.

Our critical accounting policies are as follows:

Revenue Recognition

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

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.

In-Process Research and Development

In the first quarter of 2003, we recorded a non-cash charge to operations of $94.5 million for acquired in-process research and development resulting from our merger with Biosearch. This amount represents the estimated fair value relating to incomplete research and development projects, which, at the time of the merger, had no alternative future use and for which technological feasibility had not been established.

Intangible Assets

The identifiable intangible assets arising from the merger, after allocation of negative goodwill, total $25 million as of December 31, 2003. These intangibles represent patents and core technology, a library of microbial extracts and a bioinformatics software platform. These identifiable intangible assets have estimated useful lives of between two and thirteen years.

Table of Contents

RISK FACTORS

In addition to the other information included or incorporated by reference in this Annual Report on Form 10-K, you should carefully consider the following factors in evaluating our company or an investment in any of our securities. Our actual future results and trends might differ materially from our historical results or trends to date, or those anticipated in our forward-looking statements, depending on a variety of factors, including the factors set forth in this section. Additional risks not presently known to us or that we currently deem immaterial might also harm our business.

Risks Related to Our Business

Our ability to become profitable is heavily dependent upon our obtaining FDA approval of anidulafungin and dalbavancin, our two lead product candidates, and marketing them successfully.

In order to become profitable, we anticipate that we will need to obtain FDA marketing approval for anidulafungin and dalbavancin and then commercialize them successfully. In April 2003, we filed an NDA with the FDA seeking approval to market anidulafungin for the treatment of esophageal candidiasis. In January 2004, we announced that we received notification from the FDA that the agency now anticipates completing its review of our anidulafungin NDA on May 25, 2004, which represents a 90-day extension of the original action date. The extension was triggered by the agency s request for additional pharmacokinetic data. According to PDUFA (Prescription Drug User Fee Act), the FDA can reset the action date to review any additional data. We continue to expect the launch of anidulafungin in the first half of 2004 as planned, although our plans are dependent on receiving FDA approval, which may be delayed or denied. In addition, our product candidate, dalbavancin, is in three Phase III clinical trials for the treatment of both complicated and uncomplicated skin and soft tissue infections and we recently completed a Phase II trial for catheter-related bloodstream infections. We expect to complete the Phase III trials in the first half of 2004 and file an NDA for dalbavancin in the second half of 2004.

Factors that could negatively affect or delay our receipt of FDA approval of one or both of these drugs include:

- a refusal by the FDA to approve our NDAs for these drugs or a request for additional information or data;
- delays in completing clinical trials for dalbavancin; and
- negative or inconclusive results of our ongoing clinical trials of dalbavancin.

Our success is also dependent upon successful commercialization of these two product candidates. Successful commercialization requires acceptance of anidulafungin and dalbavancin by hospital-based physicians, patients and other medical decision makers.

Our success will further depend upon our ability to protect our intellectual property and products. We rely on a combination of patent, trade secret and regulatory protections to protect us from competitors with similar technologies. With regard to anidulafungin, we rely on patents covering the compound, methods of production and methods of use to protect this product candidate from generic competition. With regard to dalbavancin, we rely primarily on regulatory provisions, such as the data exclusivity provisions under the Hatch-Waxman Act, as well as patents

and know-how to protect this product candidate from generic competition. However, in each case there can be no assurances that we will obtain protection for any specified duration.

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

To date, we have not commercialized any products or recognized any revenue from product sales and none of our product candidates are approved for sale. Successful commercialization of a new drug product requires significant investment in research and development, pre-clinical testing and clinical trials, regulatory approval,

Table of Contents

and sales and marketing activities. Most of our product candidates are in early stages of development, one is being reviewed by the FDA, and three are in clinical trials. Our efforts to commercialize our product candidates are subject to a variety of risks inherent in the development of biopharmaceutical products based on new technologies. These risks include the following:

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

- Any or all of our new drug marketing applications might be denied by the FDA and analogous foreign regulators.

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

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

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

- Even if our product candidates are successfully developed and effectively marketed, the size of their potential market might change such that our sales revenue is less than initially contemplated. In any such case, we might never generate sufficient or sustainable revenues to enable us to become profitable.

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

We have incurred net losses since our inception in 1995. As of December 31, 2003, our accumulated deficit was $326.7 million, including the $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch.

Our accumulated deficit results from our net losses of $1.1 million in 1995, $4.8 million in 1996, $6.7 million in 1997 (including $0.4 million in accretion of dividends on preferred stock), $15.1 million in 1998 (including $2.5 million in accretion of dividends on preferred stock), $67.4 million in 1999 (including deemed dividends of $35.1 million and $3.1 million in accretion of dividends on preferred stock), $18.8 million in 2000 (including $3.5 million in accretion of dividends on preferred stock), $32.8 million in 2001, $48.8 million in 2002, and $174.1 million in the year ended December 31, 2003 (including a $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch).

Our losses to date have resulted principally from:

- research and development costs relating to the in-licensing and development of our product candidates, which represented approximately 61% of our aggregate operating expenses from our inception through December 31, 2003;

write-off of in-process research and development expenses relating to our merger with Biosearch, which represented approximately 26% of our aggregate operating expenses from our inception through December 31, 2003; and

general and administrative costs relating to our operations, which represented approximately 13% of our aggregate operating expenses from our inception through December 31, 2003.

On February 28, 2003, we merged with Biosearch, which also incurred net losses since its inception in 1996. Biosearch s net losses were $23.6 million for 2000, $9.8 million for 2001, $9.0 million for 2002 and $5.4 million from January 1, 2003 through the merger date of February 28, 2003. At February 28, 2003, Biosearch had an accumulated deficit of $54.8 million. Biosearch s losses resulted principally from:

research and development costs relating to the discovery, development and manufacture of Biosearch s product candidates, representing 79% of Biosearch s aggregate operating expenses from January 1, 2000 through February 28, 2003; and

Table of Contents

general and administrative costs relating to Biosearch s operations, representing 25% of Biosearch s aggregate operating expenses from January 1, 2000 through February 28, 2003.

However, these expenses were partially offset by amortization of negative goodwill, less losses on trading securities in the net amount of (4%) of Biosearch s aggregate operating expenses from January 1, 2000 through February 28, 2003.

We expect to incur substantial and increasing losses for the foreseeable future as a result of increases in our research and development costs, including costs associated with conducting pre-clinical testing and clinical trials, and charges related to purchases of technology and other assets. We expect that our operating losses will fluctuate significantly from quarter to quarter as a result of the timing of receipt of regulatory approval of anidulafungin and our other product candidates, the success of our commercialization efforts following regulatory approval, 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 prospects of achieving profitability will depend on numerous factors, including success in:

receiving regulatory approvals for our product candidates;

developing and testing new product candidates;

licensing rights to our product candidates to third parties;

qualifying for and receiving grants and subsidies;

manufacturing products;

marketing products; and

competing with products from other companies.

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

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

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

if anidulafungin receives FDA and international marketing approval, it will face competition from commercially available drugs such as anaphotericin B, fluconazole, itraconazole, and potentially from caspofungin, which was the first to receive FDA approval of a new class of antifungal agents called echinocandins (which includes anidulafungin). One of our competitors initially obtained approval only for the narrow indication of aspergillosis salvage therapy, but has recently expanded its scope to include other serious fungal infections;

if dalbavancin receives FDA and international marketing approval, it will face competition from commercially available drugs such as vancomycin, teicoplanin, linezolid, quinupristin/dalfopristin and daptomycin; and

if ramoplanin receives FDA and international marketing approval, it will face competition from commercially available drugs such as metronidazole oral vancomycin as well as drugs focused on the treatment (as opposed to prevention) of bloodstream vancomycin-resistant enterocci infections in hospitalized patients, such as linezolid, quinupristin/dalfopristin and daptomycin.

Table of Contents

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

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

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

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

- slower than expected rate of hospital and patient recruitment;
- inability to manufacture sufficient quantities of the study drug for use in clinical trials;
- unforeseen safety issues;
- lack of efficiency during the clinical trials;
- inability to adequately follow patients after treatment;
- governmental or regulatory delays; and/or
- a decision to expand clinical trials or add studies to increase the statistical significance of the results.

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

As of December 31, 2003, we have one product candidate, anidulafungin, being reviewed by the FDA and three product candidates in clinical trials: dalbavancin in Phase III; ramoplanin in Phase III; and VIC-Acne which has completed Phase I. We also have anidulafungin in Phase III for an additional indication and dalbavancin and ramoplanin in Phase II each for an additional indication; the dalbavancin Phase II has concluded and top-line data released. Patient follow-up for these clinical trials has been limited and more trials will be required before we will expect to apply for regulatory approvals.

Clinical trials conducted by us or by third parties on our behalf might not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin, dalbavancin, ramoplanin or VIC-Acne or any other potential product candidates. Such a failure might delay development of our other product candidates and hinder our ability to conduct related pre-clinical testing and clinical trials. It might also cause regulatory authorities to prohibit us from undertaking any additional clinical trials for our other product candidates. Our other product candidates are in pre-clinical development, and we have not submitted investigational new drug applications, or INDs, to commence clinical trials involving these compounds. Our pre-clinical development

Table of Contents

efforts might not be successfully completed and we might not file further INDs. Any delays in, or termination of, our clinical trials would harm our development and commercialization timelines, which could cause our stock price to decline. Any of these events could also impede our ability to obtain additional financing.

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

As of December 31, 2003, we had 37 full-time clinical development employees. We expect to continue to rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. If these third parties fail to perform satisfactorily under the terms of our agreements with them, clinical trials for our product candidates might be delayed or unsuccessful. Furthermore, the FDA and/or other regulatory agencies of the EU, might inspect some of our clinical investigational sites, our collaborators records and our facilities and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that our clinical trials were not in compliance with applicable requirements, we might be required to repeat the clinical trials.

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

We currently do not have manufacturing facilities capable of manufacturing products in quantities necessary for large-scale trials or marketing. The Aventis plant in Brindisi, Italy, and the Chemsyn Laboratories plant in the United States will be our initial manufacturing sites for dalbavancin and anidulafungin, respectively. Subsequently, we intend to manufacture products in our own manufacturing plant in Pisticci, Italy, which is currently under construction. To the extent that our manufacturing capabilities are insufficient to produce all of the necessary active ingredients for our current and future product candidates, we anticipate that we might need to rely on third parties to manufacture some or all of these active ingredients. However, there are a limited number of facilities in which our product candidates can be produced, and third-party manufacturers have limited experience in manufacturing anidulafungin, dalbavancin, ramoplanin and VIC-Acne in quantities sufficient for conducting clinical trials or for commercialization. Difficulties are often encountered in manufacturing new products, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and other regulations, production costs, and development of advanced manufacturing techniques and process controls. Any contract manufacturer might not perform as agreed or might not remain in the contract manufacturing business for the time we require to successfully develop, produce and market our product candidates. If any of our contract manufacturers fails to perform satisfactorily under its agreements with us, such as by failing to deliver the required quantities of our product candidates for clinical use on a timely basis and at commercially reasonable prices, and if we do not find a replacement manufacturer or develop our own manufacturing capabilities, clinical trials involving our product candidates, or commercialization of our products, could be delayed.

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

We intend to sell a portion of our future products, including anidulafungin and dalbavancin, through our own sales force. At present, however, we are in the process of developing a sales and marketing infrastructure and we lack any experience in direct marketing, sales and distribution. Our future profitability will depend in part on our ability to develop a direct sales and marketing force to sell our future products, if any, to our target market. We might not be able to attract and retain qualified salespeople or be able to build an efficient and effective sales and marketing force. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts might not be successful. If we are unable to enter into third-party arrangements, then we must substantially expand our marketing and sales force in order to achieve commercial success for certain products, and to compete with other companies that have experienced and well-funded marketing and sales operations.

43

Table of Contents

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

An important component of our business strategy is to in-license drug compounds discovered by other pharmaceutical and biotechnology companies or academic research laboratories, in order to develop them ourselves. Currently we in-license anidulafungin from Eli Lilly. Anidulafungin is our lead antifungal product candidate and one of our four product candidates in clinical development. Under our license arrangement with Eli Lilly, we acquired exclusive worldwide rights to anidulafungin. This license arrangement will terminate on a country-by-country basis upon the later of the expiration of all product patents in the country or 10 years from the date of the first commercial sale of anidulafungin in the country. Competition for new promising compounds can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

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

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

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

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

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

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

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

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

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

- demonstrations of clinical efficacy and safety;
- cost-effectiveness;
- potential advantages over alternative therapies, including fewer side effects or easier administration;

Table of Contents

reimbursement policies of government and third-party payors; and

the effectiveness of our marketing and distribution capabilities.

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

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

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

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

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

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

We expect that substantially all of our revenues for the foreseeable future will result from payments under collaborative arrangements, with some European grant and subsidy revenue. To date, collaborative payments have taken the form of up-front payments, reimbursement for research and development expenses and milestone payments. Milestone payments to us under collaborative arrangements are subject to significant fluctuation in both timing and amount. As a result, comparisons of our revenues and results of operations between periods might not

produce meaningful indications of our progress toward commercializing one or more product candidates. Moreover, the historical revenues of Vicuron and Biosearch on a stand-alone basis might not be indicative of our future performance or of our ability to continue to achieve additional milestones and to receive additional milestone payments from our collaborators.

Table of Contents

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

We expect to incur increasing research and development, general and administrative and sales and marketing expenses over the next several years. Based on our current plans and assumptions, we estimate that our cash and liquid assets at December 31, 2003 will be sufficient to fund our operating losses for the next 12 to 18 months. However, if our plans change and/or our assumptions are inaccurate, we might need to seek and obtain capital sooner than anticipated. Some of our more significant plans and assumptions relate to:

- receipt of regulatory approval for anidulafungin and commencement of a marketing campaign for anidulafungin;
- payments received or made under possible future collaborative agreements;
- continued progress in the research and development of our future products;
- costs associated with protecting our patent and other intellectual property rights;
- costs associated with developing marketing and sales capabilities; and
- the rate of market acceptance of any future products.

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

We might seek to raise funds from a traditional lender or through public or private debt or equity offerings. To the extent we raise additional capital through the sale of equity or convertible debt securities, the securities could be sold at a discount to prevailing market price and the issuance of those securities could result in dilution to our stockholders. Moreover, the incurrence of debt financing could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness, and we might be subject to restrictive covenants as a result of such debt financing. This could render us more vulnerable to competitive pressures and economic downturns and could impose restrictions on our operations. If adequate funds are not available from any of those sources, our business might be harmed. We might be required to delay, reduce the scope of, or eliminate one or more of our research and development programs or otherwise significantly curtail operations. In addition, we might be required to obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to certain technologies or drug candidates that we would not otherwise relinquish in order to continue independent operations.

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

We merged with Biosearch in 2003 and, if appropriate opportunities become available, we might attempt to acquire additional products, product candidates or businesses that we believe are a strategic fit with our business. Currently, however, we are not a party to any acquisition agreements. If we pursue any transaction of that sort, the process of negotiating the acquisition and integrating an acquired product, product candidate or business might result in operating difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we might never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or impairment expenses related to goodwill and impairment or amortization expenses related to other intangible assets, which could harm our financial condition.

Table of Contents

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

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

When Nasdaq s recently approved director-independence rules become effective, compliance with both the new rules and our bylaws, as amended by the merger agreement, might require us to increase the size of our board.

We have eight directors on our board. In connection with the merger with Biosearch, we amended our bylaws in a manner that is intended, among other things, to maintain an even balance of legacy Versicor directors and legacy Biosearch directors on the board for three years from the date of the completion of the merger. If we decide to add additional directors to the board during that three-year period, our bylaws effectively require us to add an even number of directors (with one-half of the additional directors proposed by the four legacy Versicor directors and the other half proposed by the four legacy Biosearch directors) in order to maintain an equal number of legacy Versicor and Biosearch directors on the board. Our bylaws might make it more difficult for us to comply with Nasdaq s recently approved director-independence rules.

In order for a majority of our directors to be independent, we would need to (a) ask up to three of our non-independent directors to resign followed by appointment of three new independent directors and/or (b) increase the size of our board by adding up to six additional independent directors. Under the recently approved rules, our board will also need to appoint an independent director as chairman of the audit committee. Any increase in the size of our board or change in its membership might give rise to inefficiencies, which might cause some board actions to be delayed. We will need to comply with the new rules on the earlier of or before the date of our annual stockholders meeting in 2004 or October 31, 2004.

