VICURON PHARMACEUTICALS INC
Form 10-Q
August 14, 2003

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: June 30, 2003

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

VICURON PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

Delaware	**04-3278032**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

455 South Gulph Road, King of Prussia, PA 19406
(Address of principal executive offices) (Zip Code)

(610) 205-2300
(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 report(s) and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o.

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

On August 4, 2003, there were 53,839,358 common shares outstanding of the registrant s only class of common stock.

The Exhibit Index begins on page 36.

VICURON PHARMACEUTICALS INC.

Quarterly Report on Form 10-Q

For the Three Months Ended June 30, 2003

INDEX

Exhibit Index

PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

VICURON PHARMACEUTICALS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands)

	June 30, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,959	$ 28,271
Marketable securities	100,126	34,034
Accounts receivable, net	3,747	
Prepaid expenses and other current assets	9,098	5,451
Total current assets	129,930	67,756
Property, plant and equipment	31,600	4,875
Intangible assets, net	21,728	
Long-term receivables	9,551	
Long-term marketable securities - restricted	6,514	
Long-term marketable securities - other	465	
Other assets	328	105
Total assets	$ 200,116	$ 72,736
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 15,738	$ 6,491
Accrued liabilities	12,067	11,098
Current portion of long-term debt	2,352	3,500
Current portion of deferred revenue	2,532	1,519
Total current liabilities	32,689	22,608
Long-term debt, less current portion	5,149	698
Deferred revenue, less current portion	500	500
Other long-term liabilities	312	264
Total liabilities	38,650	24,070

Stockholders equity:				
Common stock		48		26
Additional paid-in capital		439,667		202,365
Deferred stock compensation		(996)		(1,171)
Accumulated other comprehensive income		8,418		65
Accumulated deficit		(285,671)		(152,619)
Total stockholders equity		161,466		48,666
Total liabilities and stockholders equity	$	200,116	$	72,736

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

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VICURON PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(in thousands, except per share amounts)

	Three Months Ended June 30, 2003	Three Months Ended June 30, 2002	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Revenues:				
Collaborative research and development, contract services and government grants	$ 2,148	$ 1,490	$ 3,865	$ 3,044
License fees and milestones	130		171	258
Total revenues	2,278	1,490	4,036	3,302
Operating expenses:				
Research and development	25,158	12,068	37,883	22,065
General and administrative	3,643	2,036	5,724	4,537
Acquired in-process research and development			94,532	
Total operating expenses	28,801	14,104	138,139	26,602
Loss from operations	(26,523)	(12,614)	(134,103)	(23,300)
Other income (expense):				
Interest income	718	436	1,168	781
Interest expense	(47)	(62)	(117)	(124)
Net loss	$ (25,852)	$ (12,240)	$ (133,052)	$ (22,643)
Net loss per share:				
Basic and diluted	$ (0.54)	$ (0.47)	$ (3.25)	$ (0.92)
Weighted average shares	47,709	26,008	40,890	24,642

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

VICURON PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Cash flows from operating activities:		
Net loss	$ (133,052)	$ (22,643)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,064	628
Non-cash stock compensation expense	845	1,291
Acquired in-process research and development	94,532	
Changes in operating assets and liabilities, net of effect of merger:		
Employee notes receivable		13
Accounts receivable	(293)	
Prepaid expenses and other current assets	2,339	860
Long-term receivables	(1,149)	
Other assets	(216)	(8)
Accounts payable	(2,128)	(173)
Accrued liabilities	1,878	592
Advances received	(403)	
Deferred revenue	(395)	(677)
Other long-term liabilities	48	54
Net cash used in operating activities	(35,930)	(20,063)
Cash flows from investing activities:		
Purchases of marketable securities		(15,091)
Sales/maturities of marketable securities	28,963	24,177
Additions to property and equipment	(7,858)	(516)
Net cash and cash equivalents acquired in Biosearch merger	746	
Net cash provided by investing activities	21,851	8,570
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	564	42,209
Proceeds from long-term debt	2,779	491
Repayments of long-term debt	(1,050)	(683)
Net cash provided by financing activities	2,293	42,017
Effect of exchange rate changes on cash and cash equivalents	474	

Net change in cash and cash equivalents		(11,312)		30,524
Cash and cash equivalents at beginning of period		28,271		31,349
Cash and cash equivalents at end of period	$	16,959	$	61,873
Supplemental cash flow information:				
Cash paid during the period for interest	$	129	$	125
Supplemental disclosure of non-cash investing activities:				
Common stock and stock options issued in Biosearch merger	$	236,089	$	

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

NOTES TO CONDENSED CONSOLDIATED FINANCIAL STATEMENTS

1. Basis of Presentation

The accompanying interim financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America 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 consolidated 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 adjustments) necessary for a fair presentation of the results for the interim periods ended June 30, 2003 and 2002.

