

VERSICOR INC /CA
Form 10-Q
May 11, 2001

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(MARK ONE)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 OF THE SECURITIES
EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED: MARCH 31, 2001
OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 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 Organization or Incorporation)

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)

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

COMMON STOCK, PAR VALUE \$.001 PER SHARE, 23,069,574 SHARES OUTSTANDING AT APRIL 24, 2001.

VERSICOR INC.
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ITEM 1. CONDENSED FINANCIAL STATEMENTS

VERSICOR INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	MARCH 31, 2001	DECEMBER 31, 2000
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$74,276	\$67,989
Marketable securities	6,820	17,945
Employee notes receivable	360	357
Prepaid expenses and other current assets	732	591
	<hr/>	<hr/>
Total current assets	82,188	86,882
Property and equipment, net	4,675	4,384
Employee notes receivable	160	188
Other assets	141	142
	<hr/>	<hr/>
Total assets	\$87,164	\$91,596
<hr/>		
LIABILITIES AND STOCKHOLDERS' EQUITY		

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Current liabilities:		
Accounts payable	\$564	\$1,421
Accrued liabilities	3,373	3,225
Related party payable	-	12
Current portion of term loan payable	862	862
Deferred revenue	1,275	1,233
	<hr/>	<hr/>
Total current liabilities	6,074	6,753
Deferred revenue	-	108
Term loan payable	3,232	3,448
Other long-term liabilities	1,000	1,000
	<hr/>	<hr/>
Total liabilities	10,306	11,309
Stockholders' equity:		
Common stock	23	23
Additional paid-in capital	161,216	160,059
Deferred stock compensation	(8,239)	(8,819)
Accumulated deficit	(76,142)	(70,976)
	<hr/>	<hr/>
Total stockholders' equity	76,858	80,287
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$87,164	\$91,596
	<hr/>	<hr/>

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	
	MARCH 31, 2001	MARCH 31, 2000
Revenues:		
Collaborative research and development and contract services	\$1,486	\$1,250
License fees and milestones	8	8
	<hr/>	<hr/>
Total revenues	1,494	1,258
	<hr/>	<hr/>
Operating expenses:		
Research and development - non-cash compensation expense	513	1,231
Research and development - other	4,813	2,406
	<hr/>	<hr/>
Total research and development	5,326	3,637
	<hr/>	<hr/>
General and administrative - non-cash compensation expense.	1,216	1,079
General and administrative - other	1,239	569
	<hr/>	<hr/>
Total general and administrative	2,455	1,648
	<hr/>	<hr/>

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Total operating expenses	7,781	5,285
Loss from operations	(6,287)	(4,027)
Other income (expense):		
Interest income	1,219	589
Interest expense	(98)	(120)
Net loss	(5,166)	(3,558)
Accretion of dividends on preferred stock.	--	(1,435)
Net loss available to common stockholders	\$(5,166)	\$(4,993)
Net loss per share:		
Basic and diluted	\$(0.22)	\$(7.09)
Weighted average shares	23,041	705

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

VERSICOR INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)
(IN THOUSANDS)

THREE MONTHS ENDED

	MARCH 31, 2001	MARCH 31, 2000
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$(5,166)	\$(3,558)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	220	225
Non-cash stock compensation expense	1,729	2,310
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(141)	(132)
Employee notes receivable	25	(7)
Other assets	1	2
Accounts payable	(857)	67
Accrued liabilities	148	174
Related party payable	(12)	25
Deferred revenue	(66)	507
Net cash used in operating activities	(4,119)	(387)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(4,847)	--
Sales and maturities of marketable securities	15,972	--
Additions to property and equipment	(511)	(45)
Net cash provided by (used in) investing activities	10,614	(45)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	8	32
Repayments of long-term debt	(216)	(216)

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Net cash used in financing activities	(208)	(184)
Net change in cash and cash equivalents	6,287	(616)
Cash and cash equivalents at beginning of period	67,989	34,619
Cash and cash equivalents at end of period	\$74,276	\$34,003

NON CASH TRANSACTIONS:

Cash paid during the period for interest	\$98	\$120
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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 generally accepted accounting principles. 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 March 31, 2001 and 2000.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the fiscal year. These condensed interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2000, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2000.

