VICURON PHARMACEUTICALS INC
Form 10-Q
May 15, 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:**

March 31, 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 May 11, 2003, there were 47,681,820 common shares outstanding of the registrant s only class of common stock.

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VICURON PHARMACEUTICALS INC.

Quarterly Report on Form 10-Q

For the Three Months Ended March 31, 2003

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

VICURON PHARMACEUTICALS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands)

	March 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,668	$ 28,271
Marketable securities	105,697	34,034
Accounts receivable, net	3,287	
Prepaid expenses and other current assets	4,905	5,451
Total current assets	153,557	67,756
Property, plant and equipment	32,151	4,875
Intangible assets, net	20,621	
Long-term receivables	8,180	
Long-term marketable securities - restricted	6,133	
Long-term marketable securities - other	440	
Other assets	357	105
Total assets	$ 221,439	$ 72,736
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 20,306	$ 6,491
Accrued liabilities	9,247	11,098
Advances received	3,296	
Current portion of long-term debt	2,242	3,500
Current portion of deferred revenue	2,186	1,519
Total current liabilities	37,277	22,608
Long-term debt, less current portion	5,455	698

Deferred revenue, less current portion	500	500
Other long-term liabilities	360	264
Total liabilities	43,592	24,070
Stockholders equity:		
Common stock	48	26
Additional paid-in capital	439,082	202,365
Deferred stock compensation	(1,249)	(1,171)
Accumulated other comprehensive income (loss)	(215)	65
Accumulated deficit	(259,819)	(152,619)
Total stockholders equity	177,847	48,666
Total liabilities and stockholders equity	$ 221,439	$ 72,736

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

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended	
	March 31, 2003	March 31, 2002
Revenues:		
Collaborative research and development, contract services and government grants	$ 1,717	$ 1,554
License fees and milestones	41	258
Total revenues	1,758	1,812
Operating expenses:		
Research and development	12,723	9,997
General and administrative	2,082	2,501
Acquired in-process research and development	94,532	
Total operating expenses	109,337	12,498
Loss from operations	(107,579)	(10,686)
Other income (expense):		
Interest income	449	345
Interest expense	(70)	(62)
Net loss	$ (107,200)	$ (10,403)
Net loss per share:		
Basic and diluted	$ (3.15)	$ (0.45)
Weighted average shares	33,995	23,261

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

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three Months Ended March 31,	
	2003	**2002**
Cash flows from operating activities:		
Net loss	$ (107,200)	$ (10,403)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	668	314
Non-cash stock compensation expense	434	696
Acquired in-process research and development	94,532	
Changes in operating assets and liabilities, net of effect of merger:		
Employee notes receivable		10
Accounts receivable	(17)	
Prepaid expenses and other current assets	3,298	578
Long-term receivables	(228)	
Other assets	(251)	2
Accounts payable	3,027	(765)
Accrued liabilities	(978)	800
Advances received	(382)	
Deferred revenue	(282)	(1,561)
Other long-term liabilities	25	27
Net cash used in operating activities	(7,354)	(10,302)
Cash flows from investing activities:		
Purchases of marketable securities		(7,526)
Sales/maturities of marketable securities	18,488	13,620
Additions to property and equipment	(2,975)	(204)
Net cash and cash equivalents acquired in Biosearch merger	746	
Net cash provided by investing activities	16,259	5,890
Cash flows from financing activities:		
Proceeds from issuance of common stock	158	292
Proceeds from long-term debt	2,764	
Repayments of long-term debt	(526)	(342)

Net cash provided by (used in) financing activities		2,396		(50)
Effect of exchange rate changes on cash and cash equivalents		96		
Net change in cash and cash equivalents		11,397		(4,462)
Cash and cash equivalents at beginning of period		28,271		31,349
Cash and cash equivalents at end of period	$	39,668	$	26,887
Supplemental cash flow information:				
Cash paid during the period for interest	$	50	$	65
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 accruals) necessary for a fair presentation of the results for the interim periods ended March 31, 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):

	March 31,	
	2003	**2002**
Shares issuable upon exercise of stock options	8,536	3,308
Shares issuable upon exercise of warrants	195	344
Shares subject to repurchase		5
	8,731	3,657

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 and 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, have been 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, fair valued at $25.0 million and a novel second-generation glycopeptide agent, dalbavancin, fair valued at $64.0 million. These in-process projects require additional significant rigorous scientific and clinical testing expected to be completed in the second half of 2004 with cash inflows from product sales forecasted to begin in 2005. One project is estimated to be approximately 80% complete (based on cost) and the other project is approximately 45% complete (based on cost), an additional $3.0 million and $16.1 million, respectively for each project, for additional

scientific research and chemical development, expenses associated with conducting clinical trials for various stages, and legal and regulatory expenses in connection with the drug approval process are projected to be required to complete the in-process projects. 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.

