VICURON PHARMACEUTICALS INC
Form 10-Q
November 08, 2004

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended: September 30, 2004

OR

¨ 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 No.)**

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)

n/a

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 x No ¨.

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

On October 17, 2004, there were 60,178,158 common shares outstanding of the registrant s only class of common stock.

The Exhibit Index begins on page 31.

VICURON PHARMACEUTICALS INC.

Quarterly Report on Form 10-Q

For the Three Months Ended September 30, 2004

INDEX

PART I.	**FINANCIAL INFORMATION**	**3**
Item 1.	**Condensed Consolidated Financial Statements**	**3**
	Consolidated Balance Sheets as of September 30, 2004 and December 31, 2003	3
	Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2004 and 2003	4
	Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2004 and 2003	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	**Management s Discussion and Analysis of Financial Condition and Results of Operations**	**9**
Item 3.	**Quantitative and Qualitative Disclosures About Market Risk**	**29**
Item 4.	**Controls and Procedures**	**29**
PART II.	**OTHER INFORMATION**	**29**
Item 1.	**Legal Proceedings**	**29**
Item 2.	**Unregistered Sales of Equity Securities and Use of Proceeds**	**30**
Item 3.	**Defaults upon Senior Securities**	**30**
Item 4.	**Submission of Matters to a Vote of Security Holders**	**30**
Item 5.	**Other Information**	**31**
Item 6.	**Exhibits and Reports on Form 8-K**	**31**
	Signatures	**31**
	Exhibit Index	**31**
	Certifications	

PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

VICURON PHARMACEUTICALS INC.

CONSOLIDATED BALANCE SHEETS

(unaudited)

(in thousands)

	September 30, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 79,576	$ 113,361
Marketable securities	16,730	52,796
Accounts receivable, net	5,013	5,533
Prepaid expenses and other current assets	5,689	6,329
Total current assets	107,008	178,019
Property, plant and equipment	53,671	43,757
Intangible assets, net	23,356	23,373
Long-term receivables	11,411	9,787
Long-term marketable securities restricted	2,983	3,232
Other assets	328	330
Total assets	$ 198,757	$ 258,498
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 8,866	$ 13,986
Accrued liabilities	13,020	15,085
Current portion of long-term debt	609	2,360
Current portion of deferred revenue	839	1,068
Total current liabilities	23,334	32,499
Long-term debt, less current portion	7,386	7,493
Deferred revenue, less current portion	1,554	1,750
Other long-term liabilities	7,786	2,973
Total liabilities	40,060	44,715
Stockholders equity:		
Common stock	55	54
Additional paid-in capital	528,694	518,275

Deferred stock compensation	(235)	(454)
Accumulated other comprehensive income	19,962	22,632
Accumulated deficit	(389,779)	(326,724)
Total stockholders equity	158,697	213,783
Total liabilities and stockholders equity	$ 198,757	$ 258,498

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		Nine Months Ended	
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Revenues:				
Collaborative research and development, contract services and government grants	$ 1,692	$ 2,173	$ 5,262	$ 6,054
License fees and milestones	136	626	411	784
Total revenues	1,828	2,799	5,673	6,838
Operating expenses:				
Research and development	12,795	18,113	54,183	55,996
General and administrative	4,891	4,164	16,154	9,886
Acquired in-process research and development				94,532
Total operating expenses	17,686	22,277	70,337	160,414
Loss from operations	(15,858)	(19,478)	(64,664)	(153,576)
Other income (expense):				
Investment income	448	607	1,678	1,777
Interest expense	(16)	(43)	(69)	(155)
Net loss	$ (15,426)	$ (18,914)	$ (63,055)	$ (151,954)
Net loss per share:				
Basic and diluted	$ (0.28)	$ (0.36)	$ (1.16)	$ (3.38)
Weighted average shares	54,882	52,799	54,511	44,903

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

VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net loss	$ (63,055)	$ (151,954)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,844	3,440
Non-cash stock compensation expense	275	1,437
Amortization of bond discounts	683	
Acquired in-process research and development		94,532
Changes in operating assets and liabilities, net of effect of merger:		
Accounts receivable	341	(1,622)
Prepaid expenses and other current assets	1,669	2,329
Long-term receivables	(1,540)	(1,130)
Other assets	2	225
Accounts payable	(4,938)	(3,581)
Accrued liabilities	(1,964)	2,573
Deferred revenue	(405)	(904)
Other long-term liabilities	(655)	72
Net cash used in operating activities	(64,743)	(54,583)
Cash flows from investing activities:		
Purchases of marketable securities	(15,016)	(49,620)
Sales/maturities of marketable securities	50,333	127,491
Additions to property and equipment	(10,947)	(11,229)
Sale of property and equipment	88	
Net cash and cash equivalents acquired in Biosearch merger		772
Net cash provided by investing activities	24,458	67,414
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	9,937	78,886
Proceeds from long-term debt		2,693
Repayments of long-term debt	(1,745)	(1,574)
Net cash provided by financing activities	8,192	80,005
Effect of exchange rate changes on cash and cash equivalents	(1,692)	2,956
Net change in cash and cash equivalents	(33,785)	95,792
Cash and cash equivalents at beginning of period	113,361	28,271

Cash and cash equivalents at end of period	$ 79,576	$ 124,063
Supplemental cash flow information:		
Cash paid during the period for interest	$ 64	$ 159
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 CONSOLIDATED 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 necessary for a fair presentation of the results for the interim periods ended September 30, 2004.