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 weighted average potentially dilutive common shares were excluded from the computation of net loss per share because their effect was anti-dilutive (in thousands):

	THREE MONTHS ENDED	
	MARCH 31, 2001	MARCH 31, 2000
Convertible and redeemable convertible preferred stock	-	16,677
Stock options	2,496	2,013
Warrants	421	439
Common stock subject to repurchase	15	24
	2,932	19,153

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 included elsewhere in this Quarterly Report on Form 10-Q and Versicor's audited financial statements for the year ended December 31, 2000 included in our Form 10-K previously filed with the SEC. This Quarterly Report on Form 10-Q contains, in addition to historical information,

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forward-looking statements, which involve risk and uncertainties. The words "believe," "expect," "estimate," "may," "will," "could," "plan," or "continue," and similar expressions are intended to identify forward-looking statements. Versicor's actual results could differ significantly from the results discussed in such forward-looking statements. See "Factors Affecting Future Operating Results" below.

OVERVIEW

Versicor is a biopharmaceutical company focused on the discovery, development and marketing of drugs for the treatment of serious bacterial and fungal infections, primarily in the hospital setting. Since our inception on May 2, 1995 as a wholly-owned subsidiary of Sepracor Inc., we have devoted substantially all of our efforts to establishing our business and carrying on research and development activities related to proprietary product candidates, including V-Echinocandin and V-Glycopeptide, as well as collaborative product candidates. Since 1996, we have been operating as an independent company located in California.

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

Since we began our operations in May 1995, we have not generated any revenues from product sales. We have one product candidate in Phase III clinical trials, one product candidate that is expected to begin Phase II clinical trials in the second quarter of 2001 and several lead compounds in pre-clinical studies.

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

Our expenses have consisted primarily of costs incurred in licensing existing product candidates, research and development of new product candidates and in connection with our collaboration agreements, and from general and administrative costs associated with our operations. We expect our licensing costs to increase as certain milestones are achieved, and our research and development expenses to increase as we continue to develop our product candidates. We also expect that our general and administrative expenses will increase as we add personnel and continue to directly assume all of the obligations of a public reporting company. In addition, we expect to incur sales and marketing expenses in the future when we establish our sales and marketing organization.

We have recorded deferred stock compensation expense in connection with the grant of stock options to employees and consultants. Deferred stock compensation for options granted to employees is the difference between the fair value for financial reporting purposes of our common stock on the date such options were granted and their exercise price. Deferred stock compensation for options granted to consultants has been determined in accordance with Statement of Financial Accounting Standards No. 123 as the fair value of the equity instruments issued. Deferred stock compensation for options granted to consultants is periodically remeasured as the underlying options vest in accordance with Emerging Issues Task Force No. 96-18.

We recorded deferred stock compensation of \$1.1 million and \$904,000 for the three months ended March 31, 2001 and 2000, respectively. These amounts were recorded as a component of stockholders' equity and are being amortized as charges to operations over the vesting periods of the options. We recorded amortization of deferred stock compensation of \$1.7 million and \$2.3 million for the three months ended March 31, 2001 and 2000, respectively.

Since our inception, we have incurred significant losses. As of March 31, 2001, we had an accumulated deficit of \$76.1 million. We anticipate incurring additional losses, which may increase, for the foreseeable future, including at least through December 31, 2001.

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.

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of V-Echinocandin, which was then known as LY303366. We began a Phase III clinical trial for V-Echinocandin in the first quarter of 2001. We paid \$11.0 million for the license and have agreed to pay an additional \$3 million for product inventory of which we have paid \$1 million. We are also obligated to make \$51.0 million in additional payments to Eli Lilly if specified milestones are achieved on the intravenous formulations of V-Echinocandin. Of the \$51.0 million payment obligation for the intravenous formulation, \$14.0 million is contingent on developments in the United States and Canada, \$16.0 million is contingent on developments in Japan and Europe and \$21.0 million is contingent on cumulative sales of the intravenous formulation. We are obligated to make \$79 million in additional payments to Eli Lilly if specified milestones are achieved on

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the oral formulations of V-Echinocandin. We are also required to pay to Eli Lilly royalties in respect of sales of any product resulting from the compound. We may terminate this agreement at any time by giving ninety days' written notice. Otherwise, the license terminates on a country-by-country basis as all of our royalty obligations are satisfied in each country.

