

VERSICOR INC /CA  
Form 10-Q  
November 13, 2002

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**FORM 10-Q**

ý **Quarterly report pursuant to section 13 or 15(d) of the Securities  
Exchange Act of 1934 for the quarterly period ended:**

September 30, 2002

o **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

---

**VERSICOR INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**04-3278032**  
(I.R.S. Employer  
Identification Number)

**34790 Ardentech Court, Fremont, California 94555**  
(Address of principal executive offices) (Zip Code)

**(510) 739-3000**  
(Registrant s telephone number, including area code)

---

Edgar Filing: VERSICOR INC /CA - Form 10-Q

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 report(s) and (2) has been subject to such filing requirements for the past 90 days. Yes  No .

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

On November 7, 2002, there were 26,377,770 common shares outstanding of the registrant's only class of common stock.

The Exhibit Index begins on page 35.

---

**VERVICOR INC.**

**Quarterly Report on Form 10-Q**

**For the Nine Months Ended September 30, 2002**

**INDEX**

<b><u>PART I.</u></b>	<b><u>FINANCIAL INFORMATION</u></b>
<b><u>Item 1.</u></b>	<b><u>Condensed Financial Statements</u></b> <u>Condensed Balance Sheets as of September 30, 2002 and December 31, 2001 (Unaudited)</u> <u>Statements of Operations for the Three and Nine Months Ended September 30, 2002 and 2001 (Unaudited)</u> <u>Statements of Cash Flows for the Nine Months Ended September 30, 2002 and 2001 (Unaudited)</u> <u>Notes to Condensed Financial Statements</u>
<b><u>Item 2.</u></b>	<b><u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u></b>
<b><u>Item 3.</u></b>	<b><u>Quantitative and Qualitative Disclosures About Market Risk</u></b>
<b><u>Item 4.</u></b>	<b><u>Controls and Procedures</u></b>
<b><u>PART II.</u></b>	<b><u>OTHER INFORMATION</u></b>
<b><u>Item 1.</u></b>	<b><u>Legal Proceedings</u></b>
<b><u>Item 2.</u></b>	<b><u>Changes in Securities and Use of Proceeds</u></b>
<b><u>Item 3.</u></b>	<b><u>Defaults upon Senior Securities</u></b>
<b><u>Item 4.</u></b>	<b><u>Submission of Matters to a Vote of Security Holders</u></b>
<b><u>Item 5.</u></b>	<b><u>Other Information</u></b>
<b><u>Item 6.</u></b>	<b><u>Exhibits and Reports on Form 8-K</u></b> <b><u>Signatures</u></b> <b><u>Certifications</u></b> <b><u>Exhibit Index</u></b>

**PART I FINANCIAL INFORMATION****ITEM 1. CONDENSED FINANCIAL STATEMENTS****VERVICOR INC.****CONDENSED BALANCE SHEETS**

(unaudited)

(in thousands)

	September 30, 2002	December 31, 2001
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 35,914	\$ 31,349
Marketable securities	36,881	32,419
Employee notes receivable		13
Prepaid expenses and other current assets	1,916	1,624
Total current assets	74,711	65,405
Property and equipment, net	4,869	5,197
Other assets	105	95
Total assets	\$ 79,685	\$ 70,697
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 3,477	\$ 4,335
Accrued liabilities	9,116	6,278
Current portion of term loan payable	3,500	3,950
Deferred revenue	635	1,561
Total current liabilities	16,728	16,124
Term loan payable	873	1,004
Deferred revenue	500	500
Other long-term liabilities	244	175
Total liabilities	18,345	17,803
Stockholders' equity:		
Common stock	26	23
Additional paid-in capital	202,262	160,163
Deferred stock compensation	(1,520)	(3,567)
Accumulated other comprehensive income	72	98
Accumulated deficit	(139,500)	(103,823)

Edgar Filing: VERSICOR INC /CA - Form 10-Q

Total stockholders' equity		61,340		52,894
Total liabilities and stockholders' equity	\$	79,685	\$	70,697

The accompanying notes are an integral part of the condensed financial statements.

## VERSICOR INC.

## STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended		Nine Months Ended	
	September 30, 2002	September 30, 2001	September 30, 2002	September 30, 2001
<b>Revenues:</b>				
Collaborative research and development and contract services	\$ 1,519	\$ 1,554	\$ 4,563	\$ 4,594
License fees and milestones		9	258	276
<b>Total revenues</b>	<b>1,519</b>	<b>1,563</b>	<b>4,821</b>	<b>4,870</b>
<b>Operating expenses:</b>				
Research and development - non-cash stock compensation expense	173	544	592	1,739
Research and development - other	12,572	8,665	34,218	21,624
<b>Total research and development</b>	<b>12,745</b>	<b>9,209</b>	<b>34,810</b>	<b>23,363</b>
General and administrative - non-cash stock compensation expense	387	32	1,259	2,141
General and administrative - other	1,756	1,458	5,421	4,262
<b>Total general and administrative</b>	<b>2,143</b>	<b>1,490</b>	<b>6,680</b>	<b>6,403</b>
<b>Total operating expenses</b>	<b>14,888</b>	<b>10,699</b>	<b>41,490</b>	<b>29,766</b>
<b>Loss from operations</b>	<b>(13,369)</b>	<b>(9,136)</b>	<b>(36,669)</b>	<b>(24,896)</b>
<b>Other income (expense):</b>				
Interest income	399	692	1,180	2,824
Interest expense	(64)	(70)	(188)	(250)
Other expense		(60)		(60)
<b>Net loss</b>	<b>\$ (13,034)</b>	<b>\$ (8,574)</b>	<b>\$ (35,677)</b>	<b>\$ (22,382)</b>
<b>Net loss per share:</b>				
<b>Basic and diluted</b>	<b>\$ (0.49)</b>	<b>\$ (0.37)</b>	<b>\$ (1.41)</b>	<b>\$ (0.97)</b>
<b>Weighted average shares</b>	<b>26,353</b>	<b>23,085</b>	<b>25,217</b>	<b>23,060</b>

The accompanying notes are an integral part of the condensed financial statements.