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 at 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 ten 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 MIUR to fund certain research projects undertaken by Biosearch. This loan matures in January 2011, and at March 31, 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 $8.1 million (at exchange rates prevailing at March 31, 2003) of which the Company has drawn down $2.8 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 $1.8 million as of March 31, 2003 and the Company may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of March 31, 2003 by the authorized bank, in the aggregate amount of up to approximately $1.1 million as of March 31, 2003 (each estimate based on exchange rates prevailing at March 31, 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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	Three Months Ended March 31,	
	2003	2002
Revenues	$ 2,213	$ 2,295
Net loss	$ (18,743)	$ (13,731)
Net loss per share:		
Basic and diluted	$ (0.39)	$ (0.31)
Weighted average shares	47,678	44,493

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 March 31,	
	2003	2002
	(in thousands, except per share data)	
Net loss, as reported	$ (107,200)	$ (10,403)
Add: stock-based emloyee compensation expense included in net loss	311	682
Less: total stock-based employee compensation, determined under fair value based method for all awards	(2,346)	(1,652)
Net loss, pro forma	$ (109,235)	$ (11,373)
Basic and diluted net loss per share:		
As reported	$ (3.15)	$ (0.45)
Pro forma	$ (3.21)	$ (0.49)

5. 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 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.

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 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.

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. Anidulafungin is also currently being studied in a Phase III clinical trial for invasive candidiasis/candidemia in approximately 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 approximately 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 BI-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 March 31, 2003, we had an accumulated deficit of $259.8 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 37% 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 March 31, 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 $14.0 million to Eli Lilly, part of which is payable to Eli Lilly in April 2003 upon 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:

26% for the three months ended March 31, 2003 compared to 37% for the three months ended March 31, 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 March 31, 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. 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 March 31, 2003, dalbavancin is in:

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

Phase II clinical trials 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:

21% for the three months ended March 31, 2003 compared to 26% for the three months ended March 31, 2002;

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

16% in the aggregate from the inception of our company through March 31, 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; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. Before we can obtain such marketing approvals, we will need to complete pivotal Phase III clinical trials with satisfactory results and submit a NDA to the FDA. In any case, we would not expect to file a NDA for dalbavancin until the second half of 2004, at the earliest. We are unable to estimate the costs to completion for our dalbavancin project due to the risks surrounding the clinical trial process, including the risk that we may repeat, revise or expand the scope of our ongoing clinical trials or conduct additional clinical trials to secure marketing approvals and the additional risks listed under the caption If clinical trials for our products are unsuccessful or delayed, we will be unable to meet our anticipated development and commercialization timelines, which could harm our

business and cause our stock price to decline. 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:

17% for the three months ended March 31, 2003 compared to 11% for the three months ended March 31, 2002;

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

8% in the aggregate from the inception of our company through March 31, 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 41% of our total research and development expenses since January 1, 2001 include 4% relating to non-cash stock compensation expense. The remaining 37% 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 March 31, 2003, Pfizer has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $14.8 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:

6% for the three months ended March 31, 2003 compared to 7% for the three months ended March 31, 2002;

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

9% in the aggregate from January 1, 1999 through March 31, 2003.

The goal of our collaboration with Pfizer is to discover, synthesize and obtain marketing approval for second and third generation oxazolidinone product candidates. We supply research product leads and other specified intellectual property to the collaboration. The collaboration also depends upon Pfizer to develop the product candidates, to obtain marketing approval from the FDA and analogous international agencies and to 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 March 31, 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:

- 5% for the three months ended March 31, 2003 compared to 6% for the three months ended March 31, 2002;
- 5% for the year 2002 compared to 8% for the year 2001 and 17% for the year 2000; and
- 8% in the aggregate from January 1, 1999 through March 31, 2003.