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

Biosearch and its subsidiary historically funded a portion of their operations through research grants and loan subsidies awarded by Italian and EU authorities. Under applicable law, any transfer of those grants and subsidies (including transfer by merger) requires written approval from the Italian bank. In connection with the merger and the subsequent contribution to Vicuron Pharmaceuticals Italy, Srl., our wholly owned Italian subsidiary, we applied for permission to transfer Biosearch s grants and subsidies to our Italian branch and subsidiary. Although the merger and the contribution have been completed, the Italian and EU authorities have not as yet reached an official decision on whether to approve our transfer requests. If the transfers are approved, we intend to apply for further permission to contribute the grants and subsidies to Vicuron Pharmaceuticals Italy S.r.l., our wholly-owned subsidiary in Italy. We face the risk that one or both of the transfers might not be approved, in which case we might be required to repay some or all of the grants and subsidies received by Biosearch prior to the merger, in the aggregate amount of up to approximately $1.8 million as of December 31, 2003, and we may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of December 31, 2003 by the authorized bank, in the aggregate amount of up to approximately $1.3 million as of December 31, 2003 (each estimate based on exchange rates then prevailing). Regardless of whether or not we are required to repay those grants, we anticipate that our Italian subsidiary will be eligible to apply for new research grants and subsidies from both the Italian and EU authorities. However, grants and subsidies are awarded in the discretion of those authorities and we face the risk that our Italian subsidiary might not qualify or be approved for any additional grants or subsidies in the future.

47

Table of Contents

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

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

- issuing each material announcement in both English and Italian might cause administrative challenges;
- submitting filings and applications with regulatory and governmental authorities in the U.S., Italy and the EU, and approving translations of each significant document into the other language, if necessary, might be time-consuming and expensive;
- under Italian employment law, our relations with our employees in Italy are governed by collective bargaining agreements negotiated at the national level (and over which we have no control), which reduce the methods customarily available in the United States to motivate and/or make changes to our Italian workforce;
- under European Union data protection regulations, we are unable to send without restriction private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices; and
- tariffs, customs, duties, import restrictions, tax effects and other trade barriers might delay or increase the cost of relocating personnel and, if marketing approvals are obtained, commercial quantities of our products between nations.

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

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

Risks Related to Operating in Our Industry

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

Our efforts to develop and market our product candidates will be subject to extensive and rigorous domestic regulation. FDA rules govern, among other matters, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products in the United States. Any products that we market abroad will also be subject to extensive regulation by foreign governments. In order to obtain permission to sell our product candidates, we must provide the FDA and

Table of Contents

foreign regulatory authorities with clinical data demonstrating that our proposed drugs are safe in humans and effective at treating an indicated condition. None of our product candidates has been approved for sale in the United States or any foreign market, and we cannot predict whether regulatory clearance will be obtained for any product that we are developing or intend to develop. The regulatory review and approval process takes many years, is dependent upon the type, complexity and novelty of the product candidate, requires the expenditure of substantial resources, involves post-marketing surveillance, and might involve ongoing requirements for post-marketing studies. Delays in obtaining regulatory approvals might:

- impede the commercialization of any drugs that we or our collaborators develop;
- require us or our collaborators to comply with costly additional procedures;
- diminish any competitive advantage that we or our collaborators might attain from early market introduction of a new product; and
- delay or eliminate our receipt of revenues or royalties.

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

- imposed delays in clinical trials or commercialization;
- refusal by the FDA and foreign regulators to review pending market approval applications or supplements to approval applications;
- product recalls or seizures;
- suspension of production;
- withdrawals of previously issued marketing approvals; and
- fines, civil penalties and criminal prosecutions.

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

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

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

Manufacturing facilities are required to comply with the FDA s Good Manufacturing Practice regulations. Even facilities outside the United States, such as the manufacturing plant we are constructing in Italy, must comply with these regulations if the manufactured products will be sold in the United States. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well

Table of Contents

as to maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. Comparable Good Manufacturing Practice regulations also apply in the EU, Italy and other foreign countries. Our contract manufacturers and our manufacturing subsidiary might not be able to comply with the applicable Good Manufacturing Practice requirements and other FDA or other EU, Italian or foreign regulatory agencies regulatory requirements.

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

Our success depends in part on our ability to protect our intellectual property from unauthorized use by third parties, which we will be able to do only to the extent that our intellectual property is covered by valid and enforceable patents or is effectively maintained as a trade secret. We have rights relating to 29 issued U.S. patents, 12 U.S. patent applications, 453 foreign patents and 51 foreign patent applications. Of these patents and patent applications:

- our non-Biosearch patent portfolio as of December 31, 2003 includes no U.S. patents, 10 U.S. patent applications and eleven foreign patent applications; and

- our Biosearch patent portfolio, as of December 31, 2003, includes an additional 29 U.S. patents, two U.S. patent applications, 453 foreign patents and 40 foreign patent applications (of which, dalbavancin-related rights include four issued U.S. patents and one hundred and thirteen foreign patent application).

Our collaborations involve the following patents:

- our license agreement with Eli Lilly with respect to anidulafungin covers 17 U.S. patents, 9 U.S. patent applications, 117 foreign patents and 106 foreign patent applications;

- our collaborative agreement with Novartis covers two U.S. patent applications; and

- our collaborative agreement with Pfizer (as successor to Pharmacia) with respect to the development of oxazolidinones covers four U.S. patents, six U.S. patent applications, two Canadian patent applications and one foreign patent application.

The patent position of biopharmaceutical companies involves complex legal and factual questions and, therefore, we cannot predict with certainty whether they will be enforceable. We have in the past and might in the future receive office actions or other notices from U.S. or foreign patent authorities seeking to limit or otherwise qualify some patent claims. Patents, if issued, might be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties might not provide any protection against competitors. Our pending patent applications, those we might file in the future, or those we might license from third parties, might not result in patents being issued. Also, we periodically review our U.S. and foreign patent filings to determine whether their maintenance is commercially justified. As a result, we may determine from time to time to abandon certain patent applications or allow certain patents to lapse. Moreover, patent rights might not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of many foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States.

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

Table of Contents

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

Our success depends in part on our ability to operate without infringing upon the intellectual property rights of others. Research has been conducted for many years in the areas in which we focus our research and development efforts. This has resulted in a substantial number of issued patents and an even larger number of still-pending patent applications. U.S. patent applications, which are not foreign filed can be maintained in secrecy until issuance. U.S. patent applications which are also intended for foreign filing usually publish 18 months after the earliest priority date or within six months of the U.S. filing date, whichever is later. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Our commercial success will depend significantly on an ability to operate without infringing the patents and other intellectual property rights of third parties. However, our technologies might infringe the patents or violate other intellectual property rights of third parties without our knowledge. In the event an infringement claim is brought against us, we might be required to pay legal and other expenses to defend such a claim and, if our defense is unsuccessful, we might be prevented from pursuing product development and commercialization and might be subject to damage awards.

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

enforce patents that we own or license;

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

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

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

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

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

sufficient to realize an appropriate return on investment in product development. Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of

Table of Contents

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

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

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

Risks Related to the Securities Markets

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

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

- the results of our clinical trials and those of our competitors, and any significant delays or unexpected complications in our clinical trials;
- decisions by regulatory authorities with respect to our development efforts and product candidates;
- public concern regarding the safety and efficacy of drugs we develop;
- new products or services introduced or announced by us or our competitors;
- announcements of scientific innovations by us or our competitors;
- actual or anticipated variations in our annual and quarterly operating results;

conditions or trends in the biotechnology and pharmaceutical industries;

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

additions or departures of key personnel;

general economic conditions;

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

new regulatory legislation adopted in the United States or abroad;

future sales of equity or debt securities by us; and

sales of our common stock by our directors, officers or significant stockholders.

Table of Contents

In addition, the stock market in general, and the Nasdaq National Market, the Nuovo Mercato and the market for biotechnology and pharmaceutical stocks in particular, have experienced significant price and volume fluctuations. Over the 52-week period ending December 31, 2003, the market price of Vicuron common stock as reported on the Nasdaq National Market ranged from a high of $19.46 to a low of $10.05 and our average daily trading volume was 287,924 shares. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company s securities. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management s attention and resources.

We have implemented anti-takeover provisions that could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our restated certificate of incorporation, our amended and restated bylaws and our shareholder rights plan, or poison pill, increase the likelihood that any third party would need to negotiate with our board prior to initiating a takeover proposal for us and could have the effect of delaying or preventing a change of control of our company. For example, our board of directors, without further stockholder approval, may issue preferred stock (or, in the face of a potential acquiror s increased ownership, rights to purchase our common stock for a nominal price) that could delay or prevent a change of control, as well as reduce the voting power of holders of our common stock. In addition, some of our stockholders have entered into a stockholders agreement in which they have agreed, for a period of three years following completion of the merger, to vote as recommended by the board on some issues. These provisions could delay or prevent an attempt to replace or remove our management. The foregoing factors could also limit the price that investors or an acquiror might be willing to pay in the future for shares of our common stock.

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

Interest rates

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

The table below presents principal amounts and related weighted average interest rates by year of maturity for our cash and cash equivalents and marketable securities at December 31, 2003 (in thousands):

	2003
Cash and cash equivalents	$ 113,361
Average interest rate	1.74%
Marketable securities	$ 52,796
Average interest rate	1.23%

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.

Table of Contents

Inflation

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

Currency Risk

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data required by Regulation S-X are included in this annual report commencing on page 71.

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

None.

ITEM 9.A. CONTROLS AND PROCEDURES.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including each of our president and chief executive officer and chief financial officer, as appropriate, to allow timely decisions regarding required disclosure. Management necessarily applied its judgment in assessing the costs and benefits of such controls and procedures which, by their nature, can provide only reasonable assurance regarding management s control objectives.

As of December 31, 2003, we carried out an evaluation, under the supervision and with the participation of our management, including our president and chief executive officer along with our chief financial officer, of the effectiveness of the design and operation of our disclosure

controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon the foregoing, our president and chief executive officer along with our chief financial officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to our company required to be included in our Exchange Act reports. There have been no significant changes in our internal controls or in other factors which could significantly affect internal controls subsequent to December 31, 2003.

Table of Contents

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Board of Directors

Our eight current directors are as follows:

Name	Age	Officer Position*	Board Position	Term Expires
James H. Cavanaugh, Ph.D.	67		Chairman (1)(2)(3)	2005
George F. Horner III	59	CEO	Director	2005
Claudio Quarta, Ph.D.	49	COO	Director (3)	2005
Ubaldo Livolsi, Ph.D.	58		Director (1)(2)	2003
Francesco Parenti, Ph.D.	63	CSO	Director (3)	2004
Costantino Ambrosio	61	CMfgO	Director	2003
Christopher T. Walsh, Ph.D.	60		Director (1)	2004
David V. Milligan, Ph.D.	63		Director (2)	2003

* See table below for full titles.
(1) Member of the audit committee
(2) Member of the compensation committee
(3) Member of the nominating committee

Executive Officers of Vicuron

The names of our current executive officers are set forth in the following table. All of our officers are employed by us other than Mr. Ambrosio, who is an independent consultant to our subsidiary.

Name	Age	Title
George F. Horner III	59	President and Chief Executive Officer
Claudio Quarta, Ph.D.	49	Chief Operating Officer
Francesco Parenti, Ph.D.	63	Executive Vice President and Chief Scientific Officer, Worldwide
Timothy J. Henkel, M.D., Ph.D.	44	Executive Vice President and Chief Medical Officer
Costantino Ambrosio	61	Executive Vice President and Chief Manufacturing Officer
Richard J. White, Ph.D.	61	Executive Vice President and Chief Scientific Officer, North America
Dov A. Goldstein, M.D.	36	Executive Vice President and Chief Financial Officer

Business Experience of Our Directors and Executive Officers

Set forth below is a brief account of the business experience and education of our directors and executive officers:

James H. Cavanaugh, Ph.D. Dr. Cavanaugh is the Chairman of our board of directors and has served as a member of our board of directors since 1999. He currently serves on our audit committee, compensation committee and nominating committee. Since 1989, he has served as president of HealthCare Ventures based in Princeton, New Jersey. Prior to joining HealthCare Ventures, Dr. Cavanaugh was president of SmithKline and French Laboratories U.S., the domestic pharmaceutical division of SmithKline Beecham Corporation, as well as president of Allergan International. Dr. Cavanaugh served as staff assistant to President Nixon for health affairs and then as deputy director, Domestic Council. Under President Ford, he was deputy assistant to the President for domestic affairs and then deputy chief of the White House staff. Dr. Cavanaugh is trustee emeritus of the

Table of Contents

California College of Medicine. He is a non-executive chairman of the board of Diversa Corporation and Shire Pharmaceuticals Group PLC and a non-executive director of MedImmune Corporation and Advancis Pharmaceutical Corporation. He is a past director of the Pharmaceutical Research and Manufacturers Association. Dr. Cavanaugh holds a Ph.D. degree in health economics from the University of Iowa.

George F. Horner III. Mr. Horner has served as our president and chief executive officer and a member of our board of directors since 1996. Prior to joining us, Mr. Horner was corporate vice president of Ligand Pharmaceuticals from 1993 to 1995. He also served in a number of executive positions during his 17 years at Abbott Laboratories from 1976 to 1993, including president, Canada; regional director, Latin America; general manager, Mexico; general manager, Southern Africa Region; and regional manager, Southeast Asia. From 1967 to 1976, Mr. Horner served in a number of sales and product management positions at E.R. Squibb, Inc.

Claudio Quarta, Ph.D. Dr. Quarta has served as our chief operating officer and a member of our board of directors since March 1, 2003. Dr. Quarta served as chief executive officer and managing director of Biosearch Italia since its formation in 1996 to February 2003. Prior to forming Biosearch through a management buy-out of the Lepetit Research Center, Dr. Quarta held a number of positions during his 19 years in the industry, a portion of which were with the Lepetit Group and its affiliates, including director of the Center and director of biological sciences of the Lepetit Research Center and fermentation development manager of the MMD Production Plant. Since 1998, Dr. Quarta has been President through 2003 of the Consorzio per le Biotecnologie Roberto Lepetit, which promotes biotechnology links between academia and industry. In 1997, Dr. Quarta was also appointed contract professor in biotechnology at the Milan University. Dr. Quarta holds a Ph.D. degree in medical genetics from Rome University and a degree in biology from Perugia University.

Francesco Parenti, Ph.D. Dr. Parenti is our chief scientific officer, worldwide and a member of our board of directors since March 1, 2003. We have also appointed Dr. Parenti as an executive vice president of our company. Dr. Parenti served in several executive positions at Biosearch since 1997, most recently as president and chief scientific officer and chairman of Biosearch s board of directors. Prior to forming Biosearch as part of a management buyout of the Lepetit Research Center, Mr. Parenti held a number of positions during his 25 years with the Lepetit Group and its affiliates, including vice president of business for Europe, Middle East and Africa at Hoechst-Marion-Roussel; president of Marion Merrel Dow, which was later purchased by Hoechst-Marion-Roussel; Managing Director and Director-General, Italy for the Lepetit Research Center; and director of pre-clinical research at Dow-Lepetit, where he was responsible for patenting teicoplanin. Dr. Parenti is the president of the board of directors of Newron Pharmaceuticals (Italy). Dr. Parenti has been a member since October 27, 1999 of the board of Convergenza Private Equity Fund. He serves as a non-executive director of Livolsi & Partners S.p.A. Dr. Parenti holds a Ph.D. degree in biological sciences from University Milan (Italy) and post-doctoral degrees from the Smithsonian Institution and the Yale University School of Medicine.

Costantino Ambrosio. Mr. Ambrosio has been our chief manufacturing officer and a member of our board of directors since March 1, 2003. We have also appointed Mr. Ambrosio as an executive vice president of our company. From December 1999 until our merger with Biosearch, he served as executive vice president of manufacturing for Biosearch. Prior to his relationship with Biosearch, Mr. Ambrosio was employed by Dow Iberica, from 1996 to 1998, most recently as its general manufacturing manager. From 1991 to 1996 he served in the same position for Dow Italia and from 1988 to 1991 he was responsible for bulk pharmaceutical manufacturing at Merrel Dow. From 1971 to 1988 Mr. Ambrosio advanced through a series of manufacturing positions at Dow Chemical s Gruppo Lepitit Brindisi. Mr. Ambrosio holds a degree in industrial chemistry from Industrial Chemistry School Naples and a degree in industrial sciences from Herisau University.