## VERSICOR INC.

## STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended	
	September 30, 2002	September 30, 2001
<b>Cash flows from operating activities:</b>		
Net loss	\$ (35,677)	\$ (22,382)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	945	750
Loss on disposal of fixed assets		60
Non-cash stock compensation expense	1,851	3,880
Changes in operating assets and liabilities:		
Employee notes receivable	13	522
Prepaid expenses and other current assets	(292)	(162)
Other assets	(10)	(15)
Accounts payable	(858)	648
Accrued liabilities	2,838	3,275
Related party payable		(12)
Deferred revenue	(926)	(624)
Other long-term liabilities	69	(841)
Net cash used in operating activities	(32,047)	(14,901)
<b>Cash flows from investing activities:</b>		
Purchases of marketable securities	(31,816)	(39,705)
Sales/maturities of marketable securities	27,328	32,579
Additions to property and equipment	(617)	(1,528)
Net cash used in investing activities	(5,105)	(8,654)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock	42,298	254
Proceeds from long-term debt	491	
Repayments of long-term debt	(1,072)	(647)
Net cash provided by (used in) financing activities	41,717	(393)
Net change in cash and cash equivalents	4,565	(23,948)
Cash and cash equivalents at beginning of period	31,349	67,989
Cash and cash equivalents at end of period	\$ 35,914	\$ 44,041
<b>Supplemental cash flow information:</b>		
Cash paid during the period for interest	\$ 187	\$ 250



Edgar Filing: VERSICOR INC /CA - Form 10-Q

The accompanying notes are an integral part of the condensed financial statements.

## NOTES TO CONDENSED FINANCIAL STATEMENTS

### 1. Basis of Presentation

The accompanying interim financial statements are unaudited and have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, certain information and footnote disclosures normally included in annual financial statements have been condensed or omitted. The year-end condensed balance sheet data was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. The interim financial statements, in the opinion of management, reflect all adjustments (including normal recurring accruals) necessary for a fair presentation of the results for the interim periods ended September 30, 2002 and 2001.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year or any other interim period. These condensed interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2001, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2001.

### 2. Basic and Diluted 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 anti-dilutive 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 anti-dilutive (in thousands):

	September 30,	
	2002	2001
Common shares issuable upon exercise of stock options	3,541	2,831
Common shares issuable upon exercise of warrants	271	421
Common shares subject to repurchase	1	10
	3,813	3,262

### 3. Merger with Biosearch Italia S.p.A.

On July 30, 2002, we entered into an agreement under which we will acquire all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. The board of directors of each company has approved the transaction which is subject to the approval of each company's shareholders, certain regulatory approvals in Italy and certain other conditions set forth in the merger agreement. If the merger is consummated,

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

we will issue 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. We also intend to issue options covering approximately 5,787,500 common shares, including options issued to replace or assume options currently held by Biosearch employees and consultants. The merger is expected to close in the first quarter of 2003.

## ITEM 2. 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 Quarterly Report on Form 10-Q and our audited financial statements for the year ended December 31, 2001 included in our Annual Report on Form 10-K previously filed with the SEC. This discussion may contain forward-looking statements that involve risks and uncertainties. The words believe, expect, anticipate, may, will, or could and similar expressions or the negatives of these words and 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 significantly from those anticipated in these forward-looking statements.*

### Overview

We are a biopharmaceutical company focused on the discovery, development and marketing of pharmaceutical products for the treatment of bacterial and fungal infections. Since our inception on May 2, 1995 as a wholly owned subsidiary of Sepracor Inc., we have devoted substantially all of our efforts to establishing our business and conducting research and development activities related to our proprietary product candidates, including anidulafungin and dalbavancin, as well as collaborative product candidates.

Since 1996 we have been operating as an independent company. 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 July 30, 2002, we entered into an agreement under which we will acquire all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. The board of directors of each company has approved the transaction which is subject to the approval of each company's shareholders, certain regulatory approvals in Italy and certain other conditions set forth in the merger agreement. If the merger is consummated, we will issue 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. We also intend to issue options covering approximately 5,787,500 common shares, including options issued to replace or assume options currently held by Biosearch employees and consultants. The merger is expected to close in the first quarter of 2003.

Since we began our operations in May 1995, we have not generated any revenues from product sales. Our lead antifungal product candidate, anidulafungin, has completed enrollment in a Phase III esophageal candidiasis trial and a Phase II invasive candidiasis/candidemia trial and is also currently in a Phase III trial for aspergillosis. Our lead antibiotic product candidate, dalbavancin, has completed Phase II clinical trials in skin and soft tissue infections and is in Phase II clinical trials for bloodstream infections. We also have several lead compounds in preclinical studies.

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

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. Some of these payments are dependent on achievement of specified milestones. If our 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 development milestones are achieved, and our research and development expenses to increase

as we continue to develop our product candidates. Assuming the completion of the proposed merger of Biosearch with and into us, we also expect that our general and administrative expenses will increase as we add personnel, integrate our operations and continue to expand our research and development operations. In addition, our expenses will increase as a result of professional fees incurred in connection with the proposed merger whether or not the proposed merger is completed. 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 September 30, 2002, we had an accumulated deficit of \$139.5 million. We anticipate incurring additional losses, which may increase, for the foreseeable future, including at least through December 31, 2003.

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

### **Major Research and Development Projects**

Our ongoing clinical trials of anidulafungin and dalbavancin are our two most significant research and development projects, comprising 42% and 21%, respectively, of our total research and development expenditure (excluding non-cash stock compensation expense) since January 1, 2001.