The goal of our collaboration with Novartis is to discover, synthesize and obtain marketing approval for deformylase inhibitor product candidates. We are responsible for supplying research to the collaboration, according to a research plan developed by a joint research committee. Our research obligations currently extend through March 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 Emerging Issues Task Force No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.

We recorded deferred stock compensation of $512,000 and $39,000 in the three months ended March 31, 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 $434,000 and $696,000 in the three months ended March 31, 2003 and 2002, respectively.

Results of Operations

Three Months Ended March 31, 2003 Compared to Three Months Ended March 31, 2002

Revenues

Revenues were $1.8 million in both the three months ended March 31, 2003 and 2002. Revenues in 2003 consisted of $1.5 million of collaborative research and development fees from Pfizer and Novartis and $0.3 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 and a milestone payment from Novartis.

Research and Development Expenses

Research and development expenses were $12.7 million and $10.0 million in the three months ended March 31, 2003 and 2002, respectively. The increase in expenditure is partly due to the fact that the 2003 number includes $1.2 million for Italian research costs resulting from our merger with Biosearch and also due to an increase in our development team headcount resulting in increased expenditure of $1.1 million.

General and Administrative Expenses

General and administrative expenses were $2.1 million and $2.5 million in the three months ended March 31, 2003 and 2002, respectively. General and administrative expenses include amortization of non-cash stock compensation of $284,000 and $455,000 in the three months ended March 31, 2003 and 2002, respectively. Other general and administrative expenses were $1.8 million for the first quarter of 2003 compared to $2.0 million for the first quarter of 2002. The increase in expenses in the first quarter of 2003 resulting from our operations in Italy of $358,000 were more than offset by a reduction in US expenses, as a result of significant business development activities in the first quarter of 2002.

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 $379,000 and $283,000 in the three months ended March 31, 2003 and 2002, respectively. The increased income in the first quarter of 2003 from our Italian investments of $207,000 was partially offset by a reduction in our US 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.

As of March 31, 2003, we have also received approximately $28.9 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, $1.4 million constitutes deferred revenue as of March 31, 2003.

We also have a $6.0 million term loan and a fully draw 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 drawdown 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 March 31, 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 $8.1 million (at exchange rates prevailing at March 31, 2003) of which we have drawn down $2.8 million. The loan matures in 2012.

Cash used in operations was $7.4 million and $10.3 million in the three months ended March 31, 2003 and 2002, respectively. The net loss for the first quarter of 2003 of $107.2 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 $1.1 million. Prepaid expenses and other current assets decreased by $3.3 million primarily due to acquisition costs paid in 2002 relating to the Biosearch merger which was only completed in 2003. Accounts payable increased by $3.0 million primarily due to the increase in our Italian accounts

payable balances in March 2003. In the first quarter of 2002, the net loss of $10.4 million was offset by non-cash charges relating to depreciation and amortization of non-cash stock compensation expense of $1.0 million. Deferred revenue decreased by $1.6 million due to the timing of receipts of quarterly collaborative research and development funding.

Cash provided by investing activities was $16.3 million and $5.9 million in the three months ended March 31, 2003 and 2002, respectively. The principal source of cash in both quarters 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 $2.8 million in 2003 is primarily due to the construction of our manufacturing plant in Pisticci, Italy. In 2003, we also acquired cash and cash equivalents of $746,000, net of acquisition costs, in connection with our merger with Biosearch.

Cash provided by (used in) financing activities was $2.4 million and $(50,000) in the three months ended March 31, 2003 and 2002, respectively. In the first quarter of 2003, we received proceeds of $2.8 million from our loan facility in Italy for the construction of our manufacturing plant.

At March 31, 2003, our cash and cash equivalents and unrestricted marketable securities totaled $145.8 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 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 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.

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

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 U.S. Food and Drug Administration, or 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; and

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. Before deemed dividends, accretion to redemption value of our preferred stock and write-off of acquired in-process research and development, our net losses were $1.1 million in 1995, $4.8 million in 1996, $6.3 million in 1997, $12.6 million in 1998, $29.2 million in 1999, $15.3 million in 2000, $32.8 million in 2001, $48.8 million in 2002 and $12.7 million for the first three months of 2003. As of March 31, 2003, our accumulated deficit was $259.8 million including the $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 82% of our aggregate operating expenses from our inception through March 31, 2003; and

general and administrative costs relating to our operations, which represented approximately 18% of our aggregate operating expenses from our inception through March 31, 2003.