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 consolidated interim financial statements should be read in conjunction with the audited financial statements for the year ended December 31, 2002, which are included in the Company s Annual Report on Form 10-K for the year ended December 31, 2002.

On March 26, 2003, the Company changed its name from Versicor Inc. to Vicuron Pharmaceuticals Inc.

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 shares of common stock are anti-dilutive for all periods presented and therefore are excluded from the calculation of diluted net loss per share. The following potentially dilutive shares of common stock were excluded from the computation of net loss per share because their effect was anti-dilutive (in thousands):

	June 30,	
	2003	**2002**
Shares issuable upon exercise of stock options	8,797	3,516
Shares issuable upon exercise of warrants	195	344
Shares subject to repurchase		3
	8,992	3,863

3. Acquisition of Biosearch Italia S.p.A.

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

Biosearch has used natural product sourcing for the discovery, development and production of novel anti-infective drugs with a primary emphasis on Europe. The acquisition will substantially enhance the Company s capabilities with respect to discovery, pre-clinical development, and manufacturing, as well as the Company s European market presence and effectiveness. The combined company will have substantially greater presence in two of the three major pharmaceutical markets (North

America and Europe) as well as an enhanced product portfolio for collaborations in Asia. The North American rights to the Company s lead antibiotic product candidate, dalbavancin, had been previously licensed from Biosearch and by acquiring the global rights the Company will eliminate royalties and manufacturing fees in North America, acquire the full potential of dalbavancin in Europe and enhance the Company s commercialization effectiveness for its lead antifungal drug, anidulafungin, in Europe. As a result, the Company believes all of these benefits will increase its margin and profitability prospects for dalbavancin and anidulafungin upon regulatory approval in North America and Europe. The Company also believes that European approval can now be obtained with only a modest increase in the clinical development expenses already planned for its North American filings.

The purchase price of the acquisition is approximately $243.1 million determined as follows (in thousands):

Issuance of Vicuron shares	$	232,912
Issuance of options to acquire Vicuron shares		3,177
Transaction costs		6,978
	$	243,067

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

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

Current assets	$	107,595
Property, plant and equipment		24,466
In-process research and development		94,532
Identifiable intangible assets		20,786
Other assets		14,356
Current liabilities		(17,535)
Long-term liabilities		(1,133)
	$	243,067

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

Both significant in-process projects are still undergoing clinical trials and have not received regulatory approval. The primary risk in completing the projects is the successful completion of the clinical testing and regulatory approval process. This process is time and research intensive and new drugs face significant challenges before they can be brought to the market. Any delay in the approval process could have significant consequences including increased costs thus jeopardizing the economic returns expected to be realized, delay in the rollout of the product with potential lower revenues due to competing products reaching the market and potential loss of credibility to the company s scientific team.

Current assets include $90.3 million in marketable securities.

As the fair value of the net assets acquired exceeds the purchase price paid, there is negative goodwill arising on the acquisition of $6.6 million. This amount has been allocated to the values of property, plant and equipment and intangible assets acquired pro rata to their deemed fair values as of the acquisition date.

The identifiable intangible assets arising from the merger, after allocation of negative goodwill, total $20.8 million and represent primarily $14.2 million for Biosearch s patents and core technology, $5.0 million for their library of microbial extracts and $1.4 million for their bioinformatics software platform. These identifiable intangible assets have estimated useful lives of between five and thirteen years.

As a result of the Company s merger with Biosearch, the Company acquired additional long-term debt relating to a loan agreement entered into by Biosearch in November 2000 with the Ministero Istruzione Università Ricerca, or MIUR, to fund certain research projects undertaken by Biosearch. This loan matures in January 2011, and at June 30, 2003, the amount outstanding under this loan was $1.2 million.