### **Anidulafungin**

Anidulafungin is our lead antifungal product candidate. We in-licensed anidulafungin from Eli Lilly pursuant to the May 1999 agreement described below. As of September 30, 2002, the intravenous formulation of anidulafungin is in:

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

Phase III clinical trials for the treatment of aspergillosis; and

Phase II clinical trials for the treatment of invasive candidiasis/candidemia, 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 \$14.0 million to Eli Lilly. We are also obligated to make additional payments of up to \$8.0 million to Eli Lilly if specified milestones on the intravenous formulation of anidulafungin are achieved in

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

Europe, and additional payments of up to \$8.0 million if specified milestones on the intravenous formulation of anidulafungin are achieved in Japan. We are obligated to make additional payments to Eli Lilly of up to \$21.0 million if sales of an intravenous formulation of anidulafungin exceed specified targets in the United States and Canada, Europe and Japan. We believe that it is unlikely that we will be obligated to make all or a significant portion of these payments to Eli Lilly. In addition, we are obligated to make royalty payments in respect of sales of any product resulting from the compound.

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

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

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

46% for the nine months ended September 30, 2002 compared to 39% for the nine months ended September 30, 2001;

37% for the year 2001 compared to 14% for the year 2000 and 65% for the year 1999; and

39% in the aggregate from the inception of our company through September 30, 2002.

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

The goal of our anidulafungin project is to obtain marketing approval from the U.S. Food and Drug Administration, or FDA, and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. To obtain the first of such approvals, we hope to file a New Drug Application, or NDA, with the FDA at the conclusion of our Phase III clinical trial for the treatment of esophageal candidiasis, which has completed patient enrollment, assuming that the clinical trial's results support a filing. The trial began in the first quarter of 2001, and assuming successful completion of the trial, we anticipate filing an NDA for anidulafungin by the end of April 2003. Subsequent to September 30, 2002 through the submission date of any NDA, we expect to incur significant additional research and development expenses relating to anidulafungin of at least \$10.0 million. Actual research and development expenses might be significantly higher as a result of 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. If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could harm our business and cause our stock price to decline. 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 late stage clinical trials, in which case we might re-assign anidulafungin staff 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.

### **Dalbavancin**

Dalbavancin is our lead antibiotic product candidate. We in-license dalbavancin from Biosearch pursuant to the February 1998 agreement described below. As of September 30, 2002, dalbavancin is in:

Phase II clinical trials for the treatment of skin and soft tissue infections, patient enrollment completed;  
and

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

In February 1998, we entered into a license agreement and a collaborative agreement with Biosearch. Under the license agreement, Biosearch granted us an exclusive license to develop and commercialize dalbavancin in the United States and Canada. In exchange for the license and upon the receipt of favorable results in pre-clinical studies, we paid an initial license fee of \$2.0 million and issued 250,000 shares of our common stock to Biosearch. In May 2001, we began a Phase II clinical trial for dalbavancin and paid Biosearch an additional milestone payment. We are obligated to make up to \$8.0 million in additional payments to Biosearch upon the achievement of specified milestones and are also required to pay Biosearch royalties in respect of sales of any product that results from the compound.

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

18% for the nine months ended September 30, 2002 compared to 23% for the nine months ended September 30, 2001;

23% for the year 2001 compared to 7% for the year 2000 and 5% for the year 1999; and

17% in the aggregate from the inception of our company through September 30, 2002.

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

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

The goal of our dalbavancin project is to obtain marketing approval from the FDA and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. Before we can obtain such marketing approvals, we will need to complete pivotal Phase III clinical trials with satisfactory results and submit a NDA to the FDA. In any case, we would not expect to file a 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. If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could harm our business and cause our stock price to decline. However, over the next nine months ending June 30, 2003, we expect to incur significant additional research and development expense relating to dalbavancin expenses relating to dalbavancin's development of at least \$18.0 million and we expect our rate of spending on the project to accelerate as we approach the filing of an NDA. Actual research and development expenses might be significantly higher. 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 dalbavancin 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 late stage clinical trials, in which case we might re-assign dalbavancin staff to those projects);

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

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

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 anidulafugin and dalbavancin projects, including those listed under the caption, Risk Factors Risks Related to Operating in Our Industry.

#### **Clinical Administration**

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

12% for the nine months ended September 30, 2002 compared to 6% for the nine months ended September 30, 2001;

7% for the year 2001 compared to 17% for the year 2000 and 0% for the year 1999; and

8% in the aggregate from the inception of our company through September 30, 2002.

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

#### **Other Research and Development Projects**

The remaining 27% of our total research and development expenses (excluding non-cash stock compensation expense) since January 1, 2001 were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pharmacia and Novartis described below.

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

2002, we agreed with Pharmacia by amendment to extend the collaboration by an additional three years, through March 2005. Through September 30, 2002, Pharmacia has made aggregate payments to us under this collaboration agreement (excluding equity investments) of \$12.1 million.

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

7% for the nine months ended September 30, 2002 compared to 11% for the nine months ended September 30, 2001;

11% for the year 2001 compared to 22% for the year 2000 and 10% for the year 1999; and

11% in the aggregate from January 1, 1999 through September 30, 2002.

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

*Deformylase inhibitors collaboration with Novartis.* In March 1999, we entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of \$3.0 million. We have also received a number of milestone payments from Novartis and are entitled to receive additional payments of up to \$2.25 million for each compound, plus up to \$13.0 million for our compounds or up to \$7.25 million for Novartis compounds upon the achievement of specified milestones. Novartis may deduct a portion of these milestone payments from the royalties it will be obligated to pay us on the worldwide sales of any drug developed and commercialized from this collaboration. As a result of progress achieved by the collaboration, in July 2002 we agreed with Novartis by amendment to extend the collaboration by an additional year, through March 2003. Through September 30, 2002, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of \$10.4 million.

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

Edgar Filing: VERSICOR INC /CA - Form 10-Q

5% for the nine months ended September 30, 2002 compared to 9% for the nine months ended September 30, 2001;

8% for the year 2001 compared to 20% for the year 2000 and 10% for the year 1999; and

9% in the aggregate from January 1, 1999 through September 30, 2002.