On February 28, 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 $9.0million 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.

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; but 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 or other assets. We expect that our operating losses will fluctuate significantly from quarter to quarter as a result of increases or decreases in our research and development efforts, the execution or termination of collaborative arrangements, the initiation, success or failure of clinical trials, or other factors. Our company s chances for achieving profitability will depend on numerous factors, including success in:

qualifying for and receiving grants and subsidies;

developing and testing new product candidates;

licensing rights to our product candidates to third parties;

receiving regulatory approvals;

manufacturing products;

marketing products; and

competing with products from other companies.

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

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

We expect that substantially all of our revenues for the foreseeable future will result from payments under collaborative arrangements. To date, these 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 candidate. 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.

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 on a country-by-country basis upon the later of 10 years from the date of

the first commercial sale of anidulafungin in the country or the expiration of all product patents 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 collaborative 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, seek and obtain regulatory approvals and 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 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 efficacy during the clinical trials;

inability to adequately follow patients after treatment;

governmental or regulatory delays; or

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

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 March 31, 2003, we have one product candidate, anidulafungin, being reviewed by the FDA and three product candidates in clinical trials: dalbavancin in Phase III; ramoplanin in Phase III; and BI-Acne which has completed Phase I. We also have anidulafungin in Phase III for additional indications. Patient follow-up for these clinical trials has been limited and more trials will be required before we will be able to apply for regulatory approvals.

Clinical trials conducted by us or by third parties on our behalf might not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin, dalbavancin, ramoplanin or BI-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 March 31, 2003, we had 31 full-time clinical development employees in the United States and one in Italy. 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 or Italy, 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 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:

- demonstration of clinical efficacy and safety;

cost-effectiveness;

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

reimbursement policies of government and third-party payors; and

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 location. 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.

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, will be our initial manufacturing site for anidulafungin and dalbavancin, and 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. We currently obtain some active ingredients from ChemSyn Laboratories, a department of Eagle-Picher Technologies, L.L.C. 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 BI-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 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.

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 and general and administrative expenses over the next several years. Based on our current plans and assumptions, we estimate that our cash and liquid assets at March 31, 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:

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

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

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

If we are unable to attract and retain skilled employees and consultants, we will be unable to develop and commerc

required to obtain funds by entering into arrangements with collaborators on unattractive terms or relinquish rights to certain technologies or drug candidates that we would not otherwise relinquish in order to continue independent operations.

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

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

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

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

Risks Related to our Recent Merger with Biosearch and International Expansion

The ongoing integration of Vicuron and Biosearch management following the recent merger will present significant challenges.

Our merger with Biosearch was only recently completed and we will face significant challenges in combining our management and internal control and disclosure systems in a timely and efficient manner. This integration will be complex and time-consuming because, among other things, our executive officers will be located in separate U.S. and Italian offices. Our U.S. management team has recently relocated from the San Francisco Bay Area to King of Prussia, Pennsylvania, while the management of our Italian operations will remain in Gerenzano, Italy. If we are unable to integrate our management and internal systems successfully, we might not achieve the anticipated potential benefits of the merger.

When Nasdaq s currently proposed director-independence rules are adopted, compliance with both the new rules and our bylaws, as amended by the merger agreement, might require us to increase the size of our board.

We have eight directors on our board, four of whom were associated with Vicuron prior to the merger and the other four of whom were associated with Biosearch. In connection with the merger, we amended our bylaws in a manner that is intended, among other things, to maintain an even balance of legacy Vicuron directors and legacy Biosearch directors on the board for three years from the date of the completion of the merger. If we decide to add additional directors to the board during that three-year period, our bylaws effectively require us to add an even number of directors (with one-half of the additional directors proposed by the four legacy Vicuron directors and the other half proposed by the four legacy Biosearch directors) in order to maintain an equal number of legacy Vicuron and Biosearch directors on the board.