In March 1999, we entered into a collaboration agreement with Pharmacia Corporation pursuant to which we are collaborating to discover second and third generation oxazolidinone product candidates. In connection with the collaboration, Pharmacia Corporation made an equity investment in us of \$3.8 million and paid research support and license fee payments of \$1.2 million to us. Under the terms of the agreement, we are entitled to receive additional research support payments, and if specified milestones are achieved, up to \$14.0 million in additional milestone payments per compound. We are also entitled to receive royalties on the worldwide sales of any drug developed and commercialized as a result of the collaboration. In October 2000, Pharmacia increased its research support payments by 30%.

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 has made a \$3.0 million equity investment in us and paid \$1.0 million in milestone payments to us. Under the terms of this agreement, we are entitled to receive up to \$21.3 million in additional payments from Novartis upon the achievement of specified milestones, a portion of which may be credited against future royalty payments that we are entitled to on the worldwide sales of any drug developed and commercialized from this collaboration.

In February 1998, we entered into two agreements with Biosearch Italia: a license agreement and a collaborative agreement. Under the license agreement, Biosearch Italia granted us an exclusive license to develop and commercialize V-Glycopeptide, then called BI-397, in the United States and Canada. We expect to begin a Phase II clinical trial for V-Glycopeptide in the second quarter of 2001. In exchange for the license and upon the receipt of favorable results in pre-clinical studies, we paid \$3.0 million and issued 250,000 shares of our common stock to Biosearch Italia. We are obligated to make up to \$9.5 million in additional payments to Biosearch Italia upon the achievement of specified milestones. We are also required to pay Biosearch Italia royalties in respect of sales of any product that results from the compound. Under the collaborative agreement with Biosearch Italia, we established a lead optimization partnership called BIOCOR. Biosearch contributes leads and we contribute our combinatorial and medicinal chemistry expertise to optimize the leads.

RESULTS OF OPERATIONS

THREE MONTHS ENDED MARCH 31, 2001 COMPARED TO THREE MONTHS ENDED MARCH 31, 2000

REVENUES

Revenues were \$1.5 million and \$1.3 million in the three months ended March 31, 2001 and 2000, respectively. Revenues consisted of \$908,000 and \$696,000 of collaborative research and development, contract service and license fees from Pharmacia Corporation and \$586,000 and \$562,000 of collaborative research and development fees from Novartis in the three months ended March 31, 2001 and 2000, respectively. The increase in revenues in the first quarter of 2001 is due to the increase in collaborative research and development funding from both Pharmacia Corporation and Novartis.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses were \$5.3 million and \$3.6 million in the three months ended March 31, 2001 and 2000, respectively. Research and development expenses include amortization of non-cash stock compensation expense of \$513,000 and \$1.2 million in the three months ended March 31, 2001 and 2000, respectively. Excluding these charges, research and development expenses increased by \$2.4 million primarily due to the increase in clinical expenses for the development of V-Echinocandin and V-Glycopeptide as well as the expansion of our collaborative and internal research projects.

GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses were \$2.5 million and \$1.6 million in the three months ended March 31, 2001 and 2000, respectively. General and administrative expenses include amortization of non-cash stock compensation expense of \$1.2 million and \$1.1 million in the three months ended March 31, 2001 and 2000, respectively. Excluding these charges, general and administrative expenses increased by \$670,000 primarily due to the increase in legal, audit, insurance, personnel, and consultant expenses associated with being a public company.

OTHER INCOME (EXPENSE)

Net interest income was \$1.1 million and \$469,000 in the three months ended March 31, 2001 and 2000, respectively. The 2001 period reflects greater interest income as a result of higher cash and investment balances resulting from our initial public offering in August 2000.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations principally with the proceeds of approximately \$78.5 million from a series of six preferred stock offerings over the period 1995 through 1999 and net proceeds of approximately \$52.7 million from the Company's initial public offering received in August and September 2000.

As of March 31, 2001 the Company had received approximately \$15.9 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, \$1.3 million constitutes deferred revenue as of March 31, 2001 that will be recognized through the first quarter of 2002.

In addition, we have a \$6 million term loan agreement with Fleet National Bank. This loan bears interest at the prime rate plus 0.50% and is payable in 15 equal quarterly installments of \$216,000, with the balance due on December 31, 2002. The net proceeds of this loan were used to repay Sepracor for leasehold improvements to our facilities and for general corporate purposes. As of March 31, 2001, there was an outstanding loan balance of \$4.1 million.

