

VERSICOR INC /CA
Form 10-Q
August 10, 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: JUNE 30, 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

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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, 23,082,087 SHARES OUTSTANDING AT AUGUST 1, 2001.

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ITEM 1. CONDENSED FINANCIAL STATEMENTS

VERSICOR INC.
CONDENSED BALANCE SHEETS
(IN THOUSANDS)

	June 30, 2001	December 31, 2000
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 51,153	\$ 67,989
Marketable securities	23,152	17,945
Employee notes receivable	356	357
Prepaid expenses and other current assets	801	591
	<hr/>	<hr/>
Total current assets	75,462	86,882
Property and equipment, net	5,132	4,384
Employee notes receivable	138	188
Other assets	158	142
	<hr/>	<hr/>
Total assets	\$ 80,890	\$ 91,596
	<hr/>	<hr/>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,060	\$ 1,421
Accrued liabilities	3,815	3,225
Related party payable	-	12
Current portion of term loan payable	862	862
Deferred revenue	1,778	1,233
	<hr/>	<hr/>
Total current liabilities	7,515	6,753
Deferred revenue	500	108
Term loan payable	3,017	3,448
Other long-term liabilities	43	1,000
	<hr/>	<hr/>
Total liabilities	11,075	11,309
Stockholders' equity:		
Common stock	23	23
Additional paid-in capital	161,492	160,059
Deferred stock compensation	(6,933)	(8,819)
Accumulated other comprehensive income	17	-
Accumulated deficit	(84,784)	(70,976)
	<hr/>	<hr/>
Total stockholders' equity	69,815	80,287
	<hr/>	<hr/>
Total liabilities and stockholders' equity	\$ 80,890	\$ 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		Six Months Ended	
	June 30, 2001	June 30, 2000	June 30, 2001	June 30, 2000
Revenues:				
Collaborative research and development and contract services	\$ 1,554	\$ 1,301	\$ 3,040	\$ 2,551
License fees and milestones	259	259	267	267
Total revenues	1,813	1,560	3,307	2,818
Operating expenses:				
Research and development - non-cash compensation expense	682	(19)	1,195	1,212
Research and development - other	8,146	2,556	12,959	4,962
Total research and development	8,828	2,537	14,154	6,174
General and administrative - non-cash compensation expense	893	1,731	2,109	2,810
General and administrative - other	1,565	515	2,804	1,084
Total general and administrative	2,458	2,246	4,913	3,894
Total operating expenses	11,286	4,783	19,067	10,068
Loss from operations	(9,473)	(3,223)	(15,760)	(7,250)
Other income (expense):				

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Interest income	913	593	2,132	1,182
Interest expense	(82)	(122)	(180)	(242)
Other income	-	18	-	18
Net loss	(8,642)	(2,734)	(13,808)	(6,292)
Accretion of dividends on preferred stock	-	(1,436)	-	(2,871)
Net loss available to common stockholders	\$ (8,642)	\$ (4,170)	\$ (13,808)	\$ (9,163)
Net loss per share:				
Basic and diluted	\$ (0.37)	\$ (4.57)	\$ (0.60)	\$ (11.30)
Weighted average shares	23,054	913	23,048	811

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

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

	Six Months Ended	
	June 30, 2001	June 30, 2001
Cash flows from operating activities:		
Net loss	\$ (13,808)	\$ (6,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	497	444
Non-cash compensation expense	3,304	4,022
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(210)	(308)
Employee notes receivable	51	(14)
Other assets	(16)	(270)
Accounts payable	(361)	129
Accrued liabilities	590	107
Related party payable	(12)	24

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Deferred revenue	937	398
Other long-term liabilities	(957)	(1,000)
	<hr/>	<hr/>
Net cash used in operating activities	(9,985)	(2,760)
	<hr/>	<hr/>
Cash flows from investing activities:		
Purchases of marketable securities	(24,904)	-
Sales/maturities of marketable securities	19,714	-
Additions to property and equipment	(1,245)	(63)
	<hr/>	<hr/>
Net cash used in investing activities	(6,435)	(63)
	<hr/>	<hr/>
Cash flows from financing activities:		
Proceeds from issuance of common stock	15	103
Repayments of long-term debt	(431)	(431)
	<hr/>	<hr/>
Net cash used in financing activities	(416)	(328)
	<hr/>	<hr/>
Net change in cash and cash equivalents	(16,836)	(3,151)
Cash and cash equivalents at beginning of period	67,989	34,619
	<hr/>	<hr/>
Cash and cash equivalents at end of period	\$ 51,153	\$ 31,468
	<hr/>	<hr/>
Supplemental cash flow information:		
Cash paid during the period for interest	\$ 180	\$ 242
	<hr/>	<hr/>

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

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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 June 30, 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		Six Months Ended	
	June 30, 2001	June 30, 2000	June 30, 2001	June 30, 2000
Convertible and redeemable convertible preferred stock	-	16,677	-	16,677
Stock options	2,663	1,712	2,580	1,644
Common stock warrants	421	213	421	213
Common stock subject to repurchase	13	17	14	18
	3,097	18,619	3,015	18,552

3. RECENT ACCOUNTING PRONOUNCEMENTS

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

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, forward-looking statements, which involve risk and uncertainties. The words "believe," "expect," "estimate," "may," "will," "could," "plan," or

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"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 our proprietary product candidates, including anidulafungin and dalbavancin, 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. Our lead product candidate, anidulafungin, is in Phase III clinical trials. Our second product candidate, dalbavancin, is in Phase II clinical trials and we also have several lead compounds in pre-clinical studies. Pharmacia Corporation recently started clinical development of one of our compounds in our oxazolidinone program for which we have received a milestone payment.