In addition, in March 2003, the Company received proceeds of $2.8 million from a loan facility entered into by Biosearch in July 2002 with the Basilicata Region of Italy for the construction of the Company s manufacturing plant in Pisticci. Under the loan agreement, the Company has a total loan facility of $8.6 million (at exchange rates prevailing at June 30, 2003) of which the Company has drawn down $2.9 million. The loan matures in 2012.

Biosearch has historically funded a portion of its operations through research grants and loan subsidies awarded by Italian and EU authorities. Under applicable law, any transfer of those grants and subsidies (including transfer by merger) requires written approval from the Italian bank authorized to make the disbursement on behalf of the government and from the appropriate Italian or EU authorities. In connection with the merger, the Company is in the process of applying for permission to transfer Biosearch s grants and subsidies to itself. However, as the merger has recently been completed, the Italian and EU authorities have not as yet reached an official decision on whether to approve the transfer requests. If the transfers are not approved, the Company might be required to repay some or all of the grants and subsidies received by Biosearch prior to the merger, in the aggregate amount of up to approximately $2.0 million as of June 30, 2003 and the Company may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of June 30, 2003 by the authorized bank, in the aggregate amount of up to approximately $1.2 million as of June 30, 2003 (each estimate based on exchange rates prevailing at June 30, 2003).

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

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	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
Revenues	$ 5,409	$ 4,809
Net loss	$ (44,539)	$ (27,740)
Net loss per share:		
Basic and diluted	$ (0.93)	$ (0.60)
Weighted average shares	47,692	45,874

The unaudited pro forma consolidated financial information are not necessarily indicative of the Company s future results of operations or the results of operations which might have occurred had the acquisition actually taken place on January 1, 2002.

4. Stock Options Fair Value Disclosures

The Company applies the measurement principles of Accounting Principles Board Opinion No. 25, Accounting for Stock issued to Employees , in accounting for its employee stock options. Had compensation expense for options granted to employees been determined based on the fair value at the grant date as prescribed by Statement of Financial Accounting Standards No. 123, Accounting for Stock Based Information , the Company s net loss and net loss per share would have been as follows:

	Three Months Ended June 30, 2003	Three Months Ended June 30, 2002	Six Months Ended June 30, 2003	Six Months Ended June 30, 2002
	(in thousands, except per share data)			
Net Loss, as reported	$ (25,852)	$ (12,240)	$ (133,052)	$ (22,643)
Add: stock-based employee compensation expense included in net loss	261	620	572	1,302
Less: total stock-based employee compensation, determined under fair value based method for all awards	(4,716)	(2,288)	(7,062)	(3,940)
Net loss pro forma	$ (30,307)	$ (13,908)	$ (139,542)	$ (25,281)
Basic and diluted net loss per share:				
As reported	$ (0.54)	$ (0.47)	$ (3.25)	$ (0.92)
Pro forma	$ (0.64)	$ (0.53)	$ (3.41)	$ (1.03)

5. Comprehensive Loss

For the three and six month periods ended June 30, 2003 and 2002, the components of total comprehensive loss are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Net loss	$ (25,852)	$ (12,240)	$ (133,052)	$ (22,643)
Foreign currency translation adjustment	8,614		8,363	
Unrealized gain (loss) on investments	19	30	(10)	(56)
Other comprehensive loss	8,633	30	8,353	(56)
Comprehensive loss	$ (17,219)	$ (12,210)	$ (124,699)	$ (22,699)

6. Recent Accounting Pronouncements

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

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

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity" ("SFAS No. 150"). The Statement establishes standards for how certain financial instruments with characteristics of both liabilities and equity must be classified and measured. SFAS No. 150 requires that a financial instrument that is within its scope be classified as a liability, or an asset in some circumstances. Many of those instruments were previously classified as equity. The Statement is effective for financial instruments entered into or modified after May 31, 2003 and is otherwise effective at the beginning of the first interim period beginning after June 15, 2003. The Company does not have any financial instruments with characteristics of both liabilities and equity.

7. Subsequent Event

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

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, 2002 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 and in our Annual Report, our actual results may differ significantly from those anticipated in these forward-looking statements.

Overview

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

Since 1996, we have been operating as an independent company and on August 8, 2000, we sold 4,600,000 shares of our common stock at $11 per share in an initial public offering, and on September 7, 2000 the underwriters exercised an over-allotment option and purchased an additional 690,000 shares of common stock at $11 per share. We received total net proceeds from the initial public offering and the over-allotment of approximately $52.7 million.