Ubaldo Livolsi, Ph.D. Dr. Livolsi has served as a member of our board of directors and a member of our audit committee and our compensation committee since March 1, 2003. He was previously a director of Biosearch from 1999 until its merger with our company in 2003. From 1983 to 1989, Dr. Livolsi was treasurer of Dow Chemical Italy s fully controlled subsidiary Gruppo Lepetit Spa, the biotechnology research organization that was renamed Biosearch following its management buy out. Currently, Dr. Livolsi is also the chairman and

Table of Contents

chief executive officer of Livolsi & Partners S.p.A., an Italian merchant bank, and the chief executive officer of Cinecittà S.p.A., an entertainment company, a position he has held since January 2003. During the period 1991 to 1998, Dr. Livolsi was employed by Gruppo Fininvest, an entertainment company, initially as chief financial officer and later as chief executive officer. During the period 1964 to 1991, Dr. Livolsi was employed by Dow Chemical Company (Italy/Europe), a chemical and agricultural products company, as its financial director. Dr. Livolsi currently serves as chairman of the board for the Convergenza Private Equity Fund, Cit S.p.A. and Bonaparte 48. Dr. Livolsi holds a degree in economics from the Catholic University of Milan.

David V. Milligan, Ph.D. Dr. Milligan has served on our board of directors since 1997 and serves on our compensation committee. He also served as the chairman of our board from early 1997 until our merger with Biosearch in early 2003. He has also been a member of our scientific advisory board since 1997 and was a paid scientific consultant to our company from 1997 to 2002. From 1979 to 1996, Dr. Milligan served in several executive positions at Abbott Laboratories, a healthcare products company, most recently as its senior vice president and chief scientific officer from 1994 to 1996. Dr. Milligan is vice-chairman of the board of directors of Caliper Technologies Corp. and serves as a member of the boards of directors of ICOS Corporation, Galileo Laboratories, Pathway Diagnostics and Reliant Pharmaceuticals. He also serves on the Chemistry Department Advisory Board of Princeton University and is a vice president of Bay City Capital, a San Francisco-based merchant bank. Dr. Milligan holds a M.S. degree and a Ph.D. degree in organic chemistry from the University of Illinois and an A.B. degree in chemistry from Princeton University.

Christopher T. Walsh, Ph.D. Dr. Walsh has served as a member of our board of directors since 1998 and currently serves on our audit committee. Since 1991, he has served as the Hamilton Kuhn professor of biological chemistry and molecular pharmacology at the Harvard Medical School. He was the President of the Dana-Farber Cancer Institute from 1992 to 1995. From 1987 to 1995, he served as the chairman of the Department of Biological Chemistry and Molecular Pharmacology at the Harvard Medical School. Dr. Walsh is a member of the scientific advisory boards of KOSAN Biosciences and Millennium Pharmaceuticals. He is a member of the board of directors of Transform Pharmaceuticals, KOSAN Biosciences, Critical Therapeutics and Microbia. He has also held various positions at Massachusetts Institute of Technology, including as chairman of the Chemistry Department and has served on the editorial boards of various scientific publications. Mr. Walsh holds a Ph.D. degree from The Rockefeller University and an A.B. degree from Harvard University.

Timothy J. Henkel, M.D., Ph.D. Dr. Henkel has served as our chief medical officer since February 2001. We have also appointed Dr. Henkel as an executive vice president of our company. Prior to joining Vicuron, Dr. Henkel was vice president of worldwide anti-infective clinical development at SmithKline Beecham where he worked from 1995 to 2000. From 1994 to 1995, Dr. Henkel was assistant professor of internal medicine and infectious diseases at Barnes Hospital and Washington University Medical Center in St. Louis. Dr. Henkel holds a M.D. and a Ph.D. degree from Washington University School of Medicine and a B.S. degree from Rhodes College.

Richard J. White, Ph.D. Dr. White is our chief scientific officer, North America. We have also appointed Dr. White as an executive vice president of our company. Dr. White joined Vicuron in 1997 as senior vice president of biology. Prior to joining Vicuron, Dr. White was vice president for infectious diseases at Bristol Myers Squibb from 1985 to 1997. Dr. White has also held research management positions at Lederle Laboratories, Glaxo Group Research in the United Kingdom, and Lepetit Research in Italy. Dr. White holds a Ph.D. degree in biochemistry from the University of Oxford and a B.S. degree in biochemistry from the University of Manchester.

Dov A. Goldstein, M.D. Dr. Goldstein has served as our chief financial officer since July 2000 and our vice president, finance from July 2000 to August 2003, when we appointed him as an executive vice president of our company. Prior to joining Vicuron, Dr. Goldstein was director of venture analysis at HealthCare Ventures from 1998 to 2000. Dr. Goldstein served as vice president, biotechnology research analysis at Brean Murray & Co. from 1997 to 1998. He completed his internship in the Department of Medicine of Columbia-Presbyterian Hospital. Dr. Goldstein holds a M.B.A. degree from Columbia Business School, a M.D. degree from Yale University and a B.S. degree from Stanford University.

57

Table of Contents

Giorgio Mosconi, M.D. Dr. Mosconi is our Senior Vice President of Business Development. Prior to his current appointment in August 2003, he served as the Vice President, Medical Affairs and Business Development at Biosearch from May 2000 to March 2003 and continued in this role with our Company after our merger with Biosearch. In addition, from 1996 to April 2000, Dr. Mosconi served as the Executive Director, European Clinical Development for Bristol-Myers Squibb (BMS). Dr. Mosconi received his M.D. degree and completed his surgical residency in ENT at the University of Milan (Italy) and holds a B.S. degree in Chemistry from the Institute of Chemistry in Bergamo (Italy).

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act, or the Exchange Act, requires our officers and directors, and persons who own 10% or more of our common stock, to report their beneficial ownership of our common stock (and any related options) to the SEC. Their initial report must be filed using the SEC s Form 3 and they must report subsequent stock purchases, sales, option exercises and other changes using the SEC s Form 4, which must be filed within two business days of most transactions. In some cases, such as changes in ownership arising from gifts and inheritances, the SEC allows delayed reporting at year-end on Form 5. Officers, directors and stockholders owning more than 10% of our common stock are required by SEC regulations to furnish us with copies of all of reports they file pursuant to Section 16(a). From and after the date of the merger, we have made the services of our legal counsel available to our officers and directors to assist them in meeting their filing obligations.

Based solely on our review of copies of these reports filed by or on behalf of our officers and directors (or oral representations that no such reports were required), we believe that since January 1, 2003 all of our officers and directors and stockholders owning greater than 10% of our common stock complied with all applicable Section 16(a) filing requirements, except as follows: in May 2003 and September 2003, Dr. Goldstein filed two Form 4s late; in September 2003, each of Mr. Horner and Drs. Cavanaugh, Henkel, Milligan, Walsh and White filed a Form 4 late; and in September 2003, Mr. Mosconi filed a Form 3 late.

Audit Committee Financial Expert

We have determined that Dr. Livolsi, a member of our audit committee, qualifies as an audit committee financial expert as defined in Item 401(h) of Regulation S-K, and that Dr. Livolsi is not independent as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Securities Exchange Act.

Code of Ethics

Our board of directors intends on adopting a code of ethics which applies to our chief executive officer, chief financial officer, corporate controller, and persons performing similar functions before our 2004 annual meeting of stockholders.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Executive Officers

The following table summarizes the compensation awarded or paid for the past three full fiscal years:

by Vicuron to our chief executive officer (Mr. Horner);

by Vicuron to the four other most highly compensated persons who were serving as executive officers of Versicor at the end of 2002 (Drs. Henkel, White, Goldstein and Patel); and

by Biosearch Italia to the three other Vicuron officers who are also members of our current board of directors (Drs. Quarta and Parenti and Mr. Ambrosio, each of whom was an officer and director of Biosearch Italia prior to the merger).

Table of Contents

We refer to the persons identified in the following table as our named executive officers.

Summary Compensation Table

		Annual Compensation (1)			Long-Term Compensation	
Name and Principal Position	Year	Salary	Bonus	Other Annual Compensation	Securities Underlying Options (2)	All Other Compensation
George F. Horner III	2003	$ 422,308	$ 142,500		375,000	$ 59,629(11)
	2002	$ 324,443	$ 100,000			
Chief Executive Officer	2001	$ 271,249	$ 52,000			
Claudio Quarta, Ph.D	2003	$ 229,603(3)	20,660(3)		700,000	$ 43,307(11)
	2002	147,409	20,660(5)			
Chief Operating Officer	2001	145,000	20,660(4)			
Francesco Parenti, Ph.D	2003	162,530(3)	20,660(3)		600,000	
Chief Scientific Officer, Worldwide	2002	148,410	20,660(5)			
	2001	147,000	20,660(4)			
Timothy J. Henkel, M.D., Ph.D	2003	$ 321,774	$ 78,625		25,655	
	2002	$ 307,957	$ 60,000		44,309	
Chief Medical Officer	2001	$ 263,230(6)				$ 154,597(7)
Costantino Ambrosio	2003	154,937(8)	110,000(8)		400,000	
	2002	154,905	103,000(5)			
Chief Manufacturing Officer	2001	152,000	103,000(4)		88,500(9)	
Richard J. White, Ph.D	2003	$ 273,876	$ 78,285		93,944	
Chief Scientific Officer, North	2002	$ 281,208	$ 47,500		187,887	
America	2001	$ 255,754	$ 36,445			$ 40,000(10)
Dov A. Goldstein, M.D.	2003	$ 239,356	$ 46,600		137,678	$ 45,215(11)
	2002	$ 218,229	$ 40,250		15,356	
Chief Financial Officer	2001	$ 208,039	$ 11,130			
Dinesh V. Patel, Ph.D	2003	$ 124,340	$ 45,900		31,250	$ 55,267(12)
	2002	$ 218,166	$ 33,250		62,500	
Vice President, Drug Discovery	2001	$ 210,102	$ 32,375			

(1) For the years 2002 and 2001, amounts denominated in U.S. dollars ($) were paid by Versicor; amounts denominated in E.U. euros ( ) were paid by Biosearch Italia, or its manufacturing subsidiary. Amounts in the Bonus column for any year represent bonus paid in that fiscal year, typically as compensation for the named executive officer s performance during the prior fiscal year. Accordingly, amounts shown for 2003 exclude bonuses paid in the first quarter of 2004 as awards for 2003 performance, which were in the following amounts: $171,500 for Mr. Horner; $81,138 for Dr. Quarta; 43,200 for Dr. Parenti; $90,250 for Dr. Henkel; 196,000 for Mr. Ambrosio; $80,750 for Dr. White; $80,750 for Dr. Goldstein; and $0 for Dr. Patel. Amounts in the Other Annual Compensation column for each year exclude the

value of perquisites which, in the aggregate for each officer in each year, did not exceed the lower of $50,000 or 10% of such officer s salary and bonus compensation for such year.

(2) Unless otherwise noted, amounts in the Securities Underlying Options column refer to shares of our common stock underlying options granted under (i) the Vicuron Pharmaceuticals Inc. 1997 Equity Incentive Plan Stock (the 1997 Plan), as amended, or (ii) the Vicuron Pharmaceuticals Inc. 2001 Stock Option Plan (the 2001 Plan). No grants of stock appreciation rights (SARs), whether freestanding or in tandem with stock options, were made during the years presented to the named executive officers.

Table of Contents

(3) Biosearch made pro rated salary payments to each of Drs. Quarta and Parenti in the amounts of 23,059 and 23,059 respectively, for the period from January 1 through February 28, 2003 (based on an annual salary of 155,652 for Dr. Quarta and 164,901 for Dr. Parenti). Vicuron, or its Italian subsidiary, made pro rated salary payments to each of Drs. Quarta and Parenti in the amounts of $204,930 and 139,471, respectively, for the period from March 1 through December 31, 2003 (based on an annual salary of $350,000 for Dr. Quarta and 164,900 for Dr. Parenti). Vicuron also made bonus payments of 20,660 and 20,660 to each of Drs. Quarta and Parenti, respectively.

(4) Amounts accrued as of December 31, 2001.

(5) Amounts accrued as of December 31, 2002.

(6) Based on an annual salary of $295,000. Dr. Henkel was hired on February 1, 2001.

(7) Dr. Henkel received a signing bonus of $154,959 on February 1, 2001.

(8) The manufacturing subsidiary of Biosearch paid Mr. Ambrosio 25,823 for the period from January 1 through February 28, 2003 as compensation for his services as an independent consultant to Biosearch or its subsidiary (based on an annual independent consultant fee of 154,937). Vicuron, through its Italian subsidiary, paid Mr. Ambrosio 129,114 for the period from March 1 through December 31, 2003 as compensation for his services as an independent consultant to Vicuron or our subsidiaries (based on an annual independent consultant fee 154,937) and an incentive bonus of 110,000.

(9) Amount shown for 2001 include options awarded by Biosearch in 2002 for the executive s performance in 2001. On February 6, 2002, the Biosearch board of directors awarded Mr. Ambrosio an option to purchase 50,000 ordinary shares of Biosearch at 21.00 per share in respect of his performance in fiscal year 2001; upon the merger of Biosearch with and into Vicuron, this option was cancelled and on March 1, 2003 we issued to Mr. Ambrosio a replacement option under our 2002 Stock Option Plan to purchase 88,500 shares of our common stock (based on the merger exchange ratio of 1.77 Vicuron shares per Biosearch share) at $10.62 per share (based on the average closing price of our stock during the one-month period immediately preceding the merger closing); 25% of this option vests on March 1, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires February 28, 2013.

(10) Dr. White executed in favor of us a non-interest bearing promissory note dated May 15, 1997 in consideration for a loan we made to him at that time. The promissory note was in the original principal amount of $200,000 and was due on May 15, 2002. We forgave $146,667 of the unpaid principal of the note in 2000 and another $40,000 in 2001.

(11) Amounts represent relocation bonuses.

(12) Dr. Patel left the Company in July 2003. The amount represents unused accrued vacation paid to him.

Table of Contents

Option Grants

The following table describes the stock options we granted to our named executive officers in 2003. The table also includes the potential realizable value of these grants over the ten-year term of the options, based on assumed rates of stock appreciation of 5% and 10%, compounded annually. These assumed rates of appreciation have been selected in accordance with the rules of the SEC and do not represent an estimate of our future stock price. There can be no assurance that the actual stock price will appreciate over the option terms at the assumed rates of 5% and 10% or at any other specific rate. Unless the market price of the underlying shares appreciates over the option term, the named executive officers will not realize value from these option grants.

Vicuron Pharmaceuticals Option Grants in 2003

	Individual Grants					
					Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (2)	
Name	Number of Securities Underlying Options Granted in 2003 (1)	Percent of Total Vicuron Options Granted in 2003	Exercise Price	Expiration Date	5%	10%
George F. Horner III	375,000(3)	6.24%	$ 10.85	3/5/2013	$ 2,516,667	$ 6,417,427
Claudio Quarta, Ph.D.	700,000(4)	11.65%	$ 10.62	2/28/2013	$ 4,914,650	$ 12,229,162
Francesco Parenti, Ph.D.	600,000(5)	9.99%	$ 10.62	2/28/2013	$ 4,212,557	$ 10,482,139
Timothy J. Henkel, M.D., Ph.D	25,655(6)	.43%	$ 12.20	5/7/2013	$ 196,838	$ 498,827
Costantino Ambrosio	488,500(7)	8.13%	(7)	(7)	$ 3,429,724	$ 8,534,207
Richard J. White, Ph.D.	93,944(8)	1.56%	$ 12.20	5/7/2013	$ 720,787	$ 1,826,615
Dov A. Goldstein, M.D.	137,678(9)	2.29%	(9)	(9)	$ 1,113,565	$ 2,821,995

(1) Vicuron option grants are shown in the table. No Biosearch options were granted to any of the named executive officers in 2003.

(2) Calculated pursuant to SEC rules on the assumption that the market price of the underlying common stock appreciates in value from the date of grant to the end of the option term at the rates shown.