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, 2003, which are included in Vicuron Pharmaceuticals Inc. s or the Company s Annual Report on Form 10-K for the year ended December 31, 2003.

On March 26, 2003, as a result of the Company s merger with Biosearch Italia S.p.A., a publicly listed company in Italy, the Company changed its name from Versicor Inc. to Vicuron Pharmaceuticals Inc.

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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(in thousands, except per share data)			
	(unaudited)			
Net Loss, as reported	$ (15,426)	$ (18,914)	$ (63,055)	$ (151,954)
Add: stock-based employee compensation expense included in net loss	18	259	87	831
Less: total stock-based employee compensation, determined under fair value based method for all awards	(1,200)	(4,908)	(6,697)	(11,970)
Net loss pro forma	$ (16,608)	$ (23,563)	$ (69,665)	$ (163,093)
Basic and diluted net loss per share: As reported	$ (0.28)	$ (0.36)	$ (1.16)	$ (3.38)

Pro forma	$ (0.30)	$ (0.45)	$ (1.28)	$ (3.63)

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):

	September 30,	
	2004	2003
Shares issuable upon exercise of stock options	8,172	9,082
Shares issuable upon exercise of warrants	39	195
	8,211	9,277

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

On February 28, 2003, the Company acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. In connection with the merger transaction, 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 of its common stock, including options issued to replace options that were held by Biosearch employees and consultants at the date of the transaction.

The following unaudited pro forma consolidated financial information has been prepared as if the merger with Biosearch had occurred as of January 1, 2003 (in thousands, except per share amounts):

	Nine Months Ended September 30, 2003
Revenues	$ 8,216
Net loss	$ (63,481)
Net loss per share:	
Basic and diluted	$ (1.28)
Weighted average shares	49,414

The unaudited pro forma consolidated financial information is not necessarily indicative of the Company s future results of operations which might have occurred had the merger actually taken place on January 1, 2003.

4. Comprehensive Loss

For the three month and nine month periods ended September 30, 2004 and 2003, the components of total comprehensive loss are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	(in thousands) (unaudited)			
	2004	2003	2004	2003
Net loss (as reported)	$(15,426)	$ (18,914)	$ (63,055)	$ (151,954)
Foreign currency translation adjustment	2,774	1,876	(2,584)	10,239
Unrealized (loss) on investments	48	47	(85)	(37)
Other comprehensive income/(loss)	2,822	1,923	(2,669)	10,202
Net Comprehensive loss	$(12,604)	$ (16,991)	$ (65,724)	$ (141,752)

5. Restructuring Charge

On May 25, 2004, the Company received an approvable letter from the U.S. Food and Drug Administration (FDA). However, the letter indicated that our NDA submission for anidulafungin does not currently support a labeling claim for the initial treatment of esophageal candidiasis. Based on the approvable letter and discussions with the FDA, the Company intends to pursue two paths for approval of anidulafungin, as follows:

amending its existing NDA for the potential treatment of esophageal candidiasis; and

submitting an additional NDA for the potential treatment of invasive candidiasis/candidemia.

The Company has also reduced its expenses in light of this delay. Between the period of May 31, 2004 and July 2, 2004, the Company reduced its workforce in the United States. The severance charge was $864,000 of which $560,000 was paid in the second quarter of 2004 and $218,000 was paid in the third quarter of 2004. The accrued severance balance at September 30, 2004 was $86,000. The Company also reduced its Italian workforce in the last week of September 2004. The related severance charge was $1.8 million. None of the severance was paid out in the third quarter and the accrued severance balance at September 30, 2004 was $1.8 million. The severance charge was included in the research and development and general and administrative expense line items on the consolidated statement of operations.

6. Recent Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51. FIN 46 was revised by FIN 46 R in December 2003. FIN 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 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 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of this standard did not have a material impact on the Company s financial statements.

7. Segment Information

The Company evaluates performance of its segments and allocates resources to them based upon its strategy related to the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of bacterial and fungal infections in the hospital setting.

The Company s revenue for the nine month period ended September 30, 2004 consisted primarily of collaborative research and development fees from Pfizer and Novartis of $2.7 million and $2.0 million, respectively.

As a result of the merger with Biosearch Italia in 2003, the Company now operates in two geographic segments, including the United States and Italy. The United States operations include the corporate headquarters, clinical development and research. The operations in Italy include a research facility and a manufacturing plant which is under construction.

The table below presents geographic information about reported segments for the nine months ended September 30, 2004:

	(in thousands) (unaudited)		
	United States	Italy	Consolidated
Net revenue	$ 4,720	$ 953	$ 5,673
Long lived assets	$ 4,081	$ 87,668	$ 91,749

8. Legal Proceedings

Beginning on June 15, 2004, six shareholder securities class action complaints were filed against the Company and certain of the Company s senior officers in the U. S. District Court for the Eastern District of Pennsylvania, collectively the Federal Class Actions. Each complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 arising from the Company s May 24, 2004 press release announcing the approvable letter from the FDA indicating anidulafungin does not currently support a labeling for initial treatment of esophageal candidiasis. Each plaintiff seeks to represent a class of Vicuron securities purchasers from January 6, 2003, through May 24, 2004, (except one complaint, whose putative class period begins March 17, 2003). The complaints seek compensatory damages, interest, attorneys fees, and injunctive and equitable relief. The Company intends to defend this litigation vigorously.