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

On February 28, 2003, we acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. We issued 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. We also issued options covering approximately 4.3 million common shares, including options issued to replace or assume options that were held by Biosearch employees and consultants at the time of the acquisition.

On March 26, 2003, we changed our name from Versicor Inc. to Vicuron Pharmaceuticals Inc.

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

Since we began our operations in May 1995, we have not generated any revenues from product sales. In April 2003, we filed a New Drug Application, or NDA, for our lead antifungal product candidate, anidulafungin, for the treatment of esophageal candidiasis which was accepted for review by the FDA in June 2003. Anidulafungin is also currently being studied in a Phase III clinical trial for invasive candidiasis/candidemia in up to 300 patients and has also completed enrollment in a 30 patient Phase III clinical trial for aspergillosis in combination with a liposomal amphotericin formulation. Our lead antibiotic product candidate, dalbavancin, is in Phase III clinical trials for both complicated and uncomplicated skin and soft tissue infections, each clinical trial with approximately 550 patients, and is in a Phase II clinical trial for catheter-related bloodstream infections with up to 90 patients. We also have two further product candidates: ramoplanin which is being developed by Genome Therapeutics, our licensee in North America, which is in a Phase III clinical trial for the reduction of vancomycin-resistant *enterococci* (VRE) bloodstream infections in patients at risk and a Phase II clinical trial for the treatment of *Clostridium difficile*-associated diarrhea, and VIC-Acne, a novel antibiotic for which we have completed a Phase I clinical trial. We also have several lead compounds in preclinical studies.

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 product candidates, we will generate revenues from sales of these product candidates and from receipt of royalties on sales of these product candidates.

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 and our merger with Biosearch. 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. We also expect that our general and administrative expenses will increase due to our integration with Biosearch and as we add personnel, combine our operations and continue to expand our research and development operations. We expect to incur sales and marketing expenses in the future when we establish our sales and marketing organization.

Since our inception, we have incurred significant losses. As of June 30, 2003, we had an accumulated deficit of $285.7 million including the $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch. Biosearch has also incurred net losses since its inception in 1996 and had an accumulated deficit of $54.8 million as at February 28, 2003. We anticipate incurring additional losses, which may increase, for the foreseeable future, including at least through December 31, 2004.

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

Major Research and Development Projects

Our ongoing clinical trials of anidulafungin and dalbavancin are our two most significant research and development projects, comprising 36% and 22%, respectively, of our total research and development expenditure since January 1, 2001.

Anidulafungin

Anidulafungin is our lead antifungal product candidate. We in-licensed anidulafugin from Eli Lilly pursuant to the May 1999 agreement described below. In April 2003, we filed an NDA for anidulafungin for the treatment of esophageal candidiasis. In addition, as of June 30, 2003, the intravenous formulation of anidulafungin is in:

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

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of anidulafungin. We paid $11.0 million for the license and an additional $3.0 million for product inventory (which we have received). As a result, we recognized $14.0 million of research and development costs in 1999. If specified milestones are achieved on the intravenous formulation of anidulafungin in the United States and Canada, we will be obligated to make additional payments of up to $8.0 million to Eli Lilly. We paid Eli Lilly $6.0 million in May 2003 in connection with the submission of the NDA. We are also obligated to make additional payments of up to $8.0 million to Eli Lilly if specified milestones on the intravenous formulation of anidulafungin are achieved in Europe, and additional payments of up to $8.0 million if specified milestones on the intravenous formulation of anidulafungin are achieved in Japan. We are obligated to make additional payments to Eli Lilly of up to $21.0 million if sales of an intravenous formulation of anidulafungin exceed specified targets in the United States and Canada, Europe and Japan. In addition, we are obligated to make royalty payments in respect of sales of any product resulting from the compound.

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

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

29% for the six months ended June 30, 2003 compared to 44% for the six months ended June 30, 2002;

42% for the year 2002 compared to 35% for the year 2001 and 12% for the year 2000; and

32% in the aggregate from the inception of our company through June 30, 2003.

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 filed an NDA with the FDA in April 2003 for the treatment of esophageal candidiasis which was accepted by the FDA for review in June 2003. 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 other product candidates or 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. As of June 30, 2003, dalbavancin is in:

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

Phase II clinical trial for the treatment of catheter-related blood stream infections.