(3) On March 6, 2003, the Company granted Mr. Horner an option to purchase 375,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $10.85 per share, 25% of this option vests on March 6, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires March 5, 2013.

(4) On March 1, 2003, the Company granted Dr. Quarta an option to purchase 700,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $10.62 per share, 25% of this option vests on March 1, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires February 28, 2013.

(5) On March 1, 2003, the Company granted Dr. Parenti an option to purchase 600,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $10.62 per share, 25% of this option vests on March 1, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires February 28, 2013.

(6) On May 8, 2003, the Company granted Dr. Henkel an option to purchase 25,655 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.20 per share, 25% of this option vests on May 8, 2004 and the balance of 75% vests in 36 equal monthly

installments thereafter; the option expires May 7, 2013.

(7) On March 1, 2003, the Company granted Mr. Ambrosio (i) an option to purchase 88,500 shares of our common stock under our 2002 Stock Option Plan at an exercise price of $10.62 per share (as a replacement stock option upon the effectiveness of the merger between us and Biosearch), and (ii) an option to purchase 400,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $10.62. 25% of each of the options described in (i) and (ii) vests on March 1, 2004 and the balance of each option vests in 36 equal monthly installments thereafter. Both options expire on February 28, 2013.

Table of Contents

(8) On May 8, 2003, the Company granted Dr. White an option to purchase 93,944 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.20 per share, 25% of this option vests on May 8, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires May 7, 2013.

(9) On May 8, 2003, the Company granted Dr. Goldstein an option to purchase 7,678 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.20 per share, 25% of this option vests on May 8, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires May 7, 2013. On August 7, 2003, we also granted Dr. Goldstein an option to purchase 130,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.90 per share, 25% of this option vests on August 7, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires August 6, 2013.

Aggregated 2003 Option Exercises and Year-End Option Values

The following table shows information for the named executive officers regarding exercises of Vicuron stock options during 2003, and the amount and values of unexercised stock options as of December 31, 2003.

2003 Option Exercises and Year-End Option Holdings

Name	Number of Shares Acquired on Exercise	Value Realized (1)	Number of Securities Underlying Options at December 31, 2003		Value of Unexercised In-the-Money Options at December 31, 2003 (2)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
George F. Horner III			738,750	375,000	$ 13,445,551	$ 2,925,000
Claudio Quarta, Ph.D.				700,000	$	$ 5,621,000
Francesco Parenti, Ph.D.				600,000	$	$ 4,818,000
Timothy J. Henkel, M.D., Ph.D.			320,307	149,657	$ 3,869,987	$ 1,455,488
Costantino Ambrosio				488,500	$	$ 3,922,655
Richard J. White, Ph.D.			319,887	195,717	$ 4,256,357	$ 605,939
Dov A. Goldstein, M.D.	2,100	$ 15,078	190,475	172,559	$ 2,555,277	$ 1,167,046
Dinesh V. Patel, Ph.D	72,885	$ 1,019,759	0	0	$ 0	$ 0

(1) Based on the closing price of our common stock on the date of exercise, minus the exercise price of the option.

(2) Based on the closing price of our common stock on December 31, 2003 of $18.65 per share, minus the exercise price of in-the-money options.

Employment Contracts, Indemnification Agreements and Change-in-Control Arrangements

In July 2000, we entered employment agreements with Mr. Horner, Dr. White, Dr. Goldstein and Dr. Patel. In December 2000, we entered an employment agreement with Dr. Henkel. The original term of each employment agreement terminates three years after its respective commencement date. However, each employment agreement contains an automatic renewal provision in which the employment agreement renews for three years on each anniversary of the employment agreement unless we give notice to the named executive officer at least 60 days prior to the renewal date that the employment agreement will not be extended. The employment agreements provide for participation in all

bonus, incentive, savings and retirement and benefit plans offered generally to our employees, among other terms and conditions. If a change in our control occurs and within two years after the change in our control we terminate the named executive officer s employment without cause or he resigns for good reason, then the named executive officer will receive payments equal to two times the sum of his annual base salary then being paid or his highest annual base salary for any one of the prior two years, depending on the particular agreement, plus the amount of the largest bonus received during any one calendar year.

Table of Contents

In March 2003, we entered into indemnity agreements with our directors and Dr. Goldstein. These agreements indemnify each director and Dr. Goldstein to the fullest extent permissible by Delaware law (including any future amendments thereto, if such future amendments increase our power to indemnify our directors and officers). The indemnification extends to any lawsuit brought against the director or officer by reason of the fact that such person is or was serving as a director or officer of our company. However, the indemnification does not extend to any conduct by a director or officer who is adjudged by a final verdict to have engaged in willful misconduct, knowing fraud or deliberate dishonesty. The indemnity agreements also obligate us to advance litigation expenses to the director or officer prior to the time when the director s or officer s right to indemnification is finally determined. In the event that the director or officer is found to be ineligible for such coverage, those advanced expenses must be repaid to our company.

Additional Employment or Independent Consulting Arrangements with Our Officers in Italy

Upon completion of the merger, Dr. Quarta, Dr. Parenti and Mr. Ambrosio became executive officers of our company. Previously, Drs. Parenti and Quarta were employed by Biosearch and Mr. Ambrosio was the managing director of Biosearch s manufacturing subsidiary. Under Italian law, all employees of Biosearch immediately before the merger continued as employees of the combined company immediately after the merger, and were entitled to essentially maintain their pre-merger employment terms and conditions as a minimal standard. In Italy, employment terms and conditions are governed:

by individual employment agreements; and

by Italian law and collective bargaining agreements.

The general manner in which each of these authorities affects our employment relationship with our Italian executives is described below.

Employment, Independent Consultant, and Non-Competition Agreements with our Officers in Italy

On July 30, 2002, concurrently with our execution of the merger agreement and subject to the completion of the merger, we entered into employment agreements with Drs. Quarta and Parenti, each of whom is now a director and an executive officer of our company. We also entered into a consulting agreement with the head of Biosearch s manufacturing subsidiary, Costantino Ambrosio, who is now a director and an executive officer of our company. Our agreements with Drs. Quarta and Parenti and Mr. Ambrosio became effective upon the closing of the merger. Under the agreements, we pay base salaries of $350,000 to Dr. Quarta, 161,000 Euros to Dr. Parenti, and we make consulting payments to Mr. Ambrosio of 155,000 per year. In addition, each executive is eligible for the fringe benefits package offered to our executive officers generally and for an annual bonus based on his performance under standards established in advance by the compensation committee. Pursuant to these agreements, on March 1, 2003, we awarded stock options to purchase shares of our common stock under our 2001 Stock Option Plan in the amounts of: 700,000 to Dr. Quarta; 600,000 to Dr. Parenti; and 400,000 to Mr. Ambrosio. The exercise price of each option is $10.62 per share (which was the average closing price of our stock during the one-month period immediately preceding the closing of the merger). Subject to continued service to our company, 25% of each option vests on the first anniversary of the date of grant and the balance of 75% vests in 36 equal monthly installments thereafter. These options expire ten years after the date of grant. In their agreements, each Italian executive agreed that for one year following any termination of service to us he will not engage in any business activity in Italy that competes against us. In exchange, in accordance with the custom in Italy, we agree to pay each executive a portion of his base compensation in a lump sum, one year following the termination of his employment. Although our Italian counsel has advised us that these non-compete agreements comply with Italian law, the courts of many jurisdictions may not enforce non-competition agreements and we face the risk that these agreements might provide incomplete or ineffective protection insofar as the non-competition provision is concerned.

In August, 2003, we relocated Dr. Quarta to our Pennsylvania offices. In connection with his relocation we, increased Dr. Quarta s base salary from 161,000 per year to $350,000 per year and we agreed to reimburse Dr. Quarta s relocation expenses in accordance with our relocation policy.

Table of Contents

Italian Law and National Collective Bargaining Agreements.

Many material terms of our Italian executives employment are mandated by Italian law and national collective bargaining agreements. In Italy, collective bargaining agreements are much more prevalent than in the United States and are negotiated at a national level beyond the control of any particular employer between the unions of a particular business sector (mechanical, commerce, banks, chemical, etc.) and the employers association in the applicable sector. In principle, the Italian national collective agreements will be legally binding on our employment relationships after the merger only if we, and the employees in question, actually join the relevant national associations or if our individual employment agreements expressly or implicitly accept that the employment relationship is to be regulated by a specified national collective agreement (which we have not done and which our executive employment agreements do not expressly provide). In practice, however, the protection provided to employees in the national collective agreements is generally considered to be the minimum acceptable and Italian courts apply the national collective agreements in every case.

In particular, our employment relationships with our Italian executives are regulated by Italy s National Collective Agreement for the Executives in the Industrial Sector of May 23, 2000, as amended, which provides, among other things:

- executives are entitled to minimum gross monthly salary and salary increases related to length of service;
- executives yearly salaries are paid in 14 installments;
- executives are not subject to working time schedules or overtime rules;
- executives are entitled to 35 days of holiday per year;
- for justified reasons, executives are entitled to an unpaid leave period;
- in case of illness, the executives are entitled to maintain their job position for a period of up to 12 months during which they will receive their full salary (with the cost being fully borne by the employer);
- executives are entitled to mandatory paid maternity leave;
- executives are entitled to insurance coverage for on- and off-duty accidents; and
- executives are entitled to indemnification for any civil and criminal liabilities incurred by the executives in the performance of their employment activities.

Finally, the Italian National Collective Agreement regulates the severance benefits we would be required to pay upon any termination by us of the employment of our officers in Italy. The severance amount varies based upon whether the termination is for cause, for justified reasons or for no justified reason, as generally described below:

Terminations for Cause. If we were to dismiss an executive in Italy for cause, he would not be entitled to any notice period or indemnity in lieu of the notice period, but he would be entitled to receive the severance compensation (so-called TFR). We would have cause to terminate an executive s employment, under Article 2119 of the Italian civil code, following any serious event that makes the continuation of the employment relationship impossible, even on a temporary basis. Events such as theft, riots and serious insubordination are generally considered cause for termination in Italy.

Terminations for Justified Reasons. If we were to terminate the employment of any executive in Italy, other than for cause, the executive would be entitled to a notice period. The notice period is equal to eight months for executives having a seniority of up to two years, and it is increased in proportion to seniority up to a maximum of 12 months for executives having more than 10 years of seniority. If we were to terminate an executive s employment for justified reasons without providing the required notice, he would be entitled to the indemnity in lieu of the notice period equal to the salary he would have

Table of Contents

received during the notice period, in addition to the severance compensation. The average amount of the bonuses paid to him during the prior three years and the value of his fringe benefits would be taken into account when calculating this indemnity. Under Article 2118 of the Italian civil code, the following events are generally considered to provide a justified reason for terminating an executive s employment: failure of the executive to comply with material management directions; a restructuring or reorganization of the company; a complete closing of the company; or the closing of the office to which the executive is assigned.

Unlawful Terminations. If we were to terminate the employment of any executive in Italy without cause or justified reasons, the executive might challenge the dismissal in court. If the termination of the employment relationship is deemed unlawful by the court, the executive may be awarded damages in the form of an indemnity (to be paid in addition to the indemnity in lieu of the notice period and the severance compensation) ranging from a minimum amount equal to the notice indemnity due to the executive, plus two months salary up to a maximum amount equal to 22 months salary. An executive is never entitled to reinstatement, regardless of the cause of termination.

Compensation Committee Interlocks and Insider Participation

During the last completed fiscal year, none of the members of our compensation committee was an officer or employee of our company. During the last completed fiscal year, none of our executive officers served as a member of the board of directors or compensation committee of any entity that had one or more executive officers serving as a member of our board of directors or compensation committee.

Compensation of Directors

We reimburse all of our directors for expenses incurred in connection with attending board and committee meetings. Currently directors who also serve as officers of our company do not receive any additional compensation for their service on the board. The compensation we pay to the officers on our board is presented in the Summary Compensation Table above.

Compensation to Non-Employee Directors

Prior to 2003, we did not compensate our non-officer directors for their service as board or committee members, other than through stock option grants. During those years, we engaged two of our directors, Dr. Walsh and Dr. Milligan, as scientific and medical consultants and paid consulting fees to them in connection with the advisory services they provided to us, as described under the caption Certain Relationships and Related Party Transactions. At the end of 2002, we terminated the consulting arrangements with Drs. Walsh and Milligan and in 2003 we began compensating them for their service on the board. In 2003, we made the following payments and stock option awards to our non-employee directors:

$50,000 per year to Dr. Walsh for his service on the board and committees. On May 8, 2003, we also granted Dr. Walsh an option to purchase 25,000 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.20 per share, 25% of this option vests on May 8, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires May 7, 2013;

$100,000 per year to Dr. Milligan for his service on the board and committees. On March 6, 2003, we also granted Dr. Milligan an option to purchase 62,188 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $10.85 per share, 25% of this option vests on March 6, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option

expires March 5, 2013;
upon our merger with Biosearch, Dr. Livolsi s outstanding option to purchase 10,000 ordinary shares of Biosearch was cancelled and on March 1, 2003, we issued to him a replacement option under our 2002 Stock Option Plan to purchase 17,700 shares of our common stock (based on the merger exchange ratio

Table of Contents

of 1.77 Vicuron common stock per Biosearch ordinary share) at $10.62 per share (based on the average closing price of our stock during the one-month period immediately preceding the merger closing); 25% of this option vests on the first anniversary of the date of grant and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires 10 years after the date of grant; and

on May 8, 2003, we granted Dr. Cavanaugh an option to purchase 2,500 shares of our common stock under our 2001 Stock Option Plan at an exercise price of $12.20 per share, 25% of this option vests on May 8, 2004 and the balance of 75% vests in 36 equal monthly installments thereafter; the option expires May 7, 2013.

Our board continues to have discretion to grant options to non-employee directors under the 1997 Equity Incentive Plan and our 2001 Stock Option Plan. We anticipate that we will grant options from time to time under these plans to our non-employee directors; however, no specific option grants are currently contemplated. Although Mr. Ambrosio is not an employee of our company, he is an independent consultant to our Italian subsidiary, and an executive officer of our company. A description of his compensation is found in the above tables and under the heading Additional Employment or Independent Consulting Arrangements with our Officers in Italy above.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth as of February 20, 2004 the names, addresses and holdings with respect to the beneficial ownership of our common stock by:

each person or entity known by us to beneficially own more than 5% of our outstanding common stock;

each of our directors;

each of the executive officers named in the Summary Compensation Table; and

all of our current directors and officers (as defined under Section 16 of the Exchange Act) as a group.

Table of Contents

The table shows beneficial ownership in accordance with the rules of the SEC to include securities over which a named person has or shares voting or investment control (such as securities held by investment funds under his control), as well as securities over which a named person has the right to acquire voting or investment control within 60 days of February 20, 2004 (such as upon exercise of an option that is currently vested or that is scheduled to vest within 60-days of February 20, 2004). Unless otherwise indicated by footnote:

the persons named in the table have sole voting and sole investment power with respect to all shares of common stock shown as beneficially owned by them, subject to applicable community property laws; and

the address of each person named in the table is in care of Vicuron Pharmaceuticals Inc., 455 South Gulph Road, Suite 305, King of Prussia, Pennsylvania 19406, United States of America.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Class Beneficially Owned (1)
James H. Cavanaugh, Ph.D (2)	1,588,453	2.9%
George F. Horner III (3)	851,562	1.6%
Claudio Quarta, Ph.D.(4)	2,568,935	4.7%
Ubaldo Livolsi, Ph.D.(5)	7,041	*
Francesco Parenti, Ph.D.(6)	1,285,538	2.4%
Costantino Ambrosio (7)	273,901	*
Christopher T. Walsh, Ph.D (8)	153,534	*
David V. Milligan, Ph.D (9)	163,717	*
Timothy J. Henkel, M.D., Ph.D (10)	361,820	*
Richard J. White, Ph.D (11)	433,781	*
Dov A. Goldstein, M.D.(12)	211,462	*
Dinesh V. Patel, Ph.D (13)	0	*
Giorgio Mosconi (14)	143,114	*
All directors and executive officers as a group (13 persons)(15)	8,042,858	14.2%

* Holdings represent less than 1% of all shares outstanding.