On August 18, 2004, counsel for all parties involved in the Federal Class Actions stipulated to consolidation of the six actions. Under the stipulation, defendants are not required to respond to the six individual complaints. Rather, defendants will respond to an amended, consolidated class action complaint that will be filed by the court-appointed lead plaintiff and lead plaintiff counsel, or the Consolidated Complaint. The District Court approved the Consolidation Stipulation on August 23, 2004. The Court s order provides that:

the designated lead plaintiff will have 60 days to file the Consolidated Complaint once appointed by the District Court;

defendants will file a responsive pleading within 60 days of service of the Consolidated Complaint; and

in the event defendants responsive pleading is a motion to dismiss, plaintiffs opposition papers will be due 60 days from the filing of the motion, and any reply papers by defendants will be due 30 days thereafter.

Three motions were filed with the District Court pursuant to 15 U.S.C. 78u-4(a)(3)(A)(i)(II) proposing a lead plaintiff and lead plaintiff counsel. On October 7, 2004, the Court entered an order appointing the group of institutional investors (Massachusetts State Guaranteed Annuity Fund, Massachusetts State Carpenters Pension Fund, and Greater Pennsylvania Carpenters Pension Fund) as lead plaintiffs, the law firm of Lerach Coughlin Stoia Geller Rudman & Robbins as lead plaintiffs counsel, and the law offices of Marc S. Henzel as liaison counsel. Based on the Court s order of August 23, 2004, plaintiffs must file a consolidated amended complaint by December 6, 2004. The Court has ordered a status conference in the Federal Class Actions for November 1, 2004.

On July 2, 2004, a shareholder derivative complaint styled *Jonathan Meyers vs. George F. Horner, III et al.* was filed against certain of the Company s officers and directors in the Court of Common Pleas of the State of Pennsylvania, Montgomery County (Case no. 04-19595). The complaint purports to allege claims of insider selling, breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment. The complaint seeks compensatory damages, disgorgement of profits, imposition of a constructive trust, equitable and injunctive relief, attorneys fees and costs. On August 11, 2004, counsel for the parties entered a stipulation to stay all proceedings in the state court derivative action, pending the District Court s resolution of the motion to dismiss that defendants expect to file in the Federal Class Actions. Under the stipulation to stay, defendants time to respond to the derivative complaint is extended until 60 days after the stay expires. The Court approved the stipulation, and stayed the derivative action, on August 17, 2004.

9. Subsequent Event

On October 5, 2004, the Company closed its public offering of 5,051,000 shares of common stock at $14.75 per share. The Company received net proceeds of approximately $71.4 million.

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements for the year-ended December 31, 2003 included in our Annual Report on Form 10-K previously filed with the Securities and Exchange Commission, or the SEC. This discussion may contain forward-looking statements that involve risks and uncertainties. The words expects, believes, anticipates, intends, will and similar expressions or the negatives of these words or 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 on Form 10-K, our actual results may differ significantly from those anticipated in these forward-looking statements. References to the Company, Vicuron, and We throughout this Form 10-Q shall all refer to Vicuron Pharmaceuticals Inc. and its subsidiaries.

Overview

We are a transatlantic biopharmaceutical company focused on discovering, developing, manufacturing and commercializing pharmaceutical products for the treatment of seriously ill patients. Since our inception on May 2, 1995 as a wholly-owned subsidiary of Sepracor Inc., we have devoted substantially all of our efforts to establishing our business and conducting research and development activities related to our proprietary product candidates, including anidulafungin and dalbavancin, as well as collaborative product candidates.

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

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

On February 28, 2003, we acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly listed company in Italy. We have issued 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares. On June 30, 2003 we contributed the former assets, liabilities and business of Biosearch to our wholly-owned subsidiary in Italy, Vicuron Pharmaceutical Italy S.r.l.

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

In February 2004, we filed a universal shelf registration statement on Form S-3, which has been declared effective. This shelf registration will allow us to offer up to $200.0 million of our securities from time to time in one or more public offerings of our common stock, preferred stock, warrants and/or debt securities.

On October 5, 2004, we closed our public offering of 5,051,000 shares of our common stock at $14.75. We received net proceeds of approximately $71.4 million.

Since we began our operations in 1995, we have not generated any revenues from product sales. In early 2003, we completed a Phase III clinical trial with anidulafungin, our lead antifungal product candidate, for the treatment of esophageal candidiasis. Based in part on the results of that trial, in April 2003 we filed a New Drug Application or NDA for anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In January 2004, we announced that we received notification from the FDA that the agency would complete its review of our anidulafungin NDA on May 25, 2004, which represented a 90-day extension of the original action date. The extension was the result of the FDA s request for additional bioanalytical data. On May 25, 2004, we received an approvable letter from the FDA. Based on the approvable letter and discussions with the FDA, we intend to pursue two paths for approval of anidulafungin, as follows:

amending our existing NDA for the potential treatment of esophageal candidiasis; and

submitting an additional NDA for the potential treatment of invasive candidiasis/candidemia.