The goal of our collaboration with Novartis is to discover, synthesize and obtain marketing approval for deformylase inhibitor product candidates. We are responsible for supplying research to the collaboration, according to a research plan developed by a joint research committee. Our research obligations currently extend through March 2003. Novartis provides us with funding to support some of our researchers on this project. The collaboration will depend upon Novartis to conduct the development of product candidates and to obtain marketing approval from the FDA and analogous international agencies. Material cash inflows in the form of royalties relating to this collaboration will not commence until after marketing approvals are obtained, and then only if the product finds acceptance in the marketplace. Currently all

compounds identified by the collaboration are still in pre-clinical stages. In order to obtain marketing approval, Novartis will need to initiate and complete Phase I, II and III clinical trials with satisfactory results and submit a NDA to the FDA. Novartis is under no obligation to continue the development of any product candidate resulting from this collaboration. Because of this, and the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our collaboration with Novartis will commence, if ever.

In addition to the work on deformedylase 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 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.

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

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

while we do not rely on any particular external development collaboration to produce marketable products (and, ultimately, royalty revenues), the failure of all 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 a reduction in deferred stock compensation of \$196,000 and \$414,000 in the nine months ended September 30, 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 \$1.9 million and \$3.9 million in the nine months ended September 30, 2002 and 2001, respectively.

#### **Results of Operations**



*Three Months Ended September 30, 2002 Compared to Three Months Ended September 30, 2001*

**Revenues**

Revenues were \$1.5 million and \$1.6 million in the three months ended September 30, 2002 and 2001, respectively. Revenues in both quarters consisted of collaborative research and development fees from Pharmacia and Novartis

### **Research and Development Expenses**

Research and development expenses were \$12.7 million and \$9.2 million in the three months ended September 30, 2002 and 2001, respectively. The increase is primarily due to increased clinical expenditure of \$3.0 million for the development of anidulafungin and dalbavancin. In the last year, we have started an additional Phase III clinical trial for anidulafungin and two Phase II clinical trials for dalbavancin. We have also increased our development team headcount resulting in increased expenditure of \$702,000.

### **General and Administrative Expenses**

General and administrative expenses were \$2.1 million and \$1.5 million in the three months ended September 30, 2002 and 2001, respectively. This increase is primarily due to business development activities.

### **Other Income (Expense)**

Net other income (expense) was \$335,000 and \$562,000 in the three months ended September 30, 2002 and 2001, respectively. The decrease is due to a significant decrease in interest rates during the last 12 months and therefore reduced interest income in 2002.

### ***Nine Months Ended September 30, 2002 Compared to Nine Months Ended September 30, 2001***

### **Revenues**

Revenues were \$4.8 million and \$4.9 million in the nine months ended September 30, 2002 and 2001, respectively. Revenues in both periods consisted of collaborative research and development, contract service and license fees from Pharmacia Corporation and collaborative research and development fees and milestone payments from Novartis.

### **Research and Development Expenses**

Research and development expenses were \$34.8 million and \$23.4 million in the nine months ended September 30, 2002 and 2001, respectively. The increase is primarily due to increased clinical expenditure of \$8.9 million for the development of anidulafungin and dalbavancin. In the last year, we have started an additional Phase III clinical trial for anidulafungin and two Phase II clinical trials for dalbavancin. We have also increased our development team headcount resulting in increased expenditure of \$2.8 million.

**General and Administrative Expenses**

General and administrative expenses were \$6.7 million and \$6.4 million in the nine months ended September 30, 2002 and 2001, respectively. General and administrative expenses include amortization of non-cash stock compensation expense of \$1.3 million and \$2.1 million in the nine months ended September 30, 2002 and 2001, respectively. Excluding these charges, general and administrative expenses increased by \$1.2 million primarily due to business development activities related to the proposed merger with Biosearch.

**Other Income (Expense)**

Net other income (expense) was \$992,000 and \$2.5 million in the nine months ended September 30, 2002 and 2001, respectively. The 2001 period reflects greater interest income as a result of higher average cash and marketable securities balances during the nine months and also higher interest rates during that period.

## Liquidity and Capital Resources

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

As of September 30, 2002, we have also received approximately \$25.5 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, \$1.1 million constitutes deferred revenue as of September 30, 2002.

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% and the equipment note's interest rate is based on the LIBOR rate plus an applicable margin. As of September 30, 2002, there was an outstanding loan balance of \$2.8 million and an outstanding note balance of \$1.6 million. Proceeds from the loan were used to repay Sepracor for leasehold improvements to our facilities and for general corporate purposes. Proceeds from drawdowns on the equipment note were used to finance capital expenditure. The final loan balance is payable on December 31, 2002 and the final note balance is payable on December 31, 2004.

Cash used in operations was \$32.0 million and \$14.9 million in the nine months ended September 30, 2002 and 2001, respectively. The net loss of \$35.7 million and \$22.4 million in 2002 and 2001, respectively, was reduced by non-cash charges for depreciation and non-cash stock compensation expense of \$2.8 million and \$4.6 million, respectively. The decrease in non-cash stock compensation expense in 2002 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. Accrued liabilities increased by \$2.8 million and \$3.3 million in the nine months ended September 30, 2002 and 2001, respectively, primarily due to the increase in development expenditure associated with our late-stage clinical trials.

Cash used in investing activities was \$5.1 million and \$8.7 million in the nine months ended September 30, 2002 and 2001, respectively. In both periods, the principal use of cash resulted from the net purchase of marketable securities of \$4.5 million and \$7.1 million, respectively. The decrease in 2002 results from lower average cash and marketable securities balances during that period. Capital expenditure was \$617,000 and \$1.5 million in the nine months ended September 30, 2002 and 2001, respectively. Increased expenditure in 2001 related to leasehold improvements at our California facility.