(1) Percentages are based on 53,996,877 common shares outstanding on February 20, 2004. In accordance with SEC rules, each person s percentage interest is calculated by dividing the number of shares that person beneficially owns (as explained in the table s lead-in paragraph) by the sum of (a) the total number of common shares outstanding on February 20, 2004 plus (b) the number of shares such person has the right to acquire within 60 days of February 20, 2004 (including, for example, upon exercise of options that are vested as of February 20, 2004 or that are scheduled to vest within 60 days of February 20, 2004).

(2) Dr. Cavanaugh s beneficial ownership includes 10,179 shares held by Dr. Cavanaugh; 16,874 shares subject to options held by Dr. Cavanaugh that are exercisable within 60 days of February 20, 2004; 1,488,657 shares held by HealthCare Ventures V, L.P. (HCV), a Delaware limited partnership; 72,743 shares of common stock subject to warrants held by HCV, which are exercisable within 60 days of February 20, 2004 and which expire on August 8, 2005. Dr. Cavanaugh is a general partner of HealthCare Partners V, L.P., which is the general partner of HCV. As such, he may be deemed to have voting and dispositive power over the shares held by HCV. However, Dr. Cavanaugh disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. Dr. Cavanaugh s beneficial ownership may be deemed to extend to another 4,706,035 shares (the sum of the shares beneficially owned by Mr. Horner, Dr. Quarta and Dr. Parenti) by virtue of the stockholders agreement as described in the amended Schedule 13D filed on March 17, 2003.

(3) Mr. Horner s beneficial ownership includes 11,250 shares held by Mr. Horner; 3,125 shares held by Mr. Horner s son; 3,125 shares held by Mr. Horner s daughter and 840,312 shares subject to options held by Mr. Horner that are exercisable within 60 days of February 20, 2004. However, Mr. Horner disclaims beneficial

Table of Contents

ownership of the shares held by his son and daughter except to the extent of his pecuniary interest therein. Mr. Horner s beneficial ownership may be deemed to extend to another 5,442,926 shares (the sum of the shares beneficially owned by Dr. Cavanaugh, Dr. Quarta and Dr. Parenti) by virtue of the stockholders agreement as described in the amended Schedule 13D filed on March 17, 2003.

(4) Dr. Quarta s beneficial ownership includes 2,379,352 shares held by Dr. Quarta. Dr. Quarta also holds options to purchase 700,000 shares, 189,583 of which are exercisable within 60 days of February 20, 2004. Dr. Quarta s beneficial ownership may be deemed to extend to another 3,725,553 shares (the sum of the shares beneficially owned by Dr. Cavanaugh, Mr. Horner and Dr. Parenti) by virtue of the stockholders agreement as described in the amended Schedule 13D filed on March 17, 2003.

(5) Dr. Livolsi s beneficial ownership includes 2,247 shares held by Dr. Livolsi. Dr. Livolsi also holds options to purchase 17,700 shares, 4,794 of which are exercisable within 60 days of February 20, 2004.

(6) Dr. Parenti s beneficial ownership includes 1,123,038 shares held by Dr. Parenti. Dr. Parenti also holds options to purchase 600,000 shares, 162,500 of which are exercisable within 60 days of February 20, 2004. Dr. Parenti s beneficial ownership may be deemed to extend to another 5,008,950 shares (the sum of the shares beneficially owned by Dr. Cavanaugh, Mr. Horner and Dr. Quarta) by virtue of the stockholders agreement as described in the amended Schedule 13D filed on March 17, 2003.

(7) Mr. Ambrosio s beneficial ownership includes 141,600 shares held by Mr. Ambrosio. Mr. Ambrosio also holds options to purchase 488,500 shares, 132,301 of which are exercisable within 60 days of February 20, 2004.

(8) Dr. Walsh s beneficial ownership includes 153,534 shares subject to options held by Dr. Walsh that are exercisable within 60 days of February 20, 2004.

(9) Dr. Milligan s beneficial ownership includes 22,500 shares held by the David V. Milligan Trust dated Oct. 19, 1991 of which Dr. Milligan is the sole trustee; and 141,217 shares subject to options held by Dr. Milligan that are exercisable within 60 days of February 20, 2004.

(10) Dr. Henkel s beneficial ownership includes 4,488 shares held by Dr. Henkel; and 357,332 shares subject to options held by Dr. Henkel that are exercisable within 60 days of February 20, 2004.

(11) Dr. White s beneficial ownership includes 98,237 shares held by Dr. White; 6,252 shares held by Dr. White s children; and 335,544 shares subject to options held by Dr. White that are exercisable within 60 days of February 20, 2004. However, Dr. White disclaims beneficial ownership of the shares held by his children except to the extent of his pecuniary interest therein. Dr. White reports that he has no power to vote or dispose of the shares held by his children.

(12) Dr. Goldstein s beneficial ownership includes 2,000 shares owned and 209,462 shares subject to options held by Dr. Goldstein that are exercisable within 60 days of February 20, 2004.

(13) Dr. Patel left the Company in July, 2003.

(14) Mr. Mosconi s beneficial ownership includes 74,987 shares held by Mr. Mosconi and 68,127 shares subject to options held by Mr. Mosconi that are exercisable within 60 days of February 2004.

(15) Includes 2,684,323 shares issuable upon exercise of options or warrants beneficially owned by our directors and executive officers that are exercisable within 60 days of February 20, 2004.

Table of Contents

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	9,310,408	$ 9.87	1,186,082
Equity compensation plans not approved by security holders			
Total	9,310,408	$ 9.87	1,186,082

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Related Party Transactions

In March 1998, we entered into a written scientific agreement with Christopher T. Walsh, Ph.D., a member of our board of directors. Under this scientific agreement, Dr. Walsh agreed to provide consulting and advisory services to us. We agreed to pay Dr. Walsh an annual consulting fee of $50,000, and to pay $50,000 in 1998 and $25,000 in 1999 to help fund his laboratory. The original term of this agreement expired in January 2001, but performance continued through the mutual consent of Dr. Walsh and us and, as a result, we paid Dr. Walsh an annualized amount of $50,000 per year during the period March 1998 through December 2002. We terminated this agreement as of December 31, 2002. Commencing as of January 1, 2003, we began paying Dr. Walsh as compensation for his service on our board and the committees to which he is appointed. See Compensation of Directors in Item 12.

In January 1997, we entered a written consulting agreement with David V. Milligan, Ph.D., who was at that time the chairman of our board of directors. Under this consulting agreement, Dr. Milligan agreed to provide consulting and advisory services to us. We agreed to pay Dr. Milligan an annual fee of $100,000. The original term of this agreement expired in December 1997, but performance continued through the mutual

consent of Dr. Milligan and us and, as a result, we paid Dr. Milligan $100,000 per year during the period 1997 through 2002. We terminated the agreement as of December 31, 2002. Commencing as of January 1, 2003, we began paying Dr. Milligan as compensation for his service on our board and the committees to which he is appointed. See Compensation of Directors in Item 12.

In February 2000, our predecessor company, Biosearch, acquired a 37.4% interest in Areta International S.r.l., a service provider active in the field of cellular biology. Areta was established in 1999, with registered offices in Milan, Italy and currently has a share capital of Lit. 222 million (or approximately 114,659). Subsequently, Biosearch s interest in Areta was reduced to 33.65% as a result of the admission of another investor. Our management believes that the holding of this interest may provide us access to biotechnologies useful to some of our discovery and profiling programs. Dr. Livolsi, who is a member of our board of directors, owns 22.38% of Areta. Dr. Quarta, who is a member of our board of directors, is a member of the board of directors of Areta. In January, 2000, our predecessor company, Biosearch entered into a services supply agreement with Areta providing for the supply by Biosearch to Areta of administrative and general services, including security, warehouse space, maintenance and cafeteria services. In addition, Biosearch and Areta entered into a lease agreement providing for the lease by Biosearch to Areta of recently renovated laboratory and office space for a term of nine years in exchange for rent in the amount of approximately Lit. 103 million (or approximately 53,473) per year. Also, in January 2001 Biosearch made a five year loan to Areta. By operation of the merger, we succeeded to Biosearch s position in these agreements. As of the date hereof, no other agreements are in effect between our company and Areta.

Table of Contents

In July 2001, Biosearch entered into an agreement with Livolsi & Partners S.p.A., a merchant bank for which Dr. Ubaldo Livolsi serves as chairman and chief executive officer and for which Dr. Parenti, our chief scientific officer, serves as a non-executive director. Dr. Livolsi was a member of Biosearch s board of directors and became a member of our board of directors upon the completion of the merger. Under this agreement, Livolsi & Partners agreed to provide various advisory services to Biosearch, including management and financial consulting and investor relations support. Biosearch agreed to pay Livolsi & Partners a monthly fee of 25,000. This original term of this agreement expired in July 2002, but was extended through February 2003 on the same terms and conditions through the mutual consent of Biosearch and Livolsi & Partners. Total payments made by Biosearch under this agreement were 105,000 in 2001, 210,000 in 2002 and 40,000 in 2003. This agreement terminated upon the completion of the merger with Biosearch on February 28, 2003. Our company never made any payments to Livolsi & Partners under this agreement.

On March 27, 2003 we entered into an agreement with Bonaparte 48, an Italian public relations firm. Bonaparte 48 is 51% owned by Livolsi & Partners S.p.A. Dr. Livolsi, one of our directors, is the non-executive chairman of Bonaparte 48. Under this agreement, we pay Bonaparte 48 50,000 per year for communications consulting and ongoing corporate and financial media relations.

We believe that all of the transactions set forth above were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table shows the fees paid or accrued by us for the audit and other services provided by PricewaterhouseCoopers LLP for fiscal 2003 and 2002.

	2003	2002
Audit Fees [1]	$ 672,861	$ 796,607
Audit-Related Fees [2]	21,500	0
Tax Fees [3]	15,000	13,500
All Other Fees	0	0
Total	$ 709,361	$ 810,107

(1) Audit fees represent fees for professional services provided in connection with the audit of our financial statements and review of our quarterly financial statements and audit services provided in connection with other statutory or regulatory filings.
(2) For fiscal 2003, audit related fees principally included special reports related to internal controls for our Italian operations.
(3) For fiscal 2003 and 2002, respectively, tax fees principally included tax compliance fees.

PricewaterhouseCoopers S.p.A., an Italian affiliate of PricewaterhouseCoopers LLP, was engaged as independent auditor to Biosearch Italia S.p.A., the company with which we merged on February 28, 2003. Total fees billed by PricewaterhouseCoopers S.p.A. for services rendered to Biosearch and its subsidiaries were 790,000 for fiscal year 2002. All fees arising from the engagement of PricewaterhouseCoopers S.p.A. by Biosearch have been excluded from the fee data presented above.

Our board of director s audit committee is required to pre-approve the audit and non-audit services performed by the independent auditor for our company in order to assure that the provision of such services do not impair the auditor s independence. Prior to the beginning of our fiscal year, our audit committee typically pre-approves certain general audit and non-audit services up to specified cost levels. Any audit or non-audit services which are not generally pre-approved in this manner, require specific pre-approval by our audit committee. While our audit committee may delegate pre-approval authority to one or more of its members, the member or members to whom such authority is delegated must report any pre-approval decisions to the audit committee at its next scheduled meeting. Our audit committee does not delegate its responsibilities to pre-approve services performed by the independent auditor to management.

All of the services described in Items 9(e)(2) through 9(e)(4) of Schedule 14A were approved by the Audit Committee pursuant to paragraph c(7)(i)(C) of Rule 2-01 of Regulation S-X.

Table of Contents

PART IV

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

Item 15(a)1. Financial Statements

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Auditors	F-1
Consolidated Balance Sheets at December 31, 2003 and 2002	F-2
Consolidated Statements of Operations for the three years ended December 31, 2003	F-3
Consolidated Statements of Stockholders Equity (Deficit) for the three years ended December 31, 2003	F-4
Consolidated Statements of Cash Flows for the three years ended December 31, 2003	F-5
Notes to Consolidated Financial Statements	F-6

Item 15(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 15(a)3. Exhibits

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

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

On November 13, 2003, we filed a Current Report on Form 8-K with the SEC, which attached a press release dated the same, reporting our financial results for the period ended September 30, 2003.

Table of Contents

REPORT OF INDEPENDENT AUDITORS

To the Board of Directors and Stockholders of

Vicuron Pharmaceuticals Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)1 on page 71 present fairly, in all material respects, the financial position of Vicuron Pharmaceuticals Inc. (the Company) at December 31, 2003 and 2002, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, 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

Philadelphia, PA

March 8, 2004

Table of Contents

VICURON PHARMACEUTICALS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

	December 31,	
	2003	**2002**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 113,361	$ 28,271
Marketable securities	52,796	34,034
Accounts receivable, net	5,533	
Prepaid expenses and other current assets	6,329	5,451
Total current assets	178,019	67,756
Property and equipment, net	43,757	4,875
Intangible assets, net	23,373	
Long-term receivables	9,787	
Long-term marketable securities-restricted	3,232	
Other assets	330	105
Total assets	$ 258,498	$ 72,736
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 13,986	$ 6,491
Accrued liabilities	15,085	11,098
Current portion of long-term debt	2,360	3,500
Deferred revenue	1,068	1,519
Total current liabilities	32,499	22,608
Long-term debt, less current portion	7,493	698
Deferred revenue, less current portion	1,750	500
Other long-term liabilities	2,973	264
Total liabilities	44,715	24,070
Commitments (Notes 8 and 13)		
Stockholders equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized at December 31, 2003 and 2002; no shares issued and outstanding		
Common stock, $0.001 par value, 100,000 shares authorized at December 31, 2003 and 2002; 53,875 and 26,430 shares issued and outstanding at December 31, 2003 and 2002, respectively	54	26
Additional paid-in capital	518,275	202,365
Deferred stock compensation	(454)	(1,171)
Accumulated other comprehensive income	22,632	65
Accumulated deficit	(326,724)	(152,619)
Total stockholders equity	213,783	48,666

Total liabilities and stockholders equity	$ 258,498	$ 72,736

The accompanying notes are an integral part of these consolidated financial statements

Table of Contents

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Year Ended December 31,		
	2003	**2002**	**2001**
Revenues:			
Collaborative research and development and contract services	$ 7,929	$ 6,083	$ 6,145
License fees and milestones	1,679	258	283
Total revenues	9,608	6,341	6,428
Operating expenses:			
Research and development	77,893	48,189	32,612
General and administrative	13,531	8,184	9,600
Acquired in-process research and development	94,532		
Total operating expenses	185,956	56,373	42,212
Loss from operations	(176,348)	(50,032)	(35,784)
Other income (expense):			
Interest income	2,749	1,483	3,313
Interest expense	(506)	(247)	(316)
Other			(60)
Net loss	$ (174,105)	$ (48,796)	$ (32,847)
Net loss per share:			
Basic and diluted	$ (3.69)	$ (1.91)	$ (1.42)
Weighted average shares	47,162	25,516	23,090

The accompanying notes are an integral part of these consolidated financial statements

Table of Contents

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

(in thousands)

	Common Stock		Additional Paid-In Capital	Deferred Stock Compensation	Accumulated Other Comprehensive Income	Accumulated Deficit	Total
	Shares	Amount					
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 in 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
Exercise of common stock options	40		47				47
Exercise of common stock warrants	139		200				200
Issuance of common stock under Employee Stock Purchase Plan	15		172				172
Issuance of common stock in private placement, net of issuance costs	2,994	3	41,897				41,900
Deferred stock compensation			(114)	114			
Amortization of deferred stock compensation				2,282			2,282
Change in unrealized gain on investments					(33)		(33)
Net loss						(48,796)	(48,796)
Balances, December 31, 2002	26,430	26	202,365	(1,171)	65	(152,619)	48,666
Exercise of common stock options	173		915				915
Issuance of common stock in connection with merger	21,232	22	236,068				236,090
Issuance of common stock under Employee Stock Purchase Plan	40		389				389
Issuance of common stock in public offering	6,000	6	77,836				77,842
Deferred stock compensation			702	(702)			
Amortization of deferred stock compensation				1,419			1,419
Foreign currency translation adjustment					22,575		22,575
Change in unrealized gain on investments					(8)		(8)
Net loss						(174,105)	(174,105)
Balances, December 31,2003	53,875	$ 54	$ 518,275	$ (454)	$ 22,632	$ (326,724)	$ 213,783

The accompanying notes are an integral part of these consolidated financial statements

Table of Contents

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2003	**2002**	**2001**
Cash flows from operating activities:			
Net loss	$ (174,105)	$ (48,796)	$ (32,847)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,873	1,267	1,026
Loss on disposal of property and equipment			60
Non-cash stock compensation expense	1,419	2,282	4,958
Amortization of bond discounts	438		
Write-off of acquired in-process research and development	94,532		
Gain on sale of securities	(931)		
Write-off of plant and equipment	53		
Changes in operating assets and liabilities:			
Employee notes receivable		13	532
Accounts receivable	(525)		
Prepaid expenses and other current assets	1,234	(3,827)	(1,033)
Other assets	(225)	(10)	47
Accounts payable	(4,767)	2,156	2,914
Accrued liabilities	3,905	4,820	3,053
Related party payable			(12)
Deferred revenue	(749)	(42)	720
Other long-term liabilities	2,688	89	(825)
Net cash used in operating activities	(72,160)	(42,048)	(21,407)
Cash flows from investing activities:			
Purchases of marketable securities	(67,002)	(40,773)	(54,714)
Sales/maturities of marketable securities	147,680	39,125	40,338
Net cash acquired in Biosearch merger	250		
Additions to property and equipment	(11,734)	(945)	(1,956)
Disposals of property and equipment			57
Net cash provided by (used in) investing activities	69,194	(2,593)	(16,275)
Cash flows from financing activities:			
Proceeds from issuance of common stock, net	79,146	42,319	398
Proceeds from long-term debt	5,834	491	1,506
Repayments of long-term debt	(2,409)	(1,247)	(862)
Net cash provided by financing activities	82,571	41,563	1,042
Effect of exchange rate changes on cash and cash equivalents	5,485		
Net change in cash and cash equivalents	85,090	(3,078)	(36,640)

Cash and cash equivalents at beginning of year	28,271	31,349	67,989
Cash and cash equivalents at end of year	$ 113,361	$ 28,271	$ 31,349
Supplemental cash flow information:			
Cash paid during the year for interest	$ 171	$ 241	$ 302
Merger with Biosearch Italia	$ 236,089	$	$

The accompanying notes are an integral part of these consolidated financial statements

Table of Contents

NOTE 1 ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

These consolidated financial statements include the accounts of Vicuron Pharmaceuticals Inc. and its subsidiaries (the Company), with appropriate elimination of intercompany balances and transactions.