We also reduced expenses in light of this delay. We can provide no assurance regarding the outcome and/or timing of the FDA review. In December 2003, we also announced the filing of our marketing authorization application for anidulafungin for the treatment of esophageal candidiasis with the European Agency for the Evaluation of Medicinal Products, which will be reviewed under the European Community centralized licensing procedure, which is the procedure used to determine the scope of marketing authorization for human therapeutic products in all member states of the European Union. A 90 day extension for submitting responses to EMEA was requested by Vicuron and granted by the EMEA.

We also plan to file an NDA for our lead antibiotic product candidate, dalbavancin, with the FDA by the end of this year. Dalbavancin is a second-generation glycopeptide antibiotic belonging to the same class as vancomycin, the most widely-used injectable antibiotic for serious Staphylococcal infections.

We also completed a Phase I clinical trial of VIC-Acne in 2003. We have several lead compounds in pre-clinical 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. Certain of these payments are dependent on the achievement of specified milestones. If the development efforts result in clinical success, regulatory approval and successful commercialization of our products, we will generate revenues from sales of these products and from receipt of royalties on sales of these products.

Our expenses have consisted primarily of costs incurred when in-licensing existing product candidates, research and development of new product candidates and in connection with our collaboration agreements, and from general and administrative costs associated with our operations. We expect licensing costs to increase as development milestones are achieved, and our research and development expenses to increase as we continue to develop our product candidates. We expect to incur sales and marketing expenses in the future as we establish our sales and marketing organization.

Since our inception we have incurred significant losses. As of September 30, 2004, we had an accumulated deficit of $389.8 million. We anticipate incurring additional losses, which may increase for the foreseeable future, including at least through December 31, 2006.

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 to ascertain.

Major Research and Development Projects

Our ongoing clinical trials of anidulafungin and dalbavancin are our two most significant research and development projects, generating 26% and 22%, respectively, of our total research and development expenditure since our inception.

Anidulafungin

Anidulafungin is our lead antifungal product candidate and a Phase III clinical trial for the treatment of esophageal candidiasis has been completed. We in-licensed anidulafungin from Eli Lilly pursuant to the May 1999 agreement described below. As of September 30, 2004, the intravenous formulation of anidulafungin is in Phase III clinical trial for the treatment of invasive candidiasis/candidemia. We have completed enrollment of this trial. We also completed a Phase III clinical trial for the treatment of aspergillosis and top line data has already been released.

In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of anidulafungin. If specified milestones are achieved on the intravenous formulation of anidulafungin in the United States and Canada, we will be obligated to make additional payments of up to $8.0 million to Eli Lilly. We 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 have also made a $6.0 million milestone payment to Eli Lilly in 2003, which was triggered by our filing of the NDA with the FDA.

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:

- 12% for the nine months ended September 30, 2004 compared to 23% for the nine months ended September 30, 2003; and
- 26% in the aggregate from our inception through September 30, 2004.

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 FDA, and analogous international agencies. We will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. 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 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 researchers 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 cause our stock price to fall and make it more difficult for us to raise equity capital on attractive terms or at all.

Dalbavancin

Dalbavancin is our lead antibiotic product candidate. As of September 30, 2004, dalbavancin has been evaluated in:

- three Phase III clinical trials for the treatment of skin and soft tissue infections (completed and top-line data released); and
- a Phase II clinical trial for the treatment of catheter-related blood stream infections, which was completed and topline data released and publicly presented.
- a Phase II trial in skin and soft tissue infections which was completed and published.

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

- 25% for the nine months ended September 30, 2004, compared to 28% for the nine months ended September 30, 2003; and
- 22% in the aggregate from our inception through September 30, 2004.

Our development administration overhead costs are included in total research and development expense for each period; these costs are not allocated among our various projects.

The goal of our dalbavancin project is to obtain marketing approval from the FDA and analogous international agencies. We will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. In August 2004, the Company announced results from pivotal Phase III clinical trials comprising more than 1,500 patients evaluating once-weekly dalbavancin in skin and soft tissue infections (SSTIs) caused by Gram-positive bacteria. All three studies met the primary endpoint of non-inferiority in evaluable patients clinical response at two weeks following therapy when compared to linezolid, cefazolin or vancomycin, the three most widely administered standard-of-care agents for SSTIs. All studies also met the secondary endpoint of non-inferiority in clinical response for the intent-to-treat (ITT) patient population. Dalbavancin was also shown to be well tolerated.

We expect to file an NDA for dalbavancin with the FDA by the end of 2004.

We are unable to estimate the costs to completion for our dalbavancin project due to the risks surrounding the clinical trial process, including the risk that we may repeat, revise or expand the scope of our ongoing clinical trials or conduct additional clinical trials to secure marketing approvals and the additional risks listed under the caption Risk Factors Risks Related to Our Business. 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. Material cash inflows relating to our dalbavancin project will not commence until after marketing approvals are obtained, and then only if dalbavancin finds acceptance in the marketplace. Because of the many risks and uncertainties relating to the completion of clinical trials, receipt of marketing approvals and acceptance in the marketplace, we cannot predict when material cash inflows from our dalbavancin project will commence, if ever.