If we are unable to attract and retain skilled employees and consultants, we will be unable to develop and commerc

Our bylaws might make it more difficult for us to comply with Nasdaq s recently proposed director-independence rule. Although Nasdaq s proposed rule is still subject to change, the current version announced by Nasdaq on March 25, 2003, includes the following requirements, among others:

Majority of Independent Directors. Nasdaq s proposed rule will require that a majority of our board must be comprised of independent directors, and a director will not be independent if, among other disqualifications, in any of the past three years he or his non-employee family members received more than $60,000 from our company, other than for his service as a director, or if the director is a controlling shareholder or officer of an entity to which our company has made payments in excess of $200,000 or 5% of either entity s gross revenues. We believe that two of our eight directors currently qualify as independent under the proposed standards.

Compliance Deadline. Nasdaq s proposed rule provides that if compliance with the new rule requires any changes to our board, we will be required to comply commencing with our 2004 annual meeting. If the Nasdaq proposal is adopted, we will comply with the new rules in their final form. In order for a majority of our directors to be independent, we would need to (a) ask up to three of our non-independent directors to resign followed by appointment of three new independent directors and/or (b) increase the size of our board by adding up to six additional independent directors. Any increase in the size of our board or change in its membership might give rise to inefficiencies, which might cause some board actions to be delayed.

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

Biosearch and its subsidiary historically funded a portion of their operations through research grants and loan subsidies awarded by Italian and EU authorities. Under applicable law, any transfer of those grants and subsidies (including transfer by merger) requires written approval from the Italian bank authorized to make the disbursement on behalf of the government and from the appropriate Italian or EU authorities. In connection with the merger, we applied for permission to transfer Biosearch s grants and subsidies to our Italian branch. Although the merger has recently been completed, the Italian and EU authorities have not as yet reached an official decision on whether to approve our transfer requests. If the transfers are approved, we intend to apply for further permission to contribute the grants and subsidies to Vicuron Italy S.r.l., our newly-formed subsidiary in Italy. We face the risk that one or both of the transfers might not be approved, in which case we might be required to repay some or all of the grants and subsidies received by Biosearch prior to the merger, in the aggregate amount of up to approximately $1.8 million as of March 31, 2003 and we may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of March 31, 2003 by the authorized bank, in the aggregate amount of up to approximately $1.1 million as of March 31, 2003 (each estimate based on exchange rates then prevailing). Regardless of whether or not we are required to repay those grants, we anticipate that our Italian subsidiary will be eligible to apply for new research grants and subsidies from both the Italian and EU authorities. However, grants and subsidies are awarded in the discretion of those authorities and we face the risk that our Italian subsidiary might not qualify or be approved for any additional grants or subsidies in the future.

As a result of our recently completed merger, we will operate in both the United States and Italy, which will increase our costs of doing business and might result in additional, unexpected challenges.

As a result of our recently completed merger, our operations will be located both in the United States and Italy. This expansion will cost us time and resources that we would not have to spend if our operations were confined within one country only, such as:

our management will need to devote additional time to overseeing operations in two countries;

language barriers within our company and with contractual counterparties in Italy might result in misunderstandings, improperly executed instructions and additional translation costs, and language translations themselves might lead to inaccuracies; and

If we are unable to attract and retain skilled employees and consultants, we will be unable to develop and commerc

internal transportation and communications costs will increase in order for personnel, resources and ideas to be shared between the two countries.

The increased time and resources we spend to manage operations internationally will result in an increase in our historical cost of doing business. In addition, international operations might present other challenges. For example, the cultural differences between business operations (generally including employer-employee relations) in the United States and those in Italy might reduce some of the benefits of the merger.

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

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

issuing each material announcement in both English and Italian might cause administrative challenges;

submitting filings and applications with regulatory and governmental authorities in the U.S., Italy and the EU, and approving translations of each significant document into the other language, if necessary, would be time-consuming and expensive and might distract our executives from their primary focus of managing our business, and language translations themselves might lead to inaccuracies;

under Italian employment law, our relations with our employees in Italy is governed by collective bargaining agreements negotiated at the national level (and over which we have no control), which reduces the methods customarily available in the United States to motivate and discipline our Italian employees;

under European Union data protection regulations, we are unable to send without restriction private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices; and tariffs, customs, duties, import restrictions, tax effects and other trade barriers might delay or increase the cost of relocating personnel and, if marketing approvals are obtained, commercial quantities of our products between nations.