The Company

Vicuron Pharmaceuticals Inc. (Vicuron or the Company) is a transatlantic biopharmaceutical company focused on the discovery, development, manufacturing and marketing of drugs for the treatment of serious bacterial and fungal infections, primarily in the hospital setting. Since the Company s inception on May 2, 1995 as a wholly owned subsidiary of Sepracor Inc., the Company has devoted substantially all of its efforts to establishing its business and conducting research and development activities related to its proprietary product candidates, including anidulafungin and dalbavancin, as well as collaborative product candidates.

Since 1996, the Company has been operating as an independent company and on August 8, 2000, the Company sold 4,600,000 shares of its 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. The Company received total net proceeds from the initial public offering and the over-allotment of approximately $52.7 million.

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

On February 28, 2003 the Company acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. The Company has issued 1.77 shares of its common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. The Company also issued options covering approximately 4.3 million common shares, including options that were held by Biosearch employees and consultants at the date of the transaction.

On March 26,2003, as a result of the merger, the Company changed its name from Versicor Inc. to Vicuron Pharmaceuticals Inc.

On July 17, 2003, the Company sold 6,000,000 shares of common stock at $13.85 per share in a public offering and received net proceeds of $77.8 million.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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 and the need to obtain financing.

Table of Contents

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 corporate notes and government agencies aggregating $13.2 million and $16.5 million at December 31, 2003 and 2002, respectively. Cash and cash equivalents contains $0.1 million in restricted cash. The restricted cash is required as security for our leases.

Marketable Securities

The Company has classified its marketable securities as available for sale in accordance with Statement of Financial Accounting Standard (SFAS) 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.

Value Added Tax Receivable

The Company s Italian subsidiaries are subject to Value Added Tax (VAT) which is applied to goods and services purchased. The VAT is included in the receivable balance at December 31, 2003. The VAT receivable of $10.9 million is included in other current assets and long term receivables at December 31, 2003.

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 thirty years for buildings, ten years for leasehold improvements and fixtures and furniture, seven years for laboratory equipment, five years for machinery and 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. Cost associated with the construction of our manufacturing facility are included in construction in progress. This amount is offset by grants received from the Italian government. See Note 3.

Intangible Assets

The Company amortizes its intangible assets on a straight-line basis over the estimated period to be benefited by the intangible assets which it estimates to be between two and thirteen years.

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, which is when the specific events which coincide with the achievement of substantive elements in the related collaboration agreements are achieved. Milestone payments received that are creditable against future royalty payments are deferred and recognized as revenue when the royalties are earned or when the payment is no longer creditable against future payments. Collaborative research and development payments are recognized as the related work is performed. 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. In 2003, the Company recognized $3.6 million and $3.9 million in revenue related to its collaborations with Pfizer and Novartis, respectively.

Table of Contents

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.

Foreign Currency Translation

The functional currency of each of the Company s subsidiaries is the currency in which the majority of their transactions occur. For the Company s operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net income but are accumulated in the cumulative translation adjustment account as a separate component of stockholders equity in accordance with SFAS No. 52.

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 amortized 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 (EITF) No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services .

During the year, the Company adopted SFAS No. 148, Accounting for Stock Based Compensation Transition and Disclosure an amendment of FAS 123. 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,		
	2003	2002	2001
	(in thousands, except per share data)		
Net loss as reported	$ (174,105)	$ (48,796)	$ (32,847)
Add: Stock-based employee compensation expense included in net loss	898	2,175	4,399
Less: total stock-based employee compensation expense, determined under fair value based method for all awards	(17,548)	(8,088)	(5,699)
Net loss pro forma	$ (190,755)	$ (54,709)	$ (34,147)

Basic and diluted net loss per share:			
As reported	$ (3.69)	$ (1.91)	$ (1.42)
Pro forma	$ (4.04)	$ (2.14)	$ (1.48)

Table of Contents

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,		
	2003	2002	2001
Risk-free interest rate	2.4 %	3.8 %	4.2 %
Expected average life	4 years	4 years	4 years
Volatility	58.0%	60%	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, 2003, 2002 and 2001 was $5.44, $8.54 and $6.13, respectively.

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. 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 realized. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset.

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,		
	2003	2002	2001
	(in thousands)		
Stock options	9,310	3,689	2,770
Common stock warrants	195	195	389

Common stock subject to repurchase			8
	9,505	3,884	3,167

The restricted shares subject to repurchase are excluded from the loss per share calculations until the restrictions lapse.

Recent Accounting Pronouncements

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

In January 2003, the FASB issued FASB Interpretation (FIN) No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN No. 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the

Table of Contents

characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN No. 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN No. 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of this standard had no material impact on the Company s financial statements.

NOTE 2 MARKETABLE SECURITIES

	December 31, 2003			December 31, 2002		
	Amortized Cost	Unrealized Gains	Estimated Fair Value	Amortized Cost	Unrealized Gains	Estimated Fair Value
			(in thousands)			
Commercial paper	$ 16,327	$ 3	$ 16,330	$ 8,979	$ 4	$ 8,983
Government agency and corporate bonds	36,457	9	$ 36,466	24,990	61	25,051
	$ 52,784	$ 12	$ 52,796	$ 33,969	$ 65	$ 34,034

At December 31, 2003 and 2002, all marketable securities were classified as available-for-sale. Realized gains were $931,000, $0 and $0 for 2003, 2002 and 2001, respectively. Realized losses were $3,000, $0 and $0 for 2003, 2002 and 2001, respectively.

NOTE 3 PROPERTY AND EQUIPMENT

	December 31,	
	2003	2002
	(in thousands)	
Land	$ 3,785	$
Buildings	5,096	
Leasehold improvements	4,933	4,797
Laboratory equipment	6,143	3,020
Machinery, equipment and vehicles	2,050	
Computers, software and office equipment	2,104	1,797
Fixtures and furniture	1,139	635
Construction in progress	27,208	
	52,458	10,249
Less: accumulated depreciation	(8,701)	(5,374)
Property and equipment, net	$ 43,757	$ 4,875

Depreciation expense was $3.2 million, $1.3 million and $1.0 for the years ended December 31, 2003, 2002 and 2001, respectively.

Biosearch Manufacturing S.r.J., one of the Company s Italian subsidiaries, has been awarded a grant by Regione Basilicata, a local authority in southern Italy, for the construction of a new manufacturing plant. This grant will be paid to the Company in installments in accordance with the completion of various stages of the construction work, and can be revoked or reduced if the Company does not comply with its obligations thereunder. In order to maintain eligibility for the entire grant awarded by Regione Basilicata, the Company must also comply with certain requirements relating to, among other things, number of its employees, its turnover levels and its independence of other companies. The amounts received are offset against construction in progress.

Table of Contents

NOTE 4 INTANGIBLE ASSETS

The identifiable intangible assets arising from the Biosearch Italia (see note 14) merger, after allocation of negative goodwill, total $25 million. These intangibles represent patents and core technology, a library of microbial extracts and a bioinformatics software platform. These identifiable intangible assets have estimated useful lives of between two and thirteen years. The changes in the value of intangible assets from March 1, 2003 to December 31, 2003 appear below:

	In Process Research and Development	Bioinformatics Platform	Patents and Core Technology	Vitachem Contracts	Microbial Extract Library	Total
Intangible balance at March 1, 2003	$ 94,532	$ 1,699	$ 17,099	$ 227	$ 5,998	$ 119,555
Write-off of IPR & D	(94,532)	0	0	0	0	(94,532)
Amortization	0	(240)	(910)	(80)	(420)	(1,650)
Intangible balance at December 31, 2003	$ 0	$ 1,459	$ 16,189	$ 147	$ 5,578	$ 23,373

The Company recorded a non-cash charge to operations in the first quarter of 2003 of $94.5 million for acquired in-process research and development. The aggregate amortization expense related to these intangible assets for the ten months ended December 31, 2003 was $1.7 million. The aggregate amortization expense for each of the next five years is expected to be $2.0 million.

NOTE 5 EMPLOYEE NOTES RECEIVABLE AND RELATED PARTY TRANSACTIONS

In 1997, the Company made an interest free, forgivable loan to an officer. The loan was collateralized by the stock options of the officer and the deeds of trust on the officer s residence. The remaining loan balance of $13,000 at December 31, 2001 was fully forgiven in April 2002.

In March 1998, the Company entered into a written scientific agreement with Christopher T. Walsh, Ph.D., a member of the board of directors. Under this scientific agreement, Dr. Walsh agreed to provide consulting and advisory services to the Company. The Company agreed to pay Dr. Walsh an annual consulting fee of $50,000, and to pay $50,000 in 1998 and $25,000 in 1999 to help fund his laboratory. The original term of this agreement expired in January 2001, but performance continued through the mutual consent of Dr. Walsh and the Company and, as a result, the Company paid Dr. Walsh an annualized amount of $50,000 per year during the period March 1998 through December 2002. The Company terminated this agreement as of December 31, 2002. Commencing as of January 1, 2003, the Company began paying Dr. Walsh as compensation for his service on our board and the committees to which he is appointed. See Compensation of Directors in Item 12.

In January 1997, the Company entered a written consulting agreement with David V. Milligan, Ph.D., who was at that time the chairman of the board of directors. Under this consulting agreement, Dr. Milligan agreed to provide consulting and advisory services to the Company. The Company agreed to pay Dr. Milligan an annual fee of $100,000. The original term of this agreement expired in December 1997, but performance continued through the mutual consent of Dr. Milligan and the Company and, as a result, the Company paid Dr. Milligan $100,000 per year during the period 1997 through 2002. The Company terminated the agreement as of December 31, 2002. Commencing as of January 1, 2003, the Company began paying Dr. Milligan as compensation for his service on the board and the committees to which he is appointed. See

Compensation of Directors in Item 12.

In February 2000, the Company s predecessor company, Biosearch, acquired a 37.4% interest in Areta International S.r.l., a service provider active in the field of cellular biology. Areta was established in 1999, with registered offices in Milan, Italy and currently has a share capital of Lit. 222 million (or approximately 114,659). Subsequently, Biosearch s interest in Areta was reduced to 33.65% as a result of the admission of another

Table of Contents

investor. Management believes that the holding of this interest may provide the Company access to biotechnologies useful to some of the Company s discovery and profiling programs. Dr. Livolsi, who is a member of our board of directors, owns 22.38% of Areta. Dr. Quarta, who is a member of our board of directors, is a member of the board of directors of Areta. In January, 2000, Biosearch entered into a services supply agreement with Areta providing for the supply by Biosearch to Areta of administrative and general services, including security, warehouse space, maintenance and cafeteria services for an annual fee of 41,000. In addition, Biosearch and Areta entered into a lease agreement providing for the lease by Biosearch to Areta of recently renovated laboratory and office space for a term of nine years in exchange for rent in the amount of approximately Lit. 103 million (or approximately 53,473) per year. Also, in January 2001 Biosearch made a five year loan to Areta. By operation of the merger, the Company succeeded to Biosearch s position in these agreements. In July, 2003, the Company entered into a quality assurance agreement with Areta which provides relevant services to the Company for a quarterly fee of 12,384. As of the date hereof, no other agreements are in effect between the Company and Areta.

In July 2001, Biosearch entered into an agreement with Livolsi & Partners S.p.A., a merchant bank for which Dr. Ubaldo Livolsi serves as chairman and chief executive officer and for which Dr. Parenti, our chief scientific officer, serves as a non-executive director. Dr. Livolsi was a member of Biosearch s board of directors and became a member of our board of directors upon the completion of the merger. Under this agreement, Livolsi & Partners agreed to provide various advisory services to Biosearch, including management and financial consulting and investor relations support. Biosearch agreed to pay Livolsi & Partners a monthly fee of 25,000. This original term of this agreement expired in July 2002, but was extended through February 2003 on the same terms and conditions through the mutual consent of Biosearch and Livolsi & Partners. Total payments made by Biosearch under this agreement were 105,000 in 2001, 210,000 in 2002 and 40,000 in 2003. This agreement terminated upon the completion of the merger with Biosearch on February 28, 2003. The Company never made any payments to Livolsi & Partners under this agreement.

On March 27, 2003 the Company entered into an agreement with Bonaparte 48, an Italian public relations firm. Bonaparte 48 is 51% owned by Livolsi & Partners S.p.A. Dr. Livolsi, one of our directors, is the non-executive chairman of Bonaparte 48. Under this agreement, the Company pays Bonaparte 48 50,000 per year for communications consulting and ongoing corporate and financial media relations.

NOTE 6 ACCRUED LIABILITIES

	December 31,	
	2003	**2002**
	(in thousands)	
Research and development	$ 10,338	$ 6,146
Employee compensation	2,524	1,931
Legal expenses	1,381	2,599
Other	$ 842	422
	$ 15,085	$ 11,098

NOTE 7 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 was originally repayable 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 $2.8 million payable on December 31, 2002. The terms of the term loan were renegotiated in January 2003 and the balance of $2.8 million is now repayable in eight equal quarterly installments of $350,000 beginning on March 31, 2003 with the final payment due on December 21, 2004. The term loan bears interest at the prime rate plus 0.50% (4.50% at December 31, 2003). The bank

Table of Contents

requires the Company to comply with certain financial covenants and as of December 31, 2003, the Company was in compliance with these covenants. The term loan is collateralized by certain assets of the Company. There was $1.4 million and $2.8 million outstanding under this term loan at December 31, 2003 and 2002, respectively.

In October 2001, the term loan was amended to include a four-year equipment note for $2.0 million that the Company was able to draw down on through June 30, 2002. The note bears interest at the prime rate unless the Company exercises 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, 2003 and 2002, there was an outstanding note balance of $698,000 and $1.4 million and the Company has exercised its option to pay interest on this portion of the loan at LIBOR plus an applicable margin (The applicable LIBOR rate was 1.20% at December 31, 2003).