A failure to obtain marketing approval for dalbavancin would likely have the following results on our operations, financial position and liquidity:

- because our research and development projects are independent, a failure to obtain marketing approval for dalbavancin would not necessarily interrupt our development programs for anidulafungin or our pre-clinical compounds, however, we might reduce our development staff (unless one or more of our other product candidates is then entering late-stage clinical trials, in which case we might be able to 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 cause our stock price to fall and 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 anidulafungin 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:

- 11% for the nine months ended September 30, 2004, compared to 14% for the nine months ended September 30, 2003; and

- 9% in the aggregate from the inception of our company through September 30, 2004.

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

Other Research and Development Projects

The remaining research and development projects were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pfizer and Novartis described below.

Oxazolidinones collaboration with Pfizer. We are party to 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 certain 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. The collaboration expires in March 2005. Through September 30, 2004, Pfizer has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $19.3 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:

5% for the nine months ended September 30, 2004, compared to 5% for the nine months ended September 30, 2003; and

7% in the aggregate from January 1, 1999 through September 30, 2004.

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 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 an 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 and the 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. We are also party to 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 payments of 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. The collaboration agreement expires in March 2005. In September 2003, we announced achievement of a late-stage preclinical milestone for which we received a milestone payment from Novartis. Through September 30, 2004, Novartis has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $17.5 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:

4% for the nine months ended September 30, 2004, compared to 4% for the nine months ended September 30, 2003; and

6% in the aggregate from January 1, 1999 through September 30, 2004.

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 one compound identified by the collaboration is in Phase I clinical trials. 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 an 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, the 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.

In the event that Pfizer or Novartis do not pursue or obtain marketing approval for any product candidate resulting from our collaborations, the following results on our operations, financial position and liquidity could arise:

- 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 likelihood that we would need to obtain additional financing for our internal research and development efforts would increase.

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, or EITF, Issue No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services.

During the period ended September 30, 2004, we increased deferred stock compensation by $56,000. We recorded deferred stock compensation of $881,000 in the nine months ended September 30, 2003. 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 $275,000 and $1.4 million in the nine months ended September 30, 2004 and 2003, respectively.

Results of Operations

Three Months Ended September 30, 2004 Compared to Three Months Ended September 30, 2003

Revenues

Revenues were $1.8 million and $2.8 million in the three months ended September 30, 2004 and 2003. Revenues in 2004 consisted of $1.6 million of collaborative research and development fees from Pfizer and Novartis and $0.2 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in 2003 consisted of $1.6 million of collaborative research and development fees from Pfizer and Novartis and $0.6 million of collaborative research and development and grant revenues from our research operations in Italy. The 2003 revenues also included an amount related to the achievement of a milestone associated with our ongoing research with Novartis.

Research and Development Expenses

Research and development expenses were $12.8 million and $18.1 million in the three months ended September 30, 2004 and 2003, respectively. The decrease in these expenditures was due to the completion of our Phase III clinical trails related to dalbavancin and the reduction of accrued expenses associated with these clinical trials of $2.1 million. This decrease was also attributable to our efforts to reduce expenditures. This decrease was partially offset by the severance charge incurred at our Italian operations.

General and Administrative Expenses

General and administrative expenses were $4.9 million and $4.2 million in the three months ended September 30, 2004 and 2003, respectively. The increase in expenses resulted primarily from costs related to the commencement of the development of a sales and marketing infrastructure.

Investment Income

Investment income was $448,000 and $607,000 in the three months ended September 30, 2004 and 2003, respectively. The decreased income in the third quarter of 2004 was due to a decrease in interest-bearing cash and marketable securities during the period.

Interest Expense

Interest expense was $16,000 and $43,000 in the three months ended September 30, 2004 and 2003, respectively. The decrease was due to a decrease in interest-bearing debt.

Nine Months Ended September 30, 2004 Compared to Nine Months Ended September 30, 2003

Revenues

Revenues were $5.7 million and $6.8 million in the nine months ended September 30, 2004 and 2003. Revenues in 2004 consisted of $4.7 million of collaborative research and development fees from Pfizer and Novartis and $1.0 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in 2003 consisted of $4.6 million of collaborative research and development fees from Pfizer and Novartis and $1.6 million of collaborative research and grant revenue from our research operations in Italy. The 2003 revenues also included an amount related to the achievement of a milestone associated with our ongoing research with Novartis.

Research and Development Fees

Research and development expenses were $54.2 million and $56 million in the nine months ended September 30, 2004 and 2003 respectively. The decrease in expenditure is partly due to the completion of enrollment in several large studies early in the quarter, a planned reduction in expenses and the reduction of estimated expenses associated with the clinical trials of $2.1 million. This decrease was partially offset by the severance charge incurred at our U.S. operations.

General and Administrative Expenses

General and administrative expenses were $16.2 and $9.9 million in the nine months ended September 30, 2004 and 2003 respectively. The increase in expenses in 2004 results from our operations in Italy acquired in the merger, commencement of the development of a sales and marketing infrastructure and amounts paid for severance.

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.