Cash used in operations was \$4.1 million and \$387,000 in the three months ended March 31, 2001 and 2000, respectively. The net loss of \$5.2 million in the first quarter of 2001 was partially offset by non-cash charges for depreciation and non-cash stock compensation of \$1.9 million. In the first quarter of 2000, the net loss of \$3.6 million was substantially offset by non-cash charges for depreciation and non-cash stock compensation of \$2.5 million.

Cash provided by (used in) investing activities was \$10.6 million and (\$45,000) in the three months ended March 31, 2001 and 2000, respectively. The principal source of cash in the first quarter of 2001 resulted from the sale and maturity of marketable securities.

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 additions to personnel and production and commercialization efforts. Our future capital requirements will depend on a number of factors, including our success in developing markets for our products, payments received or made under 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.

FACTORS AFFECTING FUTURE OPERATING RESULTS

Certain of the information contained in the Quarterly Report on Form 10-Q consist of forward-looking statements. Important factors that could cause actual results to differ materially from the forward-looking statements include the following:

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 an early stage biopharmaceutical company. All of our product candidates are in early stages of development, and only two are in clinical trials. To date we have not commercialized any products or recognized any revenue from product sales. We will require significant additional investment in research and development, pre-clinical testing and clinical trials, regulatory approval, and sales and marketing activities. Our product candidates, if successfully developed, may not generate sufficient or sustainable revenues to enable us to be 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 preferred stock, our net losses were approximately \$1.1 million in 1995, \$4.8 million in 1996, \$6.3 million in 1997, \$12.6 million in 1998, \$29.2 million in 1999, \$15.3 million in 2000 and \$5.2 million in the first quarter of 2001. As of March 31, 2001, our accumulated deficit was approximately \$76.1 million. Our losses to date have resulted principally from:

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

costs of acquiring product candidates; and

general and administrative costs relating to our operations.

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

developing and testing new product candidates;

receiving regulatory approvals;

manufacturing products;

marketing products; and

competing with products from other companies.

Many of these factors will depend on circumstances beyond our control. We expect to rely heavily on third parties with respect to many aspects of our business, including research and development, clinical testing, manufacturing and marketing. 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 collaboration agreements. To date, these payments have been in the form of upfront payments, reimbursement for research and development expenses and milestone payments. We may not be able to generate additional revenues. Furthermore, payments under our existing and any future collaboration agreements will be subject to significant fluctuation in both timing and amount. 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 COULD BE ADVERSELY AFFECTED.

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 or enter into future licensing arrangements on acceptable terms, our future product portfolio could be adversely affected.

IF OUR COLLABORATORS DO NOT PERFORM, WE WILL BE UNABLE TO DEVELOP OUR JOINT PRODUCT CANDIDATES.

We have entered into collaboration agreements with third parties to develop certain product candidates. These collaborations are necessary in order for us to:

fund our research and development activities;

fund manufacturing by third parties;

seek and obtain regulatory approvals; and

successfully commercialize 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 them will result in commercially successful products. Current or future collaboration agreements may not be successful. If we fail to maintain our existing collaboration agreements or fail to enter into additional collaboration agreements, the number of product candidates from which we could receive future revenues would decline.

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Our dependence on collaboration agreements with third parties subjects us to a number of risks. These collaboration agreements 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, and our collaborators may choose to pursue alternative products. Our collaborators may 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 under the arrangement. Moreover, we could become involved in disputes with our collaborators, which could lead to delays or termination of our development programs with them and time-consuming and expensive litigation or arbitration. Even if we fulfill our obligations under a collaborative agreement, our collaborator can terminate the agreement under certain circumstances. If any collaborator were 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 would be materially and adversely affected.

IF CLINICAL TRIALS FOR OUR PRODUCTS ARE UNSUCCESSFUL OR DELAYED, WE WILL BE UNABLE TO MEET OUR ANTICIPATED DEVELOPMENT AND COMMERCIALIZATION TIMELINES, WHICH COULD CAUSE OUR STOCK PRICE TO DECLINE.

Before obtaining regulatory approvals for the commercial sale of any products, we must demonstrate through pre-clinical testing and clinical trials that our product candidates are safe and effective for use in humans. Conducting 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:

- lack of efficacy during the clinical trials;
- unforeseen safety issues;
- slower than expected rate of patient recruitment;
- government or regulatory delays;
- inability to adequately follow patients after treatment; and
- inability to manufacture sufficient quantities of materials for use in clinical trials.