In January 2003, the term loan was amended to include a three-year equipment note for $1.5 million that the Company is able to draw down on through December 31, 2003. The note bears interest at the prime rate unless the Company exercises an option to have the interest on all or any portion of the principal amount based on the LIBOR rate plus an applicable margin. The interest on the note is payable in quarterly installments during the draw down period. The principal of the note is payable in equal installments beginning on March 31, 2004 with the final payment due on December 31, 2005. The Company did not draw down on this loan in 2003.

Future principal payments on the term loan and the equipment notes at December 31, 2003 are as follows:

Year Ending December 31, (in thousands)	
2004	$ 2,100
	$ 2,100

In November 2000 the former Biosearch Italia S.p.A. entered into a loan agreement with the Ministero Istruzione Università e Ricerca, or MIUR, to fund certain research projects undertaken by Biosearch Italia S.p.A. This loan matures in January 2011 and it bears fixed interests at 2% per year. There was 1.0 million euro and 1.1 million euro outstanding under this term loan at December 31, 2003 and 2002, respectively. The term loan has been transferred to Vicuron Pharmaceuticals Italy srl.

In addition in March 2003 and October 2003 Biosearch Manufacturing received proceeds of 2.6 million euro and 2.5 million euro respectively from a loan facility entered into by the Company with Basilicata Region of Italy for the construction of the Company s manufacturing plant in Pisticci. Under the loan agreement the Company has a total loan facility of 7.5 million euro repayable in 10 years. The term loan bears interest at 6 months Euribor rate plus a 1.65% spread. The loan matures in 2012. The interest rate was 3.75% at December 31, 2003.

Year Ending December 31, (in thousands)	
2004	$ 170
2005	832
2006	871

2007	913
2008	958
2009 and after	3,919
	$ 7,663

Table of Contents

NOTE 8 COMMITMENTS

Future minimum lease payments under all noncancelable operating leases in effect at December 31, 2003 are as follows:

Year Ending December 31, (in thousands)	
2004	$ 2,021
2005	1,898
2006	1,882
2007	1,673
2008	1,113
Thereafter	952
	$ 9,539

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 $2.0 million, $1.2 million and $849,000 for the years ended December 31, 2003, 2002 and 2001, respectively.

NOTE 9 STOCKHOLDERS EQUITY

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 over allotment 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.

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

On July 17, 2003, the Company sold 6,000,000 shares of common stock at $13.85 per share in a public offering. The Company received net proceeds of approximately $77.8 million.

NOTE 10 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

Table of Contents

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 ISOs and NSOs. In December 2002, the Plan was amended to increase the maximum number of shares available to 6,600,737. 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.

The 2002 Stock Option Plan (2002 Plan) was approved by the Company s board of directors in July 2002, and was contingent upon the completion of the merger with Biosearch. The 2002 Plan permits the Company to grant up to 442,500 shares of Common Stock as NSOs. The 2002 Plan provides for the granting of replacement stock options to former holders of Biosearch options that were cancelled in the merger. NSOs granted under the 2002 Plan will have a maximum term of ten years from the date of grant and have an exercise price of not less than the fair market value of the stock subject to the award at the time of grant.

Stock option activity under the plans for the years ended December 31, 2003, 2002 and 2001 is as follows:

	2003		2002		2001	
	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	3,688,536	$ 7.61	2,770,466	$ 4.09	2,468,312	$ 2.18
Granted	6,007,178	11.27	1,006,839	17.28	573,200	12.08
Exercised	(172,983)	5.21	(39,572)	1.19	(175,098)	2.11
Canceled	(212,323)	13.32	(49,195)	12.75	(95,948)	4.80
Balance at end of year	9,310,408	9.87	3,688,538	7.61	2,770,466	4.09

The following table summarizes information about stock options outstanding at December 31, 2003:

	Options outstanding			Options exercisable	
Exercise Price Per Share	Number Outstanding	Remaining Contractual	Weighted Exercise Price	Number Exercisable	Weighted Exercise Price

			Life	Per Share		Per Share
$ 0.09	$ 0.39	10,125	1.80	$ 0.09	10,125	$ 0.09
$ 0.40	$ 0.48	1,379,157	5.10	0.44	1,378,322	0.44
$ 4.72	$ 5.75	631,146	6.70	5.37	501,558	5.34
$ 7.38	$10.96	5,198,870	9.10	10.54	158,107	9.14
$12.20	$18.25	1,424,523	9.00	13.92	187,787	13.55
$18.83	$20.31	666,587	8.10	19.85	302,376	19.89
		9,310,408		9.87	2,538,275	5.24

There were 258,791, 213,668, 695,923 and 17,700 options available for future grant under the 1995 Plan, the 1997 Plan, the 2001 Plan and the 2002 Plan, respectively, as of December 31, 2003. The Company has reserved 10,691,492 shares of common stock for the exercise of stock options and warrants.

Table of Contents

Employee Stock Purchase Plan

In April 2001, the Company instituted an employee stock purchase plan. Under the plan, eligible employees can purchase Vicuron 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.

Deferred stock based compensation

During the period from January 1997 through December 31, 2003, the Company recorded $22.4 million of deferred stock based compensation in accordance with APB 25, SFAS No.123 and EITF Issue No. 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 3.25% and 6.2%; expected dividend yield of zero percent; volatility between 43% and 104%, and values of common stock between $0.40 and $20.31 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 $1.4 million, $2.3 million and $5.0 million for the years ended December 31, 2003, 2002 and 2001, respectively.

Warrants

In 1997, the Company issued warrants to purchase 45,000 shares of common stock at $4.45 per share. These warrants were exercised in full in 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 were exercised in full in 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, 2002 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 was reflected as interest expense in the 1999 statement of operations.

NOTE 11 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 realized. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset.

The statutory and effective tax rates were 35% 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, 2003, the Company had federal, state and foreign tax net operating loss carryforwards (NOL) of approximately $182.3 million, $104 million and $61.1 million, which will expire beginning in the year 2009, 2004 and 2005, respectively. Based upon the Internal Revenue Code and changes in the Company s ownership, utilization of the NOL will be subject to an annual limitation. The Company had federal and state research and experimentation credit carryforwards of approximately $5.7 million and $6.0 million at December 31, 2003, which will expire beginning in the year 2010.

Table of Contents

The components of net deferred taxes were as follows:

	December 31,	
	2003	2002
	(in thousands)	
Assets:		
Net operating losses U.S.	$ 71,894	$ 38,495
Net operating losses - Foreign	18,326	
Capitalized R&D	9,696	9,430
Credits	11,645	5,418
Accrued expenses and other liabilities	1,162	1,920
Property and equipment	1,190	941
Biosearch assets	(15,961)	
Less: valuation allowance	(97,952)	(56,204)
Net deferred taxes	$	$

NOTE 12 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 Vicuron 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 2003, 2002 and 2001 were $102,000, $89,000 and $62,000, respectively.

NOTE 13 AGREEMENTS

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

In March 1999, the Company entered into a collaboration agreement with Pharmacia Corporation, now Pfizer, pursuant to which we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pfizer made an equity investment in the Company of $3.8 million and paid the Company research support and license fee payments. Under the terms of the agreement and in consideration of our research obligations, the Company is entitled to receive funding from Pfizer to support certain of our full-time researchers. If specified milestones are achieved, Pfizer is obligated to pay the Company additional payments of up to $14.0 million for each compound, a portion of which may be credited against future royalty payments to which the Company is entitled on the worldwide sales of any drug developed and commercialized from the collaboration. In October 2000, Pfizer increased its funding for this collaboration by 30%, and in June 2001, the Company received a milestone payment for the initiation of clinical development of

one of the compounds. In July 2002, the Company agreed with Pfizer by amendment to extend the collaboration for an additional three years through March 2005. Through December 31, 2003, Pfizer has made aggregate payments to the Company under this collaboration agreement (excluding equity investments) of $16.6 million.

In March 1999, the Company entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in the Company of $3.0 million. The Company also received a number of milestone payments from Novartis and are entitled to receive additional payments of up to

Table of Contents

$13.0 million for our compounds or up to $7.25 million for Novartis compounds upon the achievement of specified milestones. Novartis may deduct a portion of these milestone payments from the royalties it will be obligated to pay the Company on the worldwide sales of any drug developed and commercialized from this collaboration. In February 2003, the Company amended the original agreement in order to extend the research term through March 31, 2005. In September 2003, the Company announced achievement of a late-stage pre-clinical milestone for which we received a milestone payment from Novartis, and in December 2003 the Company announced that we received an additional milestone payment form Novartis as a result of entering into Phase I work on our research collaboration with Novartis. Through December 31, 2003, Novartis has made aggregate payments to the Company under this agreement (excluding equity investments) of $15.5 million.

In May 1999, the Company entered into a license agreement with Eli Lilly to obtain an exclusive worldwide license for the development and commercialization of anidulafungin. The license agreement provides for a number of payments from us to Eli Lilly, as follows: (i) an up-front payment for the license; (ii) periodic milestone payments bearing on achieving certain goals related to intravenous and oral formulations; (iii) payments during the period 2000 through 2002 for product inventory; and (iv) royalty payments based upon the net sales of the applicable products. The Company also granted to Eli Lilly an option to license the exclusive worldwide rights to any oral formulation of anidulafungin, which is exercisable upon successful completion of Phase II clinical trials. If Eli Lilly exercises this option, Eli Lilly will pay the Company 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. The Company is not currently working on an oral formulation program.

Genome Therapeutics

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

NOTE 14 MERGER WITH BIOSEARCH ITALIA S.p.A.

On February 28, 2003, Vicuron Pharmaceuticals Inc., or the Company, acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. In connection with the merger transaction, the Company issued 1.77 shares of its common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. The Company also issued options covering approximately 4.3 million common shares, including options issued to replace options that were held by Biosearch employees and consultants at the date of the transaction.

Biosearch has used natural product sourcing for the discovery, development and production of novel anti-infective drugs with a primary emphasis on Europe. The merger transaction substantially enhances the Company s capabilities with respect to discovery, pre-clinical development, and manufacturing, as well as the Company s European market presence and effectiveness. The combined company has substantially greater presence in two of the three major pharmaceutical markets (North America and Europe) as well as an enhanced product portfolio for collaborations in Asia. The North American rights to the Company s lead antibiotic product candidate, dalbavancin, had been previously licensed from Biosearch and, by acquiring the global rights, the

Table of Contents

Company eliminated the royalties and manufacturing fees in North America, acquired the full potential of dalbavancin in Europe and enhanced the Company s commercialization effectiveness for its lead antifungal drug, anidulafungin, in Europe. As a result, the Company believes all of these benefits will increase its margin and profitability prospects for dalbavancin and anidulafungin upon regulatory approval in North America and Europe. The Company also believes that European approval can now be obtained with only a modest increase in the clinical development expenses already planned for its North American filings.

The purchase price of the merger transaction was approximately $243.6 million, determined as follows (in thousands):

Issuance of Vicuron shares	$ 232,912
Issuance of options to acquire Vicuron shares	3,177
Transaction costs	7,474
	$ 243,563

The fair value of the Vicuron shares used in determining the purchase price was $10.97 per share based on the average closing price of Vicuron s stock from the two days before through two days after July 31, 2002, the date of the public announcement of the merger. The fair value of the options to acquire Vicuron shares was determined using the Black-Scholes option pricing model assuming a market price of $10.30, an exercise price of $10.62, an expected average life of four years, a weighted average interest rate of 3.90%; volatility of 104%, and no expected dividends.

The transaction was recorded as a purchase for accounting purposes and the combined companies consolidated financial statements include Biosearch s operating results from the date of the closing of the transaction. The purchase price was allocated to the assets purchased and liabilities assumed based upon their fair values, including the fair value of in-process research and development and other intangibles. The allocation of the purchase price was as follows:

Current assets	$ 107,595
Property, plant and equipment	24,620
In-process research and development	94,532
Identifiable intangible assets	21,128
Other assets	14,356
Current liabilities	(17,535)
Long-term liabilities	(1,133)
	$ 243,563

The Company recorded a non-cash charge to operations in the first quarter of 2003 of $94.5 million for acquired in-process research and development. The valuation of in-process research and development represents the estimated fair value relating to incomplete research and development projects which, at the time of the transaction, had no alternative future use and for which technological feasibility had not been established. The valuation of the acquired in-process research and development was based on the result of a valuation using the income approach and applying the percentage completion to risk-adjust the discount rates associated with the in-process projects. The two significant in-process projects relate primarily to the development of a novel antibiotic to treat Gram-positive bacteria, ramoplanin and a novel second-generation glycopeptide agent, dalbavancin.

Both significant in-process projects are still undergoing clinical trials and have not received regulatory approval. The primary risk in completing the projects is the successful completion of the clinical testing and regulatory approval process. This process is time and research intensive and new drugs face significant challenges before they can be brought to the market. Any delay in the approval process could have significant

Table of Contents

consequences, including increased costs, thus jeopardizing the economic returns expected to be realized, delay in the rollout of the product with potential lower revenues due to competing products reaching the market and potential loss of credibility to the company s scientific team.

Current assets included $91.1 million in marketable securities.

As the fair value of the net assets acquired exceeds the purchase price paid, there is negative goodwill arising on the transaction of $6.1 million. This amount has been allocated to the values of property, plant and equipment and intangible assets acquired pro rata to their deemed fair values as of the transaction date.

The identifiable intangible assets arising from the merger, after allocation of negative goodwill, total $25.0 million and represent primarily $17.1 million for Biosearch s patents and core technology, $6.0 million for their library of microbial extracts and $1.7 million for their bioinformatics software platform. These identifiable intangible assets have estimated useful lives of between five and thirteen years.

As a result of the Company s merger with Biosearch, the Company acquired additional long-term debt relating to a loan agreement entered into by Biosearch in November 2000 with the Ministero Istruzione Università Ricerca, or MIUR, to fund certain research projects undertaken by Biosearch. This loan matures in January 2011, and at December 31, 2003, the amount outstanding under this loan was $1.3 million.

In addition, in March 2003, the Company received net proceeds of $2.8 million from a loan facility entered into by Biosearch Manufacturing in July 2002 with the Basilicata Region of Italy for the construction of the Company s manufacturing plant in Pisticci. Pursuant to the loan agreement, the Company has a total loan facility of $9.5 million (at exchange rates prevailing at December 31, 2003) of which the Company has drawn down $6.4 million. The loan matures in 2012.

Biosearch historically funded a portion of its operations through research grants and loan subsidies awarded by Italian and EU authorities. Under applicable law, any transfer of those grants and subsidies (including transfer by merger) requires written approval from the Italian bank. In connection with the merger and the subsequent contribution to Vicuron Pharmaceuticals Italy, Srl, the Company s wholly owned Italian subsidiary, the Company applied for permission to transfer Biosearch s grants and subsidies to itself. If the transfers are not approved, the Company might be required to repay some or all of the grants and subsidies received by Biosearch prior to the merger, in the aggregate amount of up to approximately $1.8 million as of December 31, 2003 and the Company may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of December 31, 2003 by the authorized bank, in the aggregate amount of up to approximately $1.3 million as of December 31, 2003 (each estimate is based upon exchange rates prevailing at December 31, 2003).

The following unaudited pro forma consolidated financial information has been prepared as if the merger with Biosearch had occurred as of January 1, 2002 (in thousands, except per share amounts):

	Twelve Months Ended December 31,	
	2003	2002

Revenues	$ 10,373	$ 9,991
Net loss	$ (84,543)	$ (60,686)
Net loss per share:		
Basic and diluted	$ (1.67)	$ (1.30)
Weighted average shares	50,535	46,748

Table of Contents

NOTE 15 COMPREHENSIVE LOSS

At December 31, 2003, the components of Accumulated Other Comprehensive Loss, reflected in the Consolidated Statement of Stockholders Equity, consisted of the following:

	2003	2002	2001
Gain from foreign currency translation	$ 22,575	$ 0	$ 0
Unrealized gain (loss) on investments	(8)	(33)	98
Other comprehensive loss	$ 22,567	(33)	98

NOTE 16 SEGMENT INFORMATION

The Company evaluates performance of its segments and allocates resources to them based upon the Company s strategy related to the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of bacterial and fungal infections in the hospital setting.

As a result of the merger with Biosearch Italia in 2003, the Company now operates in two geographic segments, including the United States and Italy. The United States operations include the Corporate headquarters, clinical development and research. The operations in Italy include a research facility and a manufacturing plant which is under construction.