Investment Income

Investment income was $1.7 million and $1.8 million in the nine months ended September 30, 2004 and 2003, respectively. The balance was approximately the same because the average interest-bearing cash and marketable securities were the same during these periods.

Interest Expense

Interest expense was $69,000 and $155,000 in the nine months ended September 30, 2004 and 2003, respectively. The decrease was due to a decrease in interest bearing-debt.

Financial Condition

Assets

As of September 30, 2004 and December 31, 2003, we held total assets of $198.8 million and $258.5 million, respectively. The decrease in total assets was primarily due to the decrease in cash and marketable securities which are used to fund our operations.

Liabilities

As of September 30, 2004 and December 31, 2003, our total liabilities equaled $40.1 million and $44.7 million, respectively. The decrease in total liabilities was primarily due to the decrease in research and development costs.

Stockholders Equity

As of September 30, 2004 and December 31, 2003, our total stockholders equity equaled $158.7 and $213.8, respectively. The decrease in our stockholders equity was primarily due to our year-to-date loss of $63.1 million.

Liquidity and Capital Resources

We have funded our operations principally with the net proceeds of $78.5 million from preferred stock offerings over the period 1995 through 1999, and net proceeds of $52.7 million from our initial public offering received in August and September 2000. In addition, in April 2002, we completed a private placement of shares of common stock to selected institutional investors from which we received net proceeds of approximately $41.9 million. We also increased our cash and cash equivalents and unrestricted marketable securities by $99.1 million as a result of our merger with Biosearch on February 28, 2003. On July 17, 2003, we sold 6,000,000 shares of our common stock at $13.85 per share in a public offering. We received net proceeds of $77.8 million.

We have also received payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor. Of these payments, $1.8 million constitutes deferred revenue as of September 30, 2004.

We also have a $6.0 million term loan and a $2.0 million equipment note with a commercial bank, the latter of which at September 30, 2004 is fully drawn. 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 expenditures. The term loan accrues interest at the prime rate plus 0.5% (the prime rate was 4.75% at September 30, 2004) and the equipment notes interest rate is based on the LIBOR rate plus an applicable margin (the applicable LIBOR rate for our note was 2.21% of September 30, 2004). The term loan and the final note balance are due and payable on December 31, 2004. The outstanding balance of these loans was $525,000 at September 30, 2004.

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 *Ministero Istruzione Università Ricerca*, or MIUR, to fund certain research projects undertaken by Biosearch. This loan matures in January 2011 and at September 30, 2004; the amount outstanding under this loan is $1.2 million.

In addition, in July 2002, we entered into a loan facility 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 $9.3 million (at exchange rates prevailing at September 30, 2004), of which we have drawn $6.3 million. The loan matures in 2012.

In February 2004, we filed a universal shelf registration statement on Form S-3, which has been declared effective. This shelf registration statement will allow us to offer $200.0 million of our securities from time to time in one or more public offerings of our common stock, preferred stock, warrants and/or debt securities.

In October 2004, we closed our public offering of 5,051,000 shares of our common stock at $14.75 per share. We received net proceeds of approximately $71.4 million.

Cash used in operations was $64.7 million and $54.6 million in the nine months ended September 30, 2004 and 2003, respectively. The net loss for the first nine months of 2004 was $63.1 million. In the first nine months of 2003, the net loss of $152.0 million was offset by non-cash charges relating to depreciation and amortization combined with the non-cash charge for acquired in process research and development of $94.5 million.

Cash provided by investing activities was $24.5 million and $67.4 million in the nine months ended September 30, 2004 and 2003, respectively. The principal source of cash in both periods resulted from the net maturity of marketable securities to fund operating losses. The capital expenditures of $11.0 million in 2004 and $11.2 million in 2003 are primarily due to the construction of our manufacturing plant in Pisticci, Italy.

Cash provided by financing activities was $8.2 million and $80.0 million in the nine months ended September 30, 2004 and 2003, respectively. The decrease was due to the fact that we sold 6,000,000 shares of our common stock in July 2003 and received net proceeds of $77.8 million.

At September 30, 2004, our cash and cash equivalents and unrestricted marketable securities totaled $96.3 million compared to $166.2 million at December 31, 2003.

We expect to have negative cash flow from operations for the foreseeable future. We also expect to incur increasing research and development, and general and administrative expenses, including expenses relating to clinical development, additions to personnel, production and commercialization efforts and the integration of our operations with those of Biosearch. Our future capital requirements will depend on a number of factors, including our success in developing markets for our products, payments received or made under collaboration agreements, the timing and outcome of regulatory approvals, the need to acquire licenses to new products or compounds, the status of competitive products and the availability of other financing. We believe our existing cash and cash equivalents and marketable securities at September 30, 2004 will be sufficient to fund our operating expenses, debt repayments and capital requirements for between the next 12 to 18 months.

Recent Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. 46, Consolidation of Variable Interest Entities, an Interpretation of RB No. 51. FIN 46 was revised by FIN 46 R in December 2003. FIN 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 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 46 must be applied for the first interim or annual period beginning after June 15, 2003. The adoption of this standard did not have a material impact on our financial statements.