The results from pre-clinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. 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 pre-clinical 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 March 31, 2001, two of our product candidates, V-Echinocandin and V-Glycopeptide, were in clinical trials. Patient follow-up for these clinical trials has been limited and more trials will be required before we will be able to apply for regulatory approvals. Clinical trials conducted by us or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for V-Echinocandin and V-Glycopeptide or any other potential product candidates. This failure may delay development of other product candidates and hinder our ability to conduct related pre-clinical 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 pre-clinical development, and we have not submitted investigational new drug applications to commence clinical trials involving these compounds. Our pre-clinical development efforts may not be successfully completed and we may not file further investigational new drug applications. Any delays in, or termination of, our clinical trials will materially and adversely affect 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 only have three 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. Our reliance on these third parties may result in delays in completing, or failing to complete, these trials if they fail to perform under the terms of our agreements with them.

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

IF WE ARE UNABLE TO ATTRACT AND RETAIN KEY EMPLOYEES AND CONSULTANTS, WE WILL BE UNABLE TO DEVELOP AND COMMERCIALIZE OUR PRODUCTS.

We are highly dependent on the principal members of our scientific, clinical 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 will need to hire personnel with experience in clinical testing, government regulation, manufacturing and marketing. We may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among high technology enterprises, including biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions. Most of our scientific and management employees do not have employment agreements. 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 materially and adversely affected.

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 strategies. All of our consultants and the members of our scientific and clinical advisory boards are employed by other entities. 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. Such impediments may materially and adversely affect our business, financial condition and results of operations. 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.

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 V-Echinocandin and V-Glycopeptide in quantities sufficient for conducting clinical trials or for commercialization.

Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA 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 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 products, 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 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.

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 collaboration agreements;
- continued progress of our 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.

We have no committed sources of additional capital. 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. We cannot assure you that funds will be available on favorable terms, if at all. To the extent that additional capital is raised through the sale of equity or convertible debt securities, 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. 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 curtail operations significantly or to obtain funds through entering into collaboration agreements on unattractive terms. Our inability to raise capital would have a material adverse effect on our business, financial condition and results of operations.

IF WE FAIL TO MANAGE OUR GROWTH, OUR BUSINESS COULD BE HARMED.

Our business plan contemplates a period of rapid and substantial growth that will place a strain on our administrative and operational infrastructure. To date, our management infrastructure has been very limited and dependent on third parties, including our former parent company, to provide significant administrative and operational assistance. Our ability to manage effectively our operations and growth requires us to expand and improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may not successfully implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

IF WE MAKE ANY ACQUISITIONS, WE WILL INCUR A VARIETY OF COSTS AND MAY NEVER REALIZE THE ANTICIPATED BENEFITS.

If appropriate opportunities become available, we may attempt to acquire products, product candidates or businesses that we believe are a strategic fit with our business. We currently have no commitments or agreements with respect to any material acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired product, product candidate or business may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which

could adversely affect our business, financial condition and results of operations.

IF OUR USE OF HAZARDOUS MATERIALS RESULTS IN CONTAMINATION OR INJURY, WE COULD SUFFER SIGNIFICANT FINANCIAL LOSS.

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

RISKS RELATED TO OPERATING IN OUR INDUSTRY

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

Many of these companies and institutions, either alone or together with their collaborators, have substantially greater financial resources and larger research and development staffs than we do. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than we do in:

- developing products;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of products; and
- manufacturing and marketing products.

Developments by others may render our product candidates or technologies obsolete or non-competitive. We face and will continue to face intense competition from other companies for collaboration agreements 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 than ours.

IF OUR INTELLECTUAL PROPERTY DOES NOT ADEQUATELY PROTECT OUR PRODUCT CANDIDATES, OTHERS COULD COMPETE AGAINST US MORE DIRECTLY, WHICH WOULD HURT OUR PROFITABILITY.

Our success depends in part on our ability to:

- obtain patents or rights to patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The patent position of biopharmaceutical companies involves complex legal and factual questions and, therefore, enforceability cannot be predicted with certainty. 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.

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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.

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 issue. 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 of such infringement or violation, we and our collaborators may be prevented from pursuing product development or commercialization.