Cash provided by financing activities was \$41.7 million and \$(393,000) in the nine months ended September 30, 2002 and 2001, respectively. The principal source of cash in the first nine months of 2002 resulted from net proceeds of \$41.9 million received from the private placement of 2,993,800 shares of common stock to selected institutional investors in April 2002. Net repayments on our long-term debt were \$581,000 and \$647,000 in the nine months ended September 30, 2002 and 2001, respectively. In 2002, higher debt repayments included repayments on our equipment loan that we entered into in the second half of 2001, but were offset by an additional draw down on the loan of \$491,000.

At September 30, 2002, our cash, cash equivalents and marketable securities totaled \$72.8 million compared to \$63.8 million at December 31, 2001.

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 will be sufficient to fund our operating expenses, debt repayments and capital requirements for at least the next two years.

### **Critical Accounting Policies**

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

Our critical accounting policies are as follows:

#### ***Revenue Recognition***

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

#### ***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.

### **Risk Factors Affecting Future Operating Results**

*Some of the information contained in this Quarterly Report on Form 10-Q consists of forward-looking statements. Important risk factors that could cause actual results to differ materially from the results implied by those forward-looking statements include risks described below and the risks described under the heading Risk Factors in our proxy statement/prospectus dated November 5, 2002 and filed with the SEC on November 7, 2002.*

### **Risks Related to Our Business**

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

You must evaluate us in light of the uncertainties and complexities present in a biopharmaceutical company. Most of our product candidates are in the early stages of development, and two are in clinical trials. We do not know whether any of our clinical trials will result in marketable products. Preclinical testing and clinical trials are long, expensive and uncertain processes. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. To date, we have not commercialized any products or recognized any revenue from product sales. To do so will require significant additional investment in research and development, preclinical testing and clinical trials, regulatory approval, and sales and marketing activities. Furthermore, our potential drug candidates will be subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies.

These risks include:

the possibilities that any or all of our drug candidates will be found to be unsafe, ineffective or toxic, or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;

that these drug candidates, if safe and effective, will be difficult to develop into commercially viable drugs or to manufacture on a large scale or will be uneconomical to market commercially;

that third party proprietary rights will preclude us from marketing such drugs; or

that third parties will market superior or equivalent drugs.

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

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

We have incurred net losses since our inception in 1995. Before deemed dividends and accretion to redemption value of our preferred stock, our net losses were approximately \$1.1 million in 1995, \$4.8 million in 1996, \$6.3 million in 1997, \$12.6 million in 1998, \$29.2 million in 1999, \$15.3 million in 2000, \$32.8 million in 2001 and \$35.7 million in the first nine months of 2002. As of September 30, 2002, our accumulated deficit was approximately \$139.5 million. Our losses to date have resulted principally from:

research and development costs (including non-cash stock compensation expenses) relating to the development of our product candidates, which represent approximately 81% of our aggregate operating expenses from the inception of our company through September 30, 2002;

costs of acquiring product candidates; and



general and administrative costs (including non-cash stock compensation expenses) relating to our operations, which represent approximately 19% of our aggregate operating expenses from the inception of our company through September 30, 2002.

We expect to incur substantial and increasing losses for the foreseeable future as a result of increases in our research and development costs, including costs associated with conducting preclinical testing and clinical trials, and charges related to purchases of technology or other assets. We also expect that our general and administrative expenses will increase as we add personnel and integrate our operations and those of Biosearch Italia. We expect that the amount of operating losses will fluctuate significantly from quarter to quarter as a result of increases or decreases in our research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, or other factors. Our chances for achieving profitability will depend on numerous factors, including success in:

developing and testing new product candidates;

licensing rights to our product candidates to third parties;

receiving regulatory approvals;

manufacturing products;

marketing products; and

competing with products from other companies.

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

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

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

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

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

**If our collaborators do not perform, we will be unable to develop our joint product candidates.**

We have entered into collaborative arrangements with third parties to develop certain product candidates. These collaborations are necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. Only a limited number of product candidates have been generated pursuant to our collaborations. We cannot assure you that any of these product candidates will result in commercially successful products. Current or future collaborative arrangements may not be successful. If we fail to maintain our existing collaborative arrangements or fail to enter into additional collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

Our dependence on collaborative arrangements with third parties subjects us to a number of risks. These collaborative arrangements may not be on terms favorable to us. Agreements with collaborators typically allow the collaborators significant discretion in electing whether to pursue any of the planned activities. We cannot control the amount and timing of resources our collaborators may devote to the product candidates or their prioritization of the product candidates, and our collaborators may choose to pursue alternative products. Our collaborators may also not perform their obligations as expected. Business combinations or significant changes in a collaborator's business strategy may adversely affect a collaborator's willingness or ability to complete its obligations to us. Moreover, we could become involved in disputes with our collaborators which could lead to delays in, or the termination of, our development programs with them, as well as time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our collaborators can generally terminate the agreements under certain circumstances. If any collaborator was to terminate or breach our agreement with it, or otherwise fail to complete its obligations in a timely manner, our chances of successfully commercializing products could be harmed.



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

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

slower than expected rate of hospital and patient recruitment;

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

unforeseen safety issues;

lack of efficacy during the clinical trials;

inability to adequately follow patients after treatment;

governmental or regulatory delays; or

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

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

As of September 30, 2002, we had two product candidates in clinical trials; anidulafungin in Phase III clinical trials and dalbavancin in Phase II clinical trials. Patient follow-up for these clinical trials has been limited and more trials will be required before we will be able to apply for

regulatory approvals. We recently extended the anticipated completion date of one of our phase III trials with anidulafungin in order to increase our patient safety data base. Clinical trials conducted by us or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin and dalbavancin or any other potential product candidates. This failure may delay development of other product candidates and hinder our ability to conduct related preclinical testing and clinical trials. Regulatory authorities may not permit us to undertake any additional clinical trials for our product candidates. Our other product candidates are in preclinical development, and we have not submitted investigational new drug applications, or INDs, to commence clinical trials involving these compounds. Our preclinical development efforts may not be successfully completed and we may not file further INDs. Any delays in, or termination of, our clinical trials will harm our development and commercialization timelines, which would cause our stock price to decline. Any of these events would also seriously impede our ability to obtain additional financing.