Application of Critical Accounting Policies

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

Our critical accounting policies are as follows:

Revenue Recognition

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

Valuation Allowance

We have established a valuation allowance to reduce our deferred tax asset to an amount that is more likely than not to be realized. We account for income taxes under the provisions of Statement of Financial Accounting Standards No. 109 Accounting for Income Taxes. Under this method, deferred tax assets and liabilities are expected to affect taxable income when using enacted tax rates in effect for the year in which the differences are expected.

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.

Intangible Assets

The identifiable intangible assets arising from the merger, after allocation of negative goodwill, total $25 million as of December 31, 2003. These intangibles represent patents and core technology, a library of microbial extracts and a bioinformatics software platform. These identifiable intangible assets have estimated useful lives of between two and thirteen years.

RISK FACTORS

In addition to the other information included or incorporated by reference into this Quarterly Report on Form 10-Q, you should carefully consider the following factors in evaluating our company or an investment in any of our securities. Our actual future results and trends may materially differ from our historical results or trends to date, or those anticipated in our forward-looking statements, depending on a variety of factors, including, but not limited to, the factors set forth in this section. The forward-looking statements contained in this Quarterly Report on Form 10-Q represent our expectations as of the date of this Quarterly Report, and subsequent events will cause our expectations to change.

However, while we may elect to update these forward-looking statements, we specifically disclaim any intention or obligation to do so. Additional risks not presently known to us or that we currently deem immaterial might also harm our business.

Risks Related to Our Business

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

In order to become profitable, we anticipate that we will need to obtain FDA marketing approval for anidulafungin and dalbavancin and then commercialize them successfully. In April 2003, we filed an NDA with the FDA seeking approval to market anidulafungin for the treatment of esophageal candidiasis, which was accepted for review by the FDA in June 2003. In May 2004, we received an approvable letter from the FDA indicating that the NDA submission for anidulafungin did not currently support a labeling claim for the initial treatment of esophageal candidiasis. Based on the approvable letter and discussions with the FDA, we intend to pursue two paths for approval of anidulafungin, as follows:

amending our existing NDA for the potential treatment of esophageal candidiasis; and

submitting an additional NDA for the potential treatment of invasive candidiasis/candidemia.

In addition, we recently completed Phase III clinical trials with dalbavancin for the treatment of both complicated and uncomplicated skin and soft tissue infections and we completed a Phase II clinical trial of dalbavancin for catheter-related bloodstream infections. We expect to file an NDA for dalbavancin later this year.

Factors that could negatively affect or delay our receipt of FDA approval of one or both of these drugs include:

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

delays in completing clinical trials for anidulafungin and dalbavancin; and

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

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

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

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

To date, we have not commercialized any products or recognized any revenue from product sales and none of our product candidates are approved for sale. Successful commercialization of a new drug product requires significant investment in research and development, pre-clinical testing and clinical trials, regulatory approval, and sales and marketing activities. Most of our product candidates are in early stages of development. The FDA reviewed our NDA for anidulafungin and found that it did not currently support a labeling claim for the initial treatment of esophageal candidiasis. Anidulafungin and three of our other product candidates 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 among others:

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 regulatory approval we ultimately obtain may be limited or subject to post-approval commitments that render the product not commercially viable.

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

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

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

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

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

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

We have incurred net losses since our inception in 1995. As of September 30, 2004, our accumulated deficit was $389.8 million, including the $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch.

Our accumulated deficit results from our net losses of $1.1 million in 1995, $4.8 million in 1996, $6.7 million in 1997 (including $0.4 million in accretion of dividends on preferred stock), $15.1 million in 1998 (including $2.5 million in accretion of dividends on preferred stock), $67.4 million in 1999 (including deemed dividends of $35.1 million and $3.1 million in accretion of dividends on preferred stock), $18.8 million in 2000 (including $3.5 million in accretion of dividends on preferred stock), $32.8 million in 2001, $48.8 million in 2002, $174.1 million in 2003 (including a $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch), and $63.1 million in the nine months ended September 30, 2004.

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

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

- receiving regulatory approvals for our product candidates;
- developing and testing new product candidates;
- licensing rights to our product candidates to third parties;
- qualifying for and receiving grants and subsidies;
- manufacturing products;
- marketing products; and
- competing with products from other companies.

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

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

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

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

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 regulatory 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 and working with regulators. As a result, these competitors products might come to market sooner or might prove to be more effective, to be less expensive, to have fewer side effects or to be easier to administer than ours. In any such case, sales of our eventual products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

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

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

slower than expected rate of hospital and patient recruitment;

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

unforeseen safety issues;

lack of efficiency during the clinical trials;

inability to adequately follow patients after treatment;

governmental or regulatory delays; and/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. For example, clinical trials may not demonstrate attributes of a product candidate that we observed in pre-clinical testing, such as potency. In addition, 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.

The FDA reviewed an NDA for one of our product candidates, anidulafungin, and found that it did not currently support a labeling claim for the initial treatment of esophageal candidiasis. We have completed enrollment for a Phase III clinical trial for anidulafungin for invasive candidiasis/candidemia. We expect to use the results of this Phase III clinical trial in a new NDA that we plan to file for anidulafungin for the treatment of invasive candidiasis and to partially support an amended NDA for anidulafungin for the treatment of esophageal candidiasis. In addition, we have three other product candidates in clinical trials; dalbavancin, which has completed Phase III; ramoplanin, which has completed Phase II; and VIC-Acne, which has completed Phase I. We also had anidulafungin in Phase III for an additional indication and dalbavancin and ramoplanin in Phase II, each for an additional indication; all of which have concluded and released top-line data. Patient follow-up for these clinical trials has been limited and more trials may be required before we will expect to apply for or obtain regulatory approvals.