The table below presents geographic information about reported segments:

	United States	Italy	Consolidated
Net revenue	$ 7,471	$ 2,137	$ 9,608
Long lived assets	$ 4,604	$ 75,875	$ 80,479

NOTE 17 QUARTERLY FINANCIAL DATA (UNAUDITED)

The following is selected unaudited quarterly financial data for the years ended December 31, 2003 and 2002. 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, 2003	June 30, 2003	September 30, 2003	December 31, 2003
	(in thousands, except per share amounts)			
Revenues	$ 1,758	$ 2,278	$ 2,799	$ 2,773
Net loss	$ (107,200)	$ (25,840)	$ (18,914)	$ (22,151)
Net loss per share, basic and diluted	$ (3.15)	$ (0.54)	$ (0.36)	$ (0.41)
Shares used in computing net loss per share, basic and diluted	33,995	47,709	52,799	53,863

	Quarter Ended			
	March 31, 2002	June 30, 2002	September 30, 2002	December 31, 2002
	(in thousands, except per share amounts)			
Revenues	$ 1,812	$ 1,490	$ 1,519	$ 1,520
Net loss	$ (10,403)	$ (12,240)	$ (13,034)	$ (13,119)
Net loss per share, basic and diluted	$ (0.45)	$ (0.47)	$ (0.49)	$ (0.50)
Shares used in computing net loss per share, basic and diluted	23,261	26,008	26,353	26,398

Table of Contents

NOTE 18 SUBSEQUENT EVENT

In February 2004, the Company filed a universal shelf registration statement on Form S-3, which the Company expect either has been or will be declared effective on the date of this filing. If the SEC declares the shelf registration effective, the Company will be able to offer up to $200 million of our securities from time to time in one or more public offerings of the Company s common stock, preferred stock, warrants and/or debt securities.

Table of Contents

SIGNATURES

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

VICURON PHARMACEUTICALS INC.

(registrant)

Dated: March 15, 2004

BY: /s/ GEORGE F. HORNER III

George F. Horner III

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ JAMES H. CAVANAUGH, PH.D. **James H. Cavanaugh, Ph.D.**	Chairman of the Board of Directors	March 15, 2004
/s/ GEORGE F. HORNER III **George F. Horner III**	President, Chief Executive Officer and Director (Principal Accounting Officer)	March 15, 2004
/s/ CLAUDIO QUARTA, PH.D. **Claudio Quarta, Ph.D.**	Chief Operating Officer and Director	March 15, 2004
/s/ UBALDO LIVOLSI, PH.D. **Ubaldo Livolsi, Ph.D.**	Director	March 15, 2004
/s/ FRANCESCO PARENTI, PH.D. **Francesco Parenti, Ph.D.**	Executive Vice President, Chief Scientific Officer Worldwide and Director	March 12, 2004
/s/ COSTANTINO AMBROSIO **Costantino Ambrosio**	Executive Vice President, Chief of Manufacturing and Director	March 12, 2004
/s/ CHRISTOPHER T. WALSH, PH.D	Director	March 11, 2004

Christopher T. Walsh, Ph.D		
/s/ DAVID V. MILLIGAN, PH.D **David V. Milligan, Ph.D**	Director	March 15, 2004
/s/ DOV A. GOLDSTEIN, M.D. **Dov A. Goldstein, M.D.**	Executive Vice President and Chief Financial Officer (Principal Finance Officer)	March 15, 2004

Table of Contents

EXHIBIT INDEX

Pursuant to Item 601(a)(2) of Regulation S-K, this exhibit index immediately precedes the exhibits.

The following exhibits are included, or incorporated by reference, in this Annual Report on Form 10-K for fiscal year 2003 (and are numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated as of July 30, 2002 by and between Versicor Inc. and Biosearch Italia, S.p.A. (the body of the agreement was previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on July 31, 2002 and is incorporated herein by reference)
2.2	First Amendment to Agreement and Plan of Merger entered into on August 14, 2002, by and between Versicor Inc. and Biosearch Italia S.p.A.(3)
2.3	Second Amendment to Agreement and Plan of Merger entered into on October 29, 2002, by and between Versicor Inc. and Biosearch Italia S.p.A.(3)
3.1	Fourth Amended and Restated Certificate of Incorporation(1)
3.2	Certificate of Amendment and Restatement of the Certificate of Designations of Versicor Inc. (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on July 11, 2001 and is incorporated herein by reference)
3.3	Certificate of Merger relating to the merger of Biosearch Italia S.p.A. with and into Versicor Inc.(4)
3.4	Certificate of Ownership and Merger Merging Vicuron Pharmaceuticals Inc. into Versicor Inc. (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on March 26, 2003 and incorporated herein by reference
3.5	Amended and Restated Bylaws, as currently in effect(4)
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 Investors Rights Agreement(1)
4.6	Shareholder Rights Agreement by and between Versicor Inc. and American Stock Transfer & Trust Company, as Rights Agent, dated June 28, 2001 (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on July 11, 2001 and is incorporated herein by reference)
4.7	First Amendment to Shareholder Rights Agreement, dated as of July 30, 2002, by and between Versicor Inc. and American Stock Transfer & Trust Company, as Rights Agent (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on July 31, 2002 and is incorporated herein by reference)
4.8	Registration Rights Agreement dated as of April 8, 2002, by and among Versicor Inc. and the Purchasers listed on Schedule A attached thereto (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on April 10, 2002 and is incorporated herein by reference)

Ex-1

Table of Contents

Exhibit Number	Description
4.9	Form of Deposit Agreement and Depositary Receipt(6)
4.10	Form of Senior Debt Indenture(6)
4.11	Form of Subordinated Debt Indenture(6)
4.12	Form of Common Stock Warrant Agreement and Warrant Certificate(6)
4.13	Form of Preferred Stock Warrant Agreement and Warrant Certificate(6)
4.14	Form of Depository Share Warrant Agreement and Warrant Certificate(6)
4.15	Form of Debt Securities Warrant Agreement and Warrant Certificate(6)
9.1	Letter Agreement dated as of February 28, 2003, by and between Vicuron Pharmaceuticals Inc. and Monte Titoli S.p.A.(7)
10.1.1	1995 Stock Option Plan (the 1995 Plan)*(1)
10.1.2	Form of 1995 Plan Incentive Stock Option Agreement*(1)
10.1.3	Form of 1995 Plan Non-Statutory Stock Option Agreement*(1)
10.2.1	1997 Equity Incentive Plan (as amended, the 1997 Plan)*(1)
10.2.2	1997 Equity Incentive Plan Amendment*(1)
10.2.3	Form of 1997 Plan Stock Option Agreement*(1)
10.3	2000 Employee Stock Purchase Plan*(1)
10.4.1	2001 Stock Option Plan, as amended (the 2001 Plan)*(8)
10.4.2	Form of 2001 Plan Stock Option Agreement*(4)
10.5.1	2002 Stock Option Plan (the 2002 Plan)*(5)
10.5.2	Form of 2002 Plan Stock Option Agreement*(4)
10.6.1	Form of 2003 New-Hire Stock Option Plan *(13)
10.6.2	Form of 2003 New-Hire Stock Option Grant Notice*(13)
10.7	License Agreement dated as of May 17, 1999 by and between Eli Lilly and Company and Versicor Inc.(1) **
10.8.1	License and Supply Agreement, dated October 8, 2001, by and between Biosearch Italia S.p.A. and Genome Therapeutics Corporation**(9)
10.8.2	Amendment No. 1 to License and Supply Agreement, dated August 8, 2002, by and between Biosearch Italia S.p.A. and Genome Therapeutics Corporation**(9)
10.9	Collaborative Research and License Agreement dated as of March 31, 1999 by and between Novartis Pharma AG and Versicor Inc.(1) **
10.10	Research Collaboration, Contract Service and License Agreement dated as of March 31, 1999 by and between Pharmacia and Upjohn Company, and Versicor Inc.(1) **

Table of Contents

Exhibit Number	Description
10.11	Administrative Services Agreement dated as of December 1997 by and between Sepracor Inc. and Versicor Inc.(1)
10.12.1	First Amendment Agreement to Term Loan dated as of December 30, 1997 by and between Fleet National Bank and Versicor Inc.(1)
10.12.2	Second Amendment Agreement dated October 22, 2001, by and between Fleet National Bank and Versicor Inc.(10)
10.12.3	Third Amendment Agreement to Term Loan, dated January 28, 2003 by and between Fleet National Bank and Versicor Inc.(4)
10.13	Industrial Lease dated as of November 18, 1996 by and between Arcadia-Tavistock, L.C. and Versicor Inc.(1)
10.14	Indemnity Agreement dated as of October 29, 1999 by and between Thomas C. McConnell and Versicor Inc.(1)
10.15	Indemnity Agreement dated as of October 29, 1999 by and between Marck Leschly and Versicor Inc.(1)
10.16	Indemnity Agreement dated as of October 29, 1999 by and between George F. Horner III and Versicor Inc.(1)
10.17	Indemnity Agreement dated as of October 29, 1999 by and between James H. Cavanaugh and Versicor Inc.(1)
10.18	Indemnity Agreement dated as of October 29, 1999 by and between Christopher T. Walsh and Versicor Inc.(1)
10.19	Indemnity Agreement dated as of October 29, 1999 by and between Richard J. White and Versicor Inc(1)
10.20	Indemnity Agreement dated as of October 29, 1999 by and between David V. Milligan and Versicor Inc.(1)
10.21	Indemnity Agreement dated as of October 29, 1999 by and between Lori Rafield and Versicor Inc.(1)
10.22	Indemnity Agreement dated as of October 29, 1999 by and between Timothy J. Barberich and Versicor Inc.(1)
10.23	Employment Agreement dated as of July 28, 2000 by and between George F. Horner III and Versicor Inc.*(1)
10.24	Employment Agreement dated as of July 28, 2000 by and between Richard J. White and Versicor Inc.*(1)
10.25	Employment Agreement dated as of July 28, 2000 by and between Dinesh V. Patel and Versicor Inc.*(1)
10.26	Employment Agreement dated as of July 28, 2000 by and between Dov A. Goldstein and Versicor Inc.*(1)
10.27	Employment Agreement dated as of July 28, 2000 by and between Mikhail F. Gordeev and Versicor Inc.*(1)
10.28	Employment Agreement dated as of July 28, 2000 by and between Joaquim Trias and Versicor Inc.*(1)

Table of Contents

Exhibit Number	Description
10.29	Employment Agreement dated as of July 28, 2000 by and between Zhengyu Yuan and Versicor Inc.*(1)
10.30	Employment Agreement, dated as of December 18, 2000, by and between Versicor Inc. and Timothy J. Henkel*(2)
10.31	Employment Agreement, dated as of July 30, 2002, by and between Versicor Inc. and Claudio Quarta, Ph.D.*(3)
10.32	Employment Agreement, dated as of July 30, 2002, by and between Versicor Inc. and Francesco Parenti*(3)
10.33	Independent Consultant Agreement, dated as of July 30, 2002, by and between Versicor Inc. and Costantino Ambrosio*(3)
10.34	Consulting Agreement dated as of March 11, 1998 by and between Christopher Walsh and Versicor Inc.*(1)
10.35	Consulting Agreement dated as of January 1, 1997 by and between David Milligan and Versicor Inc.*(1)
10.36	Promissory Note dated as of May 15, 1997 by and between Richard J. White and Versicor Inc.*(1)
10.37	Second Amendment to Lease, dated December 17, 2002, by and between Versicor Inc. and Executive Terrace Investors, L.P.(4)
10.38	Purchase Agreement dated as of April 8, 2002, by and among Versicor Inc. and the Purchasers listed on Schedule A attached thereto (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on April 10, 2002 and is incorporated herein by reference)
10.39	Agreement entered into on April 13, 2001, by and between Biosearch Italia S.p.A. and San Paolo IMI S.p.A. (English Translation) (13)**
10.40	Agreement entered into on December 4, 1998, by and between Biosearch Italia S.p.A. and San Paolo IMI S.p.A. (English Translation) (13)**
10.41	Agreement entered into on August 5, 2002, by and between Biosearch Italia S.p.A. and Ministry of Productive Activities Directorate-General for Company Incentives Co-ordination, pursuant to Italian Ministerial Decree of May 6, 2002 (English Summary) (previously attached as an exhibit to our current report on Form 8-K, which was filed with the SEC on July 7, 2003 and is incorporated herein by reference)
10.42	Bank guarantee issued on behalf of Biosearch Manufacturing S.r.l. by San Paolo IMI S.p.A. in favor of Basilicata Region on January 17, 2002 (English Translation) (13)**
10.43	Financing Agreement entered into on July 10, 2002, by and between Biosearch Manufacturing S.r.l. and Monte dei Paschi di Siena Merchant S.p.A. (English Translation) (13)**

Table of Contents

Exhibit Number	Description
10.44	Amendment to Financing Agreement entered into on January 14, 2003, by and between Biosearch Manufacturing S.r.l. and Monte dei Paschi di Siena Merchant S.p.A. (English Translation) (13)**
10.45	Master Agreement entered into on December 4, 1998, by and between Biosearch Italia S.p.A. and Gruppo Lepetit S.p.A. (English Translation) (13)**
10.46	Agreement entered into on March 8, 1999, by and between Biosearch Italia S.p.A. and Gruppo Lepetit S.p.A. (English Translation) (13)**
10.47	Agreement entered into on November 2, 1999, by and between Biosearch Italia S.p.A. and Gruppo Lepetit S.p.A. (English Translation) (13)**
10.48	Agreement entered into on November 30, 2000, by and between Biosearch Italia S.p.A. and Gruppo Lepetit S.p.A. (English Translation) (13)**
10.49	Agreement entered into as of February 28, 2002, by and between Biosearch Manufacturing S.r.l. and Aventis Bulk S.p.A. (English Translation) (13)**
10.50	Addendum entered into on March 28, 2002, by and between Biosearch Manufacturing S.r.l. and Aventis Bulk S.p.A. (English Translation) (13)**
12.1	Statement re: computation of ratios (12)
21.1	List of Subsidiaries(12)
23.1	Consent of PricewaterhouseCoopers LLP(12)
31.1	Certification of George F. Horner III under Section 302 of the Sarbanes-Oxley act of 2002(12)
31.2	Certification of Dov A. Goldstein, M.D. under Section 302 of the Sarbanes-Oxley act of 2002(12)
32.1	Certification under Section 906 of the Sarbanes-Oxley Act of 2002(12)

* Denotes a management contract or compensatory plan.

** Portions of this exhibit were omitted and filed separately with the United States Securities and Exchange Commission pursuant to a request for confidential treatment.

(1) Filed as an exhibit to our registration statement on Form S-1 (No. 333-33022) as amended, effective August 2, 2000, and incorporated herein by reference.

(2) Filed as an exhibit to our Annual Report on Form 10-K, filed April 2, 2001, and incorporated herein by reference.

(3) Filed as an exhibit to our registration statement on Form S-4 (No. 333-98935) as amended, effective November 5, 2002, and incorporated herein by reference.

(4) Filed as an exhibit to our Annual Report on Form 10-K, filed March 3, 2003, and incorporated herein by reference.

(5) Filed as an exhibit to our registration statement on Form S-8 (No. 333-103081), which was filed with the SEC on February 11, 2003, and incorporated herein by reference.

Table of Contents

(6) Filed as an exhibit to our registration statement on Form S-3 (No.333-112847), which was filed with the SEC on February 13, 2004, and incorporated herein by reference.
(7) Filed as an exhibit to our quarterly report on Form 10-Q, filed August 14, 2003, and incorporated herein by reference.
(8) Filed as Appendix B to the Proxy Statement/Prospectus comprising Part I of our registration statement on Form S-4 (No. 333-98935), effective November 5, 2002 and incorporated herein by reference.
(9) Filed as an exhibit to Amendment No.1 of our registration statement on Form S-3 (No. 333-105921), filed on June 23, 2003 and incorporated herein by reference.
(10) Filed as an exhibit to our Annual Report on Form 10-K, filed with the SEC on March 12, 2002, and incorporated herein by reference.
(11) Filed as an exhibit to our quarterly report on Form 10-Q, filed August 10, 2001, and incorporated herein by reference.
(12) Filed herewith.
(13) Filed as an exhibit to Amendment No. 1 to our Registration Statement on Form S-3 (No. 333-112847), filed with the SEC on March 12, 2004 and incorporated herein by reference.