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

We have limited experience in conducting and managing clinical trials, and currently have only 21 full-time clinical development employees. We rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. If these third parties fail to perform satisfactorily under the terms of our agreements with them, clinical trials

for our product candidates may be delayed or unsuccessful. Furthermore, the Food and Drug Administration, or the FDA, may inspect some of our clinical investigational sites, our collaborators' records and our facility and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that the trials were not in compliance, we may be required to repeat the clinical trials.

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

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

demonstration of clinical efficacy and safety;

cost-effectiveness;

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

reimbursement policies of government and third-party payors; and

effectiveness of our marketing and distribution capabilities.

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

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

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

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

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

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

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

We do not have our own manufacturing facilities to produce our product candidates and anticipate that we will continue to rely on third parties to manufacture our product candidates and our products. Our contract manufacturers have a limited number of facilities in which our product candidates can be produced. These manufacturers have limited experience in manufacturing anidulafungin and dalbavancin in quantities sufficient for conducting clinical trials or for commercialization. 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. Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our product candidates. If our contract manufacturers fail to perform satisfactorily under our agreements with them, including failing to deliver the required quantities of our product candidates for clinical use on a timely basis and at commercially reasonable prices, and if we fail to find a replacement manufacturer or develop our own manufacturing capabilities, clinical trials involving our product candidates, or commercialization of our products, could be delayed.

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

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

**If circumstances require us to obtain additional funding, we may be forced to delay or curtail the development of our product candidates.**

We expect to incur increasing research and development and general and administrative expenses over the next several years. Our requirements for additional capital may be substantial and will depend on many factors, some of which are beyond our control, including:

payments received or made under possible future collaborative agreements;



continued progress in the research and development of our products;

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

development of marketing and sales capabilities; or

market acceptance of our products.

To the extent our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds to continue the development of our product candidates. Other than with respect to our existing line of credit for equipment financing, we have no committed sources of additional capital. We cannot assure you that funds will be available to us on favorable terms, if at all. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the securities could be sold at a discount to prevailing market price and the issuance of those securities could result in dilution to our stockholders. Moreover, the incurrence of debt financing could result in a substantial portion of our operating cash flow being dedicated to the payment of principal and interest on such indebtedness, and we may be subject to restrictive covenants as a result of such debt financing. This could render us more vulnerable to competitive pressures and economic downturns and could impose restrictions on our operations. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research and development programs or otherwise significantly curtail operations, obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to certain technologies or drug candidates that we would not otherwise relinquish in order to continue independent operations. Our inability to raise capital would harm our business, financial condition and results of operations.

**If we consummate any acquisitions, such as the proposed merger with Biosearch, we will incur a variety of costs and may never realize the anticipated benefits.**

If appropriate opportunities become available, we may attempt to acquire products, product candidates or businesses that we believe are a strategic fit with our business. We have recently entered into an agreement and plan of merger with Biosearch whereby it is contemplated that Biosearch will merge with and into Versicor. The process of negotiating the proposed merger with Biosearch and, assuming the consummation of the merger, integrating Biosearch's products, product candidates or business has and may continue to result in operating difficulties and transaction costs and require significant management attention that would otherwise be available for ongoing development of our business. Some of these transaction costs include financial advisors, printing, distribution, legal and accounting fees and severance payments, certain of which will be incurred whether or not the proposed merger is consummated. Similar risks may arise in connection with other acquisitions that we may pursue in the future. We may never realize the anticipated benefits of the proposed merger with Biosearch or any other acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, as in the case with the proposed merger with Biosearch, 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 business, financial condition and results of operations.

**If the proposed merger with Biosearch does not occur, we may incur payment obligations to Biosearch.**

If the agreement and plan of merger with Biosearch is terminated under certain circumstances, we may be required to pay Biosearch a \$6 million break-up fee. If the agreement and plan of merger is terminated in certain other circumstances, we may be obligated to pay Biosearch's expenses incurred in connection with the proposed merger, which may be substantial.

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

Our research and manufacturing activities involve the controlled use of hazardous materials, primarily biological materials and chemical compounds that are used, stored, collected, analyzed and developed 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 may be held liable for any resulting damages, which may exceed our financial resources. We do not currently maintain separate insurance to cover contamination or injuries relating to hazardous materials, and arguably it may not be covered by our general liability insurance coverage.

**Risks Related to Operating in Our Industry**

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

Our product candidates under development are subject to extensive and rigorous domestic government regulation. The FDA regulates, among other things, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products. If our products are marketed abroad, they will also be subject to extensive regulation by foreign governments. We must provide the FDA and foreign regulatory authorities with clinical data that demonstrate our products' safety and efficacy in humans before they can be approved for commercial sale. None of our product candidates has been approved for sale in the United States or any foreign market, and we cannot predict whether regulatory clearance will be obtained for any product that we are developing or hope to develop. The regulatory review and approval process takes many years, is dependent upon the type, complexity and novelty of the product, requires the expenditure of substantial resources, involves post-marketing surveillance, and may involve ongoing requirements for post-marketing studies. Delays in obtaining regulatory approvals may:

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

impose costly procedures on us or our collaborators;

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

adversely affect our receipt of revenues or royalties.

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

delays in clinical trials or commercialization;

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

product recalls or seizures;

suspension of production;

withdrawals of previously approved marketing applications; and

finances, civil penalties and criminal prosecutions.