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

23% for the six months ended June 30, 2003 compared to 19% for the six months ended June 30, 2002;

23% for the year 2002 compared to 21% for the year 2001 and 6% for the year 2000; and

17% in the aggregate from the inception of our company through June 30, 2003.

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. 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 Risk Factors - Risk Related to Our Business. 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 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 other product candidates or 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 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.

Development Administration

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

16% for the six months ended June 30, 2003 compared to 14% for the six months ended June 30, 2002;

12% for the year 2002 compared to 7% for the year 2001 and 15% for the year 2000; and

14% in the aggregate from the inception of our company through June 30, 2003.

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

Other Research and Development Projects

The remaining 42% of our total research and development expenses since January 1, 2001 include 3% relating to non-cash stock compensation expense. The remaining 39% were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pfizer and Novartis described below.

Oxazolidinones collaboration with Pfizer. In March 1999, we entered into a collaboration agreement with Pharmacia Corporation, now Pfizer, pursuant to which we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pfizer made an equity investment in us of $3.8 million and paid us research support and license fee payments. Under the terms of the agreement and in consideration for our research obligations, we are entitled to receive funding from Pfizer to support some of our full-time researchers. If specified milestones are achieved, Pfizer is obligated to pay us additional payments of up to $14.0 million for each compound, a portion of which may be credited against future royalty payments to which we are entitled on the worldwide sales of any drug developed and commercialized from the collaboration. In October 2000, Pfizer increased its funding for this collaboration by 30%, and in June 2001, we received a milestone payment for the initiation of clinical development of one of the compounds. In July 2002, we agreed with Pfizer by amendment to extend the collaboration by an additional three years, through March 2005. Through June 30, 2003, Pfizer has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $15.7 million.

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

4% for the six months ended June 30, 2003 compared to 7% for the six months ended June 30, 2002;

7% for the year 2002 compared to 10% for the year 2001 and 19% for the year 2000; and

8% in the aggregate from January 1, 1999 through June 30, 2003.

The goal of our collaboration with Pfizer is to discover, synthesize and obtain marketing approval for second and third generation oxazolidinone product candidates. We supply research product leads and other specified intellectual property to the collaboration. The collaboration also depends upon Pfizer to develop the product candidates, to obtain marketing approval from the FDA and analogous international agencies and to 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, Pfizer will need to complete Phase I, II and III clinical trials with satisfactory results and submit a NDA to the FDA. Pfizer is under no obligation to continue the development of any product candidate resulting from this collaboration. Because of this, and the substantial risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our collaboration with Pfizer will commence, if ever.

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. In February 2003, we further agreed with Novartis by amendment to extend the collaboration by an additional two years through March 2005. Through June 30, 2003, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of $11.1 million.

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

3% for the six months ended June 30, 2003 compared to 5% for the six months ended June 30, 2002;

5% for the year 2002 compared to 8% for the year 2001 and 17% for the year 2000; and

7% in the aggregate from January 1, 1999 through June 30, 2003.

The goal of our collaboration with Novartis is to discover, synthesize and obtain marketing approval for deformylase inhibitor product candidates. We are responsible for supplying research to the collaboration, according to a research plan developed by a joint research committee. Our research obligations currently extend through March 2005. 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 deformylase inhibitors, under the collaboration agreement we have been delivering to Novartis a series of screening assays based on novel anti-bacterial targets. For each screen that Novartis accepts as validated, we receive a milestone payment. In August 2001 and January 2002, Novartis paid us our fourth and fifth milestone 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 and upon which we will be eligible for milestones and royalties.

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

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

while we do not rely on any particular external development collaboration to produce marketable products (and, ultimately, royalty revenues), the failure of all 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 EITF No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.

We recorded deferred stock compensation of $670,000 and $52,000 in the six months ended June 30, 2003 and 2002, 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 $845,000 and $1.3 million in the six months ended June 30, 2003 and 2002, respectively.

Results of Operations

Three Months Ended June 30, 2003 Compared to Three Months Ended June 30, 2002

Revenues

Revenues were $2.3 million and $1.5 million in the three months ended June 30, 2003 and 2002. Revenues in 2003 consisted of $1.5 million of collaborative research and development fees from Pfizer and Novartis and $0.8 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in 2002 also consisted primarily of collaborative research and development fees from Pfizer and Novartis.