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

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

Risks Related to Operating in Our Industry

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

Our efforts to develop and market our product candidates will be subject to extensive and rigorous domestic regulation. FDA rules govern, among other matters, the development, testing, manufacture, safety, efficacy, record-keeping, labeling, storage, approval, advertising, promotion, sale and distribution of pharmaceutical products in the United States. Any products that we market abroad will also be subject to extensive regulation by foreign governments. In order to obtain permission to sell our product candidates, we must provide the FDA and foreign regulatory authorities with clinical data demonstrating that our proposed drugs are safe in humans and effective at treating an indicated condition. None of our product candidates has been approved for sale in the United States or any foreign market, and we cannot predict whether regulatory clearance will be obtained for any product that we are developing or intend to develop. The regulatory review and approval process takes many years, is dependent upon the type, complexity and novelty of the product candidate, requires the expenditure of substantial resources, involves post-marketing surveillance, and might involve ongoing requirements for post-marketing studies. Delays in obtaining regulatory approvals might:

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

require us or our collaborators to comply with costly additional procedures;

diminish any competitive advantage that we or our collaborators might attain from early market introduction of a new product; and

delay or eliminate our receipt of revenues or royalties.

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

imposed delays in clinical trials or commercialization;

refusal by the FDA and foreign regulators to review pending market approval applications or supplements to approval applications;

product recalls or seizures;

suspension of production;

withdrawals of previously issued marketing approvals; and

fines, civil penalties and criminal prosecutions.

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

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

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

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

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

Manufacturing facilities are required to comply with FDA Good Manufacturing Practice regulations. Even facilities outside the United States must comply with these regulations if the manufactured products will be sold in the United States. Good Manufacturing Practice regulations include requirements relating to quality control and quality assurance as well as to maintenance of records and documentation. Manufacturing facilities are subject to inspection by the FDA. These facilities must be approved before we can use them in commercial manufacturing of our products. Comparable Good Manufacturing Practice regulations also apply in the EU, Italy and other foreign countries. Our contract manufacturers and our manufacturing subsidiary might not be able to comply with the applicable Good Manufacturing Practice requirements and other FDA or other EU, Italian or foreign regulatory agencies regulatory requirements.

If 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 amphotericin B (marketed by several manufacturers), fluconazole (marketed as Difulcan by Pfizer), itraconazole (marketed as Sporanox by Johnson & Johnson), and potentially from caspofungin (marketed as Cancidas by Merck), which was the first to receive FDA approval of a new class of antifungal agents called echinocandins (which includes anidulafungin). Merck initially obtained approval only for the narrow indication of aspergillosis salvage therapy, but might in the future expand the scope of Cancidas to include other serious fungal infections, such as esophageal and invasive candidiasis;

if dalbavancin receives FDA and international marketing approval, it will face competition from commercially available drugs such as vancomycin (marketed generically by several manufacturers), teicoplanin (marketed as Targocid by Aventis only outside of the United States), linezolid (marketed as Zyvox by Pfizer) and quinupristin/dalfopristin (marketed as Synercid by Aventis), and drug candidates in clinical development such as daptomycin (expected to be marketed as Cidecin by Cubist), which is currently 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 (marketed generically by several manufacturers) as well as drugs focused on the treatment (as opposed to prevention) of bloodstream vancomycin-resistant enterocci infections in hospitalized patients, such as linezolid (marketed as Zyvox by Pfizer) and quinupristin/dalfopristin (marketed as Synercid by Aventis).

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

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.

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

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

Our success depends in part on our ability to:

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

We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that our intellectual property is covered by valid and enforceable patents or is effectively maintained as a trade secret. Based on information available as of March 31, 2003, we have 34 issued U.S. patents and 12 U.S. patent applications, 429 foreign patents and 87 foreign patent applications. Our license agreement with Eli Lilly with respect to anidulafungin covers 14 U.S. patents, 12 U.S. patent applications, 71 foreign patents and 125 foreign patent applications. Our collaborative agreement with Pfizer with respect to the development of oxazolidinones includes three U.S. patents and four U.S. patent applications. Our collaborative agreement with Novartis includes three U.S. patent applications. We also acquired 452 additional patents and 96 patent applications as a result of our recent merger with Biosearch.

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

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

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

Research has been conducted for many years in the areas in which we focus our research and development efforts. This has resulted in a substantial number of issued patents and an even larger number of still-pending patent applications. Patent applications in the United States are,

in most cases, maintained in secrecy until patents are issued. The publication of discoveries in the scientific or patent literature frequently occurs substantially later than the date on which the underlying discoveries were made. Our commercial success will depend significantly on an ability to operate without infringing the patents and other intellectual property rights of third parties. However, our technologies might infringe the patents or violate other intellectual property rights of third parties without our knowledge. In the event an infringement claim is brought against us, we might be required to pay legal and other expenses to defend such a claim and, if our defense is unsuccessful, we might be prevented from pursuing product development and commercialization and might be subject to damage awards.

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

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

enforce patents that we own or license;

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

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

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

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

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

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

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

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

Risks Related to the Securities Markets

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

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

clinical trial data;

general economic conditions;

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

future sales of equity or debt securities;

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

announcements of scientific innovations by us or our competitors;

actual or anticipated variations in our annual and quarterly operating results;

conditions or trends in the biotechnology and pharmaceutical industries;

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

additions or departures of key personnel;

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

sales of our common stock.

In addition, the stock market in general, and the Nasdaq National Market, the Nuovo Mercato and the market for biotechnology and pharmaceutical stocks in particular, have experienced significant price and volume fluctuations. Over the 52-week period ending April 30, 2003, the market price of Vicuron common stock as reported on the Nasdaq National Market ranged from a high of $14.10 to a low of $7.85. Volatility in the market price for particular companies has often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors might seriously harm the market price of our common stock, regardless of our operating performance. In addition, securities class action litigation has often been initiated following periods of volatility in the market price of a company s securities. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management s attention and resources.

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

We have implemented anti-takeover provisions that could delay or prevent any attempt to replace or remove the management.

Provisions of our restated certificate of incorporation, our bylaws, as amended and restated upon completion of the merger, and our shareholder rights plan might increase the likelihood that any third party would need to negotiate with our board prior to initiating a takeover proposal for our company and could have the effect of delaying or preventing a change of control of our company. In addition, some of our stockholders have entered into a stockholders agreement in which they have agreed, for a period of three years following completion of the merger, to vote as recommended by the board on some issues. These provisions could delay or prevent an attempt to replace or remove our management.

We are subject to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro, which could

ITEM 3: Quantitative and Qualitative Disclosures about Market Risk

Interest Rates

Our exposure to interest rate risk relates to our cash and cash equivalents and marketable securities as well as our loans and notes with commercial banks. Our marketable securities are subject to interest rate risk and could decline in value if interest rates fluctuate. However, due to the conservative and short-term nature of these investments, such exposure is limited. Our borrowings are also exposed to interest rate risk as the majority of our debt is based on variable interest rates.

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

	2003	2004	2005	2006
Cash and cash equivalents	$ 39,668	$	$	$
Average interest rate	1.51%			
Marketable securities	$ 105,429	$ 6,046	$ 105	$ 336
Average interest rate	2.38%	2.74%	3.30%	4.00%

Our cash and cash equivalents and marketable securities have increased substantially since December 31, 2002 as a result of our recent merger with Biosearch.

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

The estimated fair value of our cash and cash equivalents and marketable securities approximate the principal amo

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

The estimated fair value of our debt obligations approximates the principal amounts due based on the interest rates

Inflation

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

Exchange Rates

As a result of our recent merger with Biosearch, we are exposed to risks resulting from fluctuations in the exchange rate of the dollar relative to the euro. A portion of our consolidated revenues and costs now arise in euros. To manage this risk, we intend to maintain a portion of our cash and cash equivalents and marketable securities denominated in euros.

As a result of our recent merger with Biosearch, we are exposed to risks resulting from fluctuations in the exchange

ITEM 4. CONTROLS AND PROCEDURES

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

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our President and Chief Executive Officer along with our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon the foregoing, our President and Chief Executive Officer along with our Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to our company required to be included in our Exchange Act reports. There have been no significant changes in our internal controls or in other factors which could significantly affect internal controls subsequent to the date we carried out our evaluation.

As a result of our recent merger with Biosearch, we are exposed to risks resulting from fluctuations in the exchange

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not a party to any significant legal proceedings.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

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

On April 9, 2002, we completed a private placement of 2,993,800 shares of our common stock to selected institutional investors for gross proceeds of $44.9 million. The private placement was conducted pursuant to an exception under Rule 506 of Regulation D of the Securities Act. These shares were subsequently registered with the SEC.

On February 28, 2003, we issued approximately 21.4 million shares to acquire all of the outstanding shares of Biosearch Italia S.p.A.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

Exhibits

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

Reports on Form 8-K

On March 3, 2003, we filed a Form 8-K announcing the completion of our merger with Biosearch.

On March 17, 2003, we filed a Form 8-K attaching the conference call script for a presentation made by management regarding our Phase III trial results with anidulafungin for esophageal canididiasis.

On March 26, 2003, we filed a Form 8-K reporting the change of our name from Versicor Inc. to Vicuron Pharmaceuticals Inc.

SIGNATURES

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

VICURON PHARMACEUTICALS INC.

Date: May 15, 2003

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

Date: May 15, 2003

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

CERTIFICATIONS

I, George F. Horner III, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vicuron Pharmaceuticals Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

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

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

Date: May 15, 2003

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

I, Dov A. Goldstein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Vicuron Pharmaceuticals Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) Evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

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

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

Date: May 15, 2003

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

EXHIBIT INDEX

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

The following exhibits are included, or incorporated by reference, in this Quarterly Report on Form 10-K for fiscal year 2002 (and are numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	**Description**
2.1	Agreement and Plan of Merger, dated as of July 30, 2002, by and between Vicuron Pharmaceuticals Inc. and Biosearch Italia, S.p.A. (the body of the agreement was previously attached as Exhibit 2.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on July 31, 2002 and is incorporated by reference herein)
2.2	First Amendment to Agreement and Plan of Merger entered into on August 14, 2002, by and between Vicuron Pharmaceuticals Inc. and Biosearch Italia S.p.A. (3)
2.3	Second Amendment to Agreement and Plan of Merger entered into on October 29, 2002, by and between Vicuron Pharmaceuticals Inc. and Biosearch Italia S.p.A. (3)
3.1	Fourth Amended and Restated Certificate of Incorporation of Vicuron Pharmaceuticals Inc. (1)
3.2	Certificate of Amendment and Restatement of the Certificate of Designations of Vicuron Pharmaceuticals Inc. (previously attached as Exhibit 3.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on July 11, 2001 and is incorporated herein by reference)
3.3	Certificate of Merger relating to the merger of Biosearch Italia S.p.A. with and into Vicuron Pharmaceuticals Inc. (4)
3.4	Certificate of Ownership and Merger Merging Vicuron Pharmaceuticals Inc. into Versicor Inc. (previously attached as Exhibit 3.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on March 26, 2003 and is incorporated herein by reference)
3.5	Amended and Restated Bylaws of Vicuron Pharmaceuticals Inc., as currently in effect (4)
4.1	Form of Common Stock Certificate (1)
4.2	Warrant for the Purchase of Shares of Common Stock dated as of March 10, 1997, by and between Genome Therapeutics, Inc. and Vicuron Pharmaceuticals Inc. (1)
4.3	Form of Warrant for the Purchase of Shares of Series F Preferred Stock dated as of June 25, 1999(1)
4.4	Second Amended and Restated Investors Rights Agreement (1)
4.5	Shareholder Rights Agreement by and between Vicuron Pharmaceuticals Inc. and American Stock Transfer & Trust Company, as Rights Agent, dated June 28, 2001 (previously attached as Exhibit 4.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on July 11, 2001 and is incorporated herein by reference)

4.6 First Amendment to Shareholder Rights Agreement, dated as of July 30, 2002, by and between Vicuron Pharmaceuticals Inc. and American Stock Transfer & Trust Company, as Rights Agent (previously attached as Exhibit 4.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on July 31, 2002 and is incorporated by reference herein)

4.7 Registration Rights Agreement dated as of April 8, 2002, by and between Vicuron Pharmaceuticals Inc. and the Purchasers listed on Schedule A attached thereto (previously attached as Exhibit 4.1 to Vicuron s current report on Form 8-K, which was filed with the SEC on April 10, 2002 and is incorporated by reference herein)

9.1 Letter Agreement dated as of February 28, 2003, by and between Vicuron Pharmaceuticals Inc. and Monte Titoli S.p.A. (4)

10.1 Form of Indemnity Agreement (4)

99.1 Certification under Section 906 of the Sarbanes-Oxley Act of 2002(4)

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

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

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

(4) Filed herewith.