We expect to file INDs and generally direct the regulatory approval process for proprietary products we develop, and we expect to rely on our collaborators to generally direct the regulatory approval process for our collaboration products. Our collaborators may not be able to conduct clinical testing or obtain necessary approvals from the FDA or other regulatory authorities for any product candidates. In addition, we may encounter delays or rejections based upon additional government regulation resulting from future legislation or administrative action or changes in FDA policy or interpretation during the period of product development, clinical trials and FDA regulatory review. If we fail to obtain required governmental approvals, we or our collaborators will experience delays in or be precluded from marketing products developed through our research. In addition, the commercial use of our products will be limited. If regulatory clearance for a product is granted, this clearance will be limited to those disease states and conditions for which the product is demonstrated through clinical trials to be safe and efficacious. We

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

We and our contract manufacturers also are required to comply with the applicable FDA current Good Manufacturing Practice regulations. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. We or our contract manufacturers may not be able to comply with the applicable Good Manufacturing Practice requirements and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, we could be subject to fines or other sanctions, or be precluded from marketing our products.

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

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

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies for treatment. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. We are aware of several pharmaceutical and biotechnology companies that are actively engaged in research and development in areas related to antibiotic and antifungal products. These companies have commenced clinical trials or have successfully commercialized their products. Specifically:

if anidulafungin receives FDA and international marketing approval, it will face competition from commercially available drugs such as amphotericin B (marketed by several manufacturers), fluconazole (marketed as Diflucan by Pfizer), itraconazole (marketed as Sporanox by Johnson & Johnson), and potentially from caspofungin (marketed as Cancidas by Merck), which is the first to receive FDA approval of a new class of antifungal agents called echinocandins (which includes anidulafungin). Merck initially obtained approval only for the narrow indication of aspergillosis salvage therapy, but might in the future expand the scope of Cancidas to include other serious fungal infections, such as esophageal and invasive candidiasis; or

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

## Edgar Filing: VERSICOR INC /CA - Form 10-Q

Many of these companies are addressing the same diseases and disease indications as we, or our collaborators, are addressing. Many of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development 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.

Developments by others may render our product candidates or technologies obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborative arrangements with pharmaceutical and biotechnology companies for establishing relationships with academic and

research institutions, and for licenses of proprietary technology. These competitors, either alone or with their collaborators, may succeed in developing technologies or products that are more effective, less expensive, have fewer side effects or are easier to administer than ours. In addition, some of our competitors have greater experience than us in conducting preclinical and human clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than us. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sales of their drugs before their competitors may achieve a significant competitive advantage, including certain patent and FDA marketing exclusivity rights that would delay our ability to market certain products. There can be no assurance that drugs resulting from our research and development efforts, or from joint efforts with our collaborators, will obtain regulatory approval in the United States or elsewhere or will be able to compete successfully with our competitors' existing products or products under development. In any such case, sales of our eventual products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

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

Our success depends in part on our ability to:

obtain patents or rights to patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. As of September 30, 2002, we have four issued U.S. patents and eight U.S. patent applications. Our license agreement with Eli Lilly with respect to anidulafungin includes 12 U.S. patents, 12 U.S. patent applications, 37 foreign patents and 132 foreign patent applications. The patent position of biopharmaceutical companies involves complex legal and factual questions, and, therefore, we cannot predict with certainty whether they will be enforceable. We have in the past and might in the future receive office actions or other notices from U.S. or foreign patent authorities seeking to limit or otherwise qualify some patent claims. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from third parties may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. Also, patent rights may not provide us with adequate proprietary protection or competitive advantages against competitors with similar technologies. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the United States.



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

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

Research has been conducted for many years in the areas in which we have focused our research and development efforts. This has resulted in a substantial number of issued patents and an even larger number

of still-pending patent applications. Patent applications in the United States are, in most cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Our technologies may infringe the patents or violate other proprietary rights of third parties. In the event an infringement claim is brought against us, we may be required to pay legal and other expenses to defend such claim and, if we are unsuccessful, we and our collaborators may be prevented from pursuing product development and commercialization and may be subject to damage awards.

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

enforce patents that we own or license;

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

determine the enforceability, scope and validity of the proprietary rights of others.

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

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

In both domestic and foreign markets, sales of our product candidates will depend in part upon the availability of reimbursement from third-party payors. Such third-party payors include government health administration authorities, managed care providers, private health insurers and other organizations. These third-party payors are increasingly challenging the price, and examining the cost effectiveness, of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of our products. Such studies may require us to commit a significant amount of management time and financial and other resources. Our product candidates may not ultimately be considered cost-effective. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare. For example, in some foreign markets, the government controls prescription pharmaceuticals pricing and profitability. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenues and profitability.

Accordingly, legislation and regulations affecting the pricing of pharmaceuticals may change before our proposed products are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

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

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

#### **Risks Related to Ownership of Our Stock**

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

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

clinical trial data;

general economic conditions;

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

future sales of equity or debt securities;

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 partnerships, joint ventures or capital commitments;

additions or departures of key personnel;

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

sales of our common stock.

In addition, the stock market in general, and the Nasdaq National Market and the market for biotechnology stocks in particular, have experienced significant price and volume fluctuations. Over the 52-week period ending October 31, 2002, the intra-day sales prices of our common stock as reported on the Nasdaq National Market have ranged from a high of \$25.40 to a low of \$7.71. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. Further, there has been particular volatility in the market prices of securities of biotechnology and pharmaceutical companies. These broad market and industry factors may 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 and our amended and restated bylaws could make it more difficult for a third-party to acquire us, even if doing so would be beneficial to our stockholders. These provisions include:

establishing a classified board of directors of which approximately one-third of the members of the board will be elected each year, lengthening the time needed to elect a new majority of the board;

authorizing the issuance of "blank check" preferred stock that could be issued by our board of directors to increase the number of outstanding shares or change the balance of voting control and thwart a takeover attempt;

prohibiting stockholder action by written consent and requiring all stockholder actions to be taken at a meeting of our stockholders; and

requiring the affirmative vote of 75% of our capital stock to approve amendments to our bylaws and certain provisions of our restated certificate of incorporation.