Research and Development Expenses

Research and development expenses were $25.2 million and $12.1 million in the three months ended June 30, 2003 and 2002, respectively. The increase in expenditure is partly due to the fact that the 2003 number includes a $6.0 million payment to Eli Lilly for the anidulafungin milestone payment, $4.3 million for Italian research costs resulting from our merger with Biosearch and an increase in our development team expenditures resulting in increased expenditures.

General and Administrative Expenses

General and administrative expenses were $3.6 million and $2.0 million in the three months ended June 30, 2003 and 2002, respectively. General and administrative expenses include amortization of non-cash stock compensation of $227,000 and $417,000 in the three months ended June 30, 2003 and 2002, respectively. Other general and administrative expenses were $3.4 million for the second quarter of 2003 compared to $1.6 million for the second quarter of 2002. The increase in expenses in the second quarter of 2003 resulted from our operations in Italy of $1.1 million plus additional costs related to legal fees, insurance and salaries.

Other Income (Expense)

Net other income (expense) was $671,000 and $374,000 in the three months ended June 30, 2003 and 2002, respectively. The increased income in the second quarter of 2003 from our Italian investments of $588,000 was partially offset by a reduction in our US interest income as a result of lower returns on investments during the 2003 period.

Six Months Ended June 30, 2003 Compared to Six Months Ended June 30, 2002

Revenues

Revenues were $4.0 million and $3.3 million in the six months ended June 30, 2003 and 2002. Revenues in 2003 consisted of $3.0 million of collaborative research and development fees from Pfizer and Novartis and $1.0 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in 2002 consisted primarily of collaborative research and development fees from Pfizer and Novartis.

Research and Development Expenses

Research and development expenses were $37.8 million and $22.1 million in the six months ended June 30, 2003 and 2002, respectively. The increase in expenditure is partly due to the fact that the 2003 number includes a $6.0 million payment to Eli Lilly for the anidulafungin milestone payment, $4.7 million for Italian research costs resulting from our merger with Biosearch and also an increase in our development team expenditures resulting in increased expenditures.

General and Administrative Expenses

General and administrative expenses were $5.7 million and $4.5 million in the six months ended June 30, 2003 and 2002, respectively. General and administrative expenses include amortization of non-cash stock compensation of $511,000 and $872,000 in the six months ended June 30, 2003 and 2002, respectively. Other general and administrative expenses were $5.2 million for the first half of 2003 compared to $3.6 million for the second half of 2002. The increase in expenses in the second half of 2003 resulted from our operations in Italy of $1.5 million.

Acquired In-Process Research and Development

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

Other Income (Expense)

Net other income (expense) was $1.1 million and $657,000 in the six months ended June 30, 2003 and 2002, respectively. The increased income in the second quarter of 2003 from our Italian investments was partially offset by a reduction in our United States interest income as a result of lower returns on investments during the 2003 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, in April 2002, we completed a private placement of shares of common stock to selected institutional investors from which we received net proceeds of approximately $41.9 million. We also increased our cash and cash equivalents and unrestricted marketable securities by $99.1 million as a result of our merger with Biosearch on February 28, 2003. On July 17, 2003, we sold 6,000,000 shares of our common stock at $13.85 per share in a stock offering. We received net proceeds of $77.8 million.

We have also received payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, $1.4 million constitutes deferred revenue as of June 30, 2003.

We also have a $6.0 million term loan and a fully drawn down $2.0 million equipment note with a commercial bank. Proceeds from the loan were used to repay Sepracor for leasehold improvements to our facilities and for general corporate purposes. Proceeds from draw downs on the equipment note were used to finance capital expenditure. The terms of the term loan were renegotiated in January 2003 and the final payment on the loan is now due on December 31, 2004. The final note balance is also payable on December 31, 2004. Also, in January 2003, the term loan was amended to include a three-year equipment note for $1.5 million that we are able to draw down on through December 31, 2003. The principal of this note is payable in equal installments beginning on March 31, 2004 with the final payment due on December 31, 2005. To date, we have not drawn down on this note.

As a result of our merger with Biosearch, we acquired additional long-term debt relating to a loan agreement entered into by Biosearch in November 2000 with MIUR to fund certain research projects undertaken by Biosearch. This loan matures in January 2011 and at June 30, 2003, the amount outstanding under this loan is $1.2 million.