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, U.S. Patent and Trademark Office interference proceedings and related legal and administrative proceedings in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time-consuming to pursue and their outcome is uncertain. Litigation 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 WE EXPERIENCE DELAYS IN OBTAINING REGULATORY APPROVALS, OR ARE UNABLE TO OBTAIN THEM AT ALL, WE COULD BE DELAYED 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. None of our product candidates has been approved for sale in the United States or any foreign market. The regulatory review and approval process takes many years, 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 obtained, may be withdrawn. Further, if we fail to comply with applicable FDA and other regulatory requirements at any stage during the regulatory process, we may be subject to sanctions, including:

- delays in clinical trials or commercialization;
- refusal of the FDA to review pending market approval applications or supplements to approval applications;

product recalls or seizures;

suspension of production;

withdrawals of previously approved marketing applications; and

fines, civil penalties and criminal prosecutions.

We expect to rely on our collaborators to file investigational new drug applications and generally direct the regulatory approval process for many of our 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. 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.

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.

IF THE GOVERNMENT AND THIRD-PARTY PAYORS FAIL TO PROVIDE ADEQUATE COVERAGE AND REIMBURSEMENT RATES FOR OUR PRODUCT CANDIDATES, THE MARKET ACCEPTANCE OF OUR PRODUCTS MAY BE ADVERSELY AFFECTED.

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 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. 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 liability claims and financial losses resulting from the use or sale of our products. We have obtained limited product liability insurance coverage for our clinical trials. Our insurance coverage limits are \$4 million per occurrence and \$4 million in the aggregate. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for product candidates in development. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses.

RISKS RELATED TO OWNERSHIP OF OUR STOCK

OUR STOCK PRICE COULD BE VOLATILE, AND YOUR INVESTMENTS 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:

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

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

announcements of technological innovations by us or our competitors;

actual or anticipated variations in quarterly operating results;

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conditions or trends in the biotechnology and pharmaceutical industries;

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

additions or departures of key personnel; and

sales of our common stock.

In addition, the stock market in general, and the Nasdaq National Market in particular, has experienced significant price and volume fluctuations. 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.

OUR PRINCIPAL STOCKHOLDERS, DIRECTORS AND EXECUTIVE OFFICERS OWN A SIGNIFICANT PORTION OF OUR COMMON STOCK, WHICH MAY PREVENT NEW INVESTORS FROM INFLUENCING CORPORATE DECISIONS.

Our principal stockholders, directors and executive officers currently own a significant portion of our common stock. These stockholders will be able to exercise significant influence over all matters requiring stockholder approval, including the election of directors and the approval of significant corporate transactions. This concentration of ownership may also delay or prevent a change in control of Versicor even if beneficial to our stockholders and deprive the stockholders of a control premium for their shares.

FUTURE SALES OF OUR COMMON STOCK MAY DEPRESS OUR STOCK PRICE.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or the perception that these sales could occur. In addition, these factors could make it more difficult for us to raise funds through future offerings of common stock. There were 23,069,574 shares of common stock outstanding as of April 24, 2001. The 5,290,000 shares sold in our public offering are freely transferable without restriction or further registration under the Securities Act, except for any shares purchased by our "affiliates," as defined in Rule 144 of the Securities Act. The remaining 17,779,574 shares of common stock outstanding are "restricted securities" as defined in Rule 144. These shares may be sold in the future without registration under the Securities Act to the extent permitted by Rule 144 or other exemption under the Securities Act.

We have registered, 1,100,000 shares for offering in our 2000 Employee Stock Purchase Plan. We also intend to register approximately 3,789,848 shares of common stock which are reserved for issuance upon exercise of options granted under our stock option plans. Once we register these shares, they can be sold in the public market upon issuance, subject to restrictions under the securities laws applicable to resales by affiliates.

ITEM 3.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk relates to our cash and cash equivalents and our available-for-sale securities. Our available-for-sale investments are sensitive to changes in interest rates; however such exposure is limited due to the short-term nature of our investments.

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None.

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 6. EXHIBITS AND REPORTS ON FORM 8-K

- | | |
|------|---------------------|
| a) | Exhibits |
| None | |
| b) | Reports on Form 8-K |
| None | |

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.

VERSICOR INC.

Date: May 11, 2001

/s/ GEORGE F. HORNER III

George F. Horner III
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 11, 2001

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

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