In addition, in June 2001, our board of directors adopted a shareholder rights plan in which preferred stock purchase rights were distributed to our common stockholders as a dividend. These provisions may make it more difficult for stockholders to take corporate actions and may have the effect of delaying or preventing a change in control. We are also subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. Subject to specified exceptions, this section provides that a corporation may not engage in any business combination with any interested stockholder during the three-year period following the time that such stockholder becomes an interested stockholder. This provision could have the effect of delaying or preventing a change in our control. The foregoing factors could also limit the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

**We may need additional capital in the future, which could dilute our shareholders or impose burdensome financial restrictions on our business, and we may not be able to obtain any funds we need.**

We anticipate that our available cash resources will be sufficient to fund our operating losses for at least the next two years. In the future, we may not have any bank credit facility or other working capital credit line under which we may borrow funds for working capital or other general corporate purposes. If our plans or assumptions change or are inaccurate, we may need to seek capital sooner than anticipated. We may seek to raise any funds we need through public or private debt or equity offerings. Additional equity financing may be dilutive to the holders of our common stock. If we obtain funds through a bank credit facility or through issuance of debt securities or preferred shares, this indebtedness or preferred shares would have rights senior to the rights of holders of our common stock, and their terms could impose significant restrictions on our operations. If we need to raise additional funds, we may not be able to do so on favorable terms, or at all. If we cannot obtain adequate funds on acceptable terms, we may not be able to carry out our business strategy.

**Future sales of shares of our common stock may cause our stock price to decline.**

Our stockholders hold a substantial number of shares of our common stock which they are able to sell in the public market today. Sales of shares of our common stock, or the perception that these sales could

occur, could materially and adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.



**ITEM 3. 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 note 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 note are also exposed to interest rate risk as they are subject to interest rates based on the bank's base rate or LIBOR.

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

	2002	2003
Cash and cash equivalents	\$ 35,914	\$
Average interest rate	1.78%	
Marketable securities	\$ 11,668	\$ 25,141
Average interest rate	2.20%	2.07%

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

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

**Inflation**

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

**ITEM 4. 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 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.

Within 90 days prior to the date of this report, 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 the date we carried out our evaluation.

## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

We are not a party to any significant legal proceedings.

### **ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS**

On August 8, 2000 we sold 4,600,000 shares of common stock at \$11 per share in an initial public offering and on September 7, 2000, the underwriters executed an over-allotment option and purchased an additional 690,000 shares of common stock at \$11. We received net proceeds from the initial public offering and the over-allotment of approximately \$52.7 million. The net proceeds are being used for the clinical development of our two product candidates, anidulafungin and dalbavancin, as well as for general corporate and working capital purposes.

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 an exception under Rule 506 of Regulation D of the Securities Act. These shares were subsequently registered with the SEC.

### **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

### **ITEM 5. OTHER INFORMATION**

None.

### **ITEM 5. OTHER INFORMATION**

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

*Exhibits*

The exhibits listed on the Exhibit List, which appears below following the signature page, are included or incorporated by reference in this Quarterly Report.

*Reports on Form 8-K*

Form 8-K dated July 30, 2002 reported under Item 5, Other Events for the following:

First Amendment to Shareholder Rights Agreement.

Merger Agreement with Biosearch Italia S.p.A.

Financial results for the second quarter of 2002.

**SIGNATURES**

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

**VERVICOR INC.**

Date: November 13, 2002

/s/ GEORGE F. HORNER III  
George F. Horner III  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2002

/s/ DOV A. GOLDSTEIN, M.D.  
Dov A. Goldstein, M.D.  
Vice President, Finance and Chief Financial Officer  
(Principal Financial and Accounting Officer)

**CERTIFICATIONS**

I, George F. Horner III, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versicor Inc.;
  
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
  
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
  
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
  
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: VERSICOR INC /CA - Form 10-Q

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ GEORGE F. HORNER III

**George F. Horner III**

*President and Chief Executive Officer*

I, Dov A. Goldstein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Versicor Inc.;
  
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
  
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
  
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
  
  - c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
  
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and



6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ DOV A. GOLDSTEIN, M.D.

**Dov A. Goldstein, M.D.**

*Vice President, Finance and Chief Financial  
Officer*

**EXHIBIT INDEX**

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

The following exhibits are part of this Quarterly Report on Form 10-Q (and are numbered in accordance with Item 601 of Regulation S-K).

<b>No.</b>	<b>Description</b>
2.1	Agreement and Plan of Merger, dated as of July 30, 2002 by and between Versicor Inc. and Biosearch Italia, S.p.A.(1)
2.2	First Amendment to Agreement and Plan of Merger dated as of August 14, 2002 by and between Versicor Inc. and Biosearch Italia S.p.A.(2)
2.3	Second Amendment to Agreement and Plan of Merger dated as of October 29, 2002 by and between Versicor Inc. and Biosearch Italia S.p.A.(3)
3.1	Restated Certificate of Incorporation of Versicor Inc.(4)
3.2	Amended and Restated Bylaws of Versicor Inc.(5)
4.1	Form of Common Stock Certificate (4)
4.2	Form of Warrant for the Purchase of Shares of Series C Preferred Stock dated as of December 9, 1997(4)
4.3	Form of Warrant for the Purchase of Shares of Series F Preferred Stock dated as of June 25, 1999(4)
4.5	Second Amended and Restated Investor Rights Agreement (4)
4.6	Registration Rights Agreement dated as of April 8, 2002(6)
99.1	Certification under Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith)

---

(1) The Agreement and Plan of Merger was previously filed as an exhibit to the Company's Form 8-K filed with the SEC on July 31, 2002 and is incorporated by reference herein.

(2) Previously filed as an exhibit to the Company's registration statement on Form S-4 (file no. 333-98935) filed with the SEC on August 29, 2002 and is incorporated by reference herein.

(3) Previously filed as an exhibit to the Company's registration statement on Form S-4/A (file no. 333-98935) filed with the SEC on November 5, 2002 and is incorporated by reference herein.

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

(5) Previously filed as an exhibit to the Company's current report on Form 8-K filed with the SEC on March 22, 2002, and incorporated herein by reference.

(6) Previously filed as an exhibit to the Company's current report on Form 8-K filed with the SEC on April 10, 2002, and incorporated herein by reference.