In addition, in March 2003, we received proceeds of $2.8 million from a loan facility entered into by Biosearch in July 2002 with the Basilicata Region of Italy for the construction of our manufacturing plant in Pisticci. Under the loan agreement, we have a total loan facility of $8.6 million (at exchange rates prevailing at June 30, 2003) of which we have drawn down $2.9 million. The loan matures in 2012.

Cash used in operations was $35.9 million and $20.1 million in the six months ended June 30, 2003 and 2002, respectively. The net loss for the first half of 2003 of $133.1 million was reduced for non-cash charges for acquired in-process research and development of $94.5 million resulting from our merger with Biosearch and non-cash charges for depreciation and amortization and amortization of non-cash stock compensation expense of $2.9 million. Prepaid expenses and other current assets decreased by $2.3 million primarily due to acquisition costs paid in 2002 relating to the Biosearch merger which was only completed in 2003. Accounts payable increased by $2.0 million primarily due to the increase in our Italian accounts payable balances in June 2003. In the first half of 2002, the net loss of $22.6 million was offset by non-cash charges relating to depreciation and amortization of non-cash stock compensation expense of $1.9 million.

Cash provided by investing activities was $21.9 million and $8.6 million in the six months ended June 30, 2003 and 2002, respectively. The principal source of cash in both periods resulted from the net sale of marketable securities to fund operating losses and the mix of our investment portfolio of cash and cash equivalents and marketable securities. The increase in capital expenditure of $7.9 million in 2003 is primarily due to the construction of our manufacturing plant in Pisticci, Italy.

Cash provided by financing activities was $2.3 million and $42.0 in the six months ended June 30, 2003 and 2002, respectively. In the first six months of 2003, we received proceeds of $2.8 million from our loan facility in Italy for the construction of our manufacturing plant. The $42.2 million in the first six months of 2002 was primarily due to the completion of a private placement of shares of common stock to selected institutional investors.

At June 30, 2003, our cash and cash equivalents and unrestricted marketable securities totaled $117.1 million compared to $62.3 million at December 31, 2002.

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 at June 30, 2003 will be sufficient to fund our operating expenses, debt repayments and capital requirements for between the next 18 to 24 months.

Recent Accounting Pronouncements

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

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

RISK FACTORS

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

Risks Related to Our Business

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

In order to become profitable, we anticipate that we will need to obtain FDA marketing approval for anidulafungin and dalbavancin and then commercialize them successfully. In April 2003, we filed a NDA with the FDA seeking approval to market anidulafungin for the treatment of esophageal candidiasis. Dalbavancin is in Phase III clinical trials for the treatment of both complicated and uncomplicated skin and soft tissue infections and in a Phase II trial for catheter-related bloodstream infections. We expect to complete the Phase III trials in the first half of 2004 and file a NDA for dalbavancin in the second half of 2004. Factors that could negatively affect or delay our receipt of FDA approval of one or both of these drugs include:

a refusal by the FDA to approve our NDAs for these drugs or a request for additional information or data.

delays in completing clinical trials for dalbavancin; and

negative or inconclusive results of our ongoing clinical trials of dalbavancin.

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

Our success will further depend upon our ability to protect our intellectual property and products. We rely on a combination of patent, trade secret and regulatory protections to protect us from competitors with similar technologies. With regard to anidulafungin, we rely on patents covering the compound, methods of production and methods of use to protect this product candidate from generic competition. With regard to dalbavancin, we rely primarily on regulatory provisions, such as the data exclusivity provisions under the Hatch-Waxman Act, as well as patents and know-how to protect this product candidate from generic competition. However, in each case there can be no assurances that we will obtain protection for any specified duration.

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

To date, we have not commercialized any products or recognized any revenue from product sales and none of our product candidates are approved for sale. Successful commercialization of a new drug product requires significant investment in research and development, pre-clinical testing and clinical trials, regulatory approval, and sales and marketing activities. Most of our product candidates are in early stages of development, one is being reviewed by the FDA, and three are in clinical trials. Our efforts to commercialize our product candidates are subject to a variety of risks inherent in the development of biopharmaceutical products based on new technologies. These risks include the following:

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

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

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

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

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

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

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

We have incurred net losses since our inception in 1995. As of June 30, 2003, our accumulated deficit was $285.7 million including the $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch. Our accumulated deficit results from our net losses of $1.1 million in 1995; $4.8 million in 1996; $6.7 million in 1997 (including $0.4 million in accretion of dividends on preferred stock); $15.1 million in 1998 (including $2.5 million in accretion of dividends on preferred stock); $67.4 million in 1999 (including deemed dividends of $35.1 million and $3.1 million in accretion of dividends on preferred stock); $18.8 million in 2000 (including $3.5 million in accretion of dividends on preferred stock); $32.8 million in 2001; $48.8 million in 2002; and $133.1 million in the six months ended June 30, 2003 (including a $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch).