Our revenues in the near term are expected to consist primarily of 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 \$1.4 million and \$4.7 million for the six months ended June 30, 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 \$3.3 million and \$4.0 million for the six months ended June 30, 2001 and 2000, respectively.

Since our inception, we have incurred significant losses. As of June 30, 2001, we had an accumulated deficit of \$84.8 million. We anticipate incurring additional losses, which may increase, for the foreseeable future, including at least through December 31, 2002.

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 anidulafungin (formerly known as V-Echinocandin). We began a Phase III clinical trial for anidulafungin 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 \$2.0 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 anidulafungin. 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 the oral formulations of anidulafungin. We are also required to pay to Eli Lilly royalties in respect of sales of any product resulting from the compound.

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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 approximately 30% and in June 2001 we received a milestone payment for the initiation of clinical development of one of the oxazolidinone compounds.

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 \$1.3 million in milestone payments to us. Under the terms of this agreement, we are entitled to receive up to \$21.0 million in additional payments from Novartis upon the achievement of specified milestones, a portion of which may be credited against future royalty payments to which we are entitled on the worldwide sales of any drug developed and 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 dalbavancin (formerly known as V-Glycopeptide) in the United States and Canada. 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. In May 2001, we began a Phase II clinical trial for dalbavancin and paid Biosearch Italia an additional milestone payment. We are obligated to make up to \$8.0 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.

In June 2001, we entered into an agreement with Abbott Laboratories. Pursuant to this agreement, Abbott has agreed to manufacture, develop and supply commercial quantities of both API (the bulk form of the final active pharmaceutical ingredient for anidulafungin) and ECBN-HC1 (the bulk form of intermediate anidulafungin B nucleus hydrochloride used in the production of API).

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2001 COMPARED TO THREE MONTHS ENDED JUNE 30, 2000

REVENUES

Revenues were \$1.8 million and \$1.6 million in the three months ended June 30, 2001 and 2000, respectively. Revenues consisted of \$952,000 and \$723,000 of collaborative research and development, contract service and license fees from Pharmacia Corporation and \$861,000 and \$837,000 of collaborative research and development fees and milestone payments from Novartis in the three months ended June 30, 2001 and 2000, respectively. The increase in revenues in the second 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 \$8.8 million and \$2.5 million in the three months ended June 30, 2001 and 2000, respectively. Research and development expenses include amortization of non-cash stock compensation expense of \$682,000 and \$(19,000) in the three months ended June 30, 2001 and 2000, respectively. Excluding these charges, research and development expenses increased by \$5.6 million primarily due to the increase in clinical expenses for the development of anidulafungin which moved into Phase III trials in the first half of 2001 and dalbavancin, which moved into Phase II trials in the second quarter of 2001 and for which we made a one-time payment to Biosearch Italia, 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 \$2.2 million in the three months ended June 30, 2001 and 2000, respectively. General and administrative expenses include amortization of non-cash stock compensation expense of \$893,000 and \$1.7 million in the three months ended June 30, 2001 and 2000, respectively. Excluding these charges, general and administrative expenses increased by \$1.1 million 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 \$831,000 and \$471,000 in the three months ended June 30, 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.

SIX MONTHS ENDED JUNE 30, 2001 COMPARED TO SIX MONTHS ENDED JUNE 30, 2000

REVENUES

Revenues were \$3.3 million and \$2.8 million in the six months ended June 30, 2001 and 2000, respectively. Revenues consisted of \$1.9 million and \$1.4 million of collaborative research and development, contract service and license fees from Pharmacia Corporation in the six months ended June 30, 2001 and 2000, respectively and \$1.4 million of collaborative research and development fees and milestone payments from Novartis in both the six months ended June 30, 2001 and 2000. The increase in revenues in the first half 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 \$14.2 million and \$6.2 million in the six months ended June 30, 2001 and 2000, respectively. Research and development expenses include amortization of non-cash stock compensation expense of \$1.2 million in both in the six months ended June 30, 2001 and 2000. Excluding these charges, research and development expenses increased by \$8.0 million primarily due to the increase in clinical expenses for the development of anidulafungin, which moved into Phase III trials in the first half of 2001 and dalbavancin which moved into Phase II trials in the second quarter of 2001 and for which we paid a one-off milestone payment to Biosearch Italia, as well as the expansion of our collaborative and internal research projects.

GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses were \$4.9 million and \$3.9 million in the six months ended June 30, 2001 and 2000, respectively. General and administrative expenses include amortization of non-cash stock compensation expense of \$2.1 million and \$2.8 million in the six months ended June 30, 2001 and 2000, respectively. Excluding these charges, general and administrative expenses increased by \$1.7 million 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 \$2.0 million and \$940,000 in the six months ended June 30, 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 our initial public offering received in August and September 2000.

As of June 30, 2000, we had received approximately \$18.7 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, \$2.3 million constitutes deferred revenue as of June 30, 2001.