Clinical trials conducted by us or by third parties on our behalf might not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for anidulafungin, dalbavancin, ramoplanin or VIC-Acne or any other potential product candidates. Such a failure might delay development of our other product candidates and hinder our ability to conduct related pre-clinical testing and clinical trials. It might also cause regulatory authorities to prohibit us from undertaking any additional clinical trials for our other product candidates. In addition, the final label of any product candidate that receives regulatory approval will be the subject of discussions with the FDA and the product label may be more restrictive than the labeling initially sought by us. 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 September 30, 2004, we had 33 full-time development employees. We expect to continue to rely on third parties, including our collaborators, clinical research organizations and outside consultants, to assist us in managing and monitoring clinical trials. If these third parties fail to perform satisfactorily under the terms of our agreements with them, clinical trials for our product candidates might be delayed or

unsuccessful. Furthermore, the FDA and/or other regulatory agencies of the EU, might inspect some of our clinical investigational sites, our collaborators records and our facilities and files to determine if the clinical trials were conducted according to good clinical practices. If the FDA determines that our clinical trials were not in compliance with applicable requirements, we might be required to repeat the clinical trials.

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

We currently do not have our own manufacturing facilities capable of manufacturing our own products in quantities necessary for large-scale trials or marketing. The Aventis plant in Brindisi, Italy, and the Eagle Picher Pharmaceutical Services plant in the United States will be our initial manufacturing sites for dalbavancin and anidulafungin, respectively. We do not, however, have any long term manufacturing agreement with these or any other third parties. Subsequently, we intend to manufacture products in our own manufacturing plant in Pisticci, Italy, which is currently under construction. To the extent that our manufacturing capabilities are insufficient to produce all of the necessary active ingredients for our current and future product candidates, we anticipate that we might need to rely on third parties to manufacture some or all of these active ingredients. However, there are a limited number of facilities in which our product candidates can be produced, and third-party manufacturers have limited experience in manufacturing

anidulafungin, dalbavancin, ramoplanin and VIC-Acne in quantities sufficient for conducting clinical trials or for commercialization. Difficulties are often encountered in manufacturing new products, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and other regulations, production costs, and development of advanced manufacturing techniques and process controls. Any contract manufacturer might not perform as agreed or might not remain in the contract manufacturing business for the time we require to successfully develop, produce and market our product candidates. If any of our contract manufacturers fails to perform satisfactorily under its agreements with us, such as by failing to deliver the required quantities of our product candidates for clinical use on a timely basis and at commercially reasonable prices, and if we do not find a replacement manufacturer or develop our own manufacturing capabilities, clinical trials involving our product candidates, or commercialization of our products, could be delayed.

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

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

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

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

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

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

The collaborative arrangements might not be on terms favorable to us. Agreements with collaborators typically allow the collaborators significant discretion in electing whether to pursue any of the planned activities. We cannot control the amount and timing of

resources our collaborators devote to the product candidates or their prioritization of the product candidates, and our collaborators might choose to pursue alternative products. In addition, agreements with collaborators frequently contain prohibitions on, and may in the future prohibit us from, conducting certain types of research or other activities in the field that is the subject of the collaboration. In such event, these prohibitions may limit the areas of research and development that we may pursue, either alone or in cooperation with other third parties.

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 any collaborative agreement, our collaborators can generally terminate the agreements under specified circumstances.

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

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

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

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

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

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

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

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

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

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

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

We might seek additional funding, which could dilute our stockholders interest in our company 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 significant research and development, general and administrative and sales and marketing expenses over the next several years. Based on our current plans and assumptions, we estimate that our cash and liquid assets at September 30, 2004 will be sufficient to fund our operating losses for the next 14 to 20 months. However, if our plans change and/or our assumptions are inaccurate, we might need to seek and obtain capital sooner than anticipated. Some of our more significant plans and assumptions relate to:

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

Other than 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, perhaps on unfavorable terms, 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 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 enter into any strategic transactions, we will incur a variety of costs and might never realize the anticipated benefits.

If appropriate opportunities become available, we might attempt to acquire additional products, product candidates or businesses, or enter into joint ventures or reciprocal licensing arrangements, that we believe are a strategic fit with or potentially advantageous to, our business. We are not currently a party to any such strategic agreements. If we pursue any transaction or arrangement of that sort, the process of negotiating the

transaction and integrating an acquired product, product candidate or business or entering into the joint venture or reciprocal licensing arrangement 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 transaction or arrangement. Future acquisitions or other such transactions 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 incur remediation expense and 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.

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 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. In connection with the merger, and the subsequent contribution of Biosearch s assets to Vicuron Pharmaceuticals Italy S.r.l., our wholly owned Italian subsidiary, we applied for permission to transfer Biosearch s grants and subsidies to our Italian branch and subsidiary. Although the merger and the contribution have 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 Pharmaceuticals Italy S.r.