Our losses to date have resulted principally from:

research and development costs relating to the in-licensing and development of our product candidates, which represented approximately 58% of our aggregate operating expenses from our inception through June 30, 2003;

write-off of in-process research and development expenses relating to our merger with Biosearch, which represented approximately 30% of our aggregate operating expenses from our inception through June 30, 2003; and

general and administrative costs relating to our operations, which represented approximately 12% of our aggregate operating expenses from our inception through June 30, 2003.

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

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

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

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

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

receiving regulatory approvals for our product candidates;

developing and testing new product candidates;

licensing rights to our product candidates to third parties;

qualifying for and receiving grants and subsidies;

manufacturing products;

marketing products; and

competing with products from other companies.

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

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

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

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

if dalbavancin receives FDA and international marketing approval, it will face competition from commercially available drugs such as vancomycin, teicoplanin, linezolid and quinupristin/dalfopristin, and drug candidates in clinical development such as daptomycin, which is currently being reviewed by the FDA; and

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

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

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

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

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

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

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

As of June 30, 2003, we have one product candidate, anidulafungin, being reviewed by the FDA and three product candidates in clinical trials: dalbavancin in Phase III; ramoplanin in Phase III; and VIC-Acne which has completed Phase I. We also have anidulafungin in Phase III for an additional indication and dalbavancin and ramoplanin in Phase II each for an additional indication. Patient follow-up for these clinical trials has been limited and more trials will be required before we will expect to apply for regulatory approvals.

Clinical trials conducted by us or by third parties on our behalf might not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin, dalbavancin, ramoplanin or VIC-Acne or any other potential product candidates. Such a failure might delay development of our other product candidates and hinder our ability to conduct related pre-clinical testing and clinical trials. It might also cause regulatory authorities to prohibit us from undertaking any additional clinical trials for our other product candidates. Our other product candidates are in pre-clinical development, and we have not submitted investigational new drug applications, or INDs, to commence clinical trials involving these compounds. Our pre-clinical development efforts might not be successfully completed and we might not file further INDs. Any delays in, or termination of, our clinical trials would harm our development and commercialization timelines, which could cause our stock price to decline. Any of these events could also impede our ability to obtain additional financing.

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

As of June 30, 2003, we had 35 full-time clinical development employees. We expect to continue to rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. If these third parties fail to perform satisfactorily under the terms of our agreements with them, clinical trials for our product candidates might be delayed or unsuccessful. Furthermore, the FDA and/or other regulatory agencies of the EU, might inspect some of our clinical investigational sites, our collaborators records and our facilities and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that our clinical trials were not in compliance with applicable requirements, we might be required to repeat the clinical trials.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- demonstrations of clinical efficacy and safety;
- cost-effectiveness;
- potential advantages over alternative therapies, including fewer side effects or easier administration;
- reimbursement policies of government and third-party payors; and
- the effectiveness of our marketing and distribution capabilities.

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

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

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

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

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

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

We expect that substantially all of our revenues for the forseeable future will result from payments under collaborative arrangements, with some European grant and subsidy revenue. To date, collaborative payments have taken the form of up-front payments, reimbursement for research and development expenses and milestone payments. Milestone payments to our company under collaborative arrangements are subject to significant fluctuation in both timing and amount. As a result, comparisons of our revenues and results of operations between periods might not produce meaningful indications of our progress toward commercializing one or more product candidates. Moreover, the historical revenues of Vicuron and Biosearch on a stand-alone basis might not be indicative of our future performance or of our ability to continue to achieve additional milestones and to receive additional milestone payments from our collaborators.

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

We expect to incur increasing research and development, general and administrative and sales and marketing expenses over the next several years. Based on our current plans and assumptions, we estimate that our cash and liquid assets at June 30, 2003 will be sufficient to fund our operating losses for the next 18 to 24 months. However, if our plans change and/or our assumptions are inaccurate, we might need to seek capital sooner than anticipated. Some of our more significant plans and assumptions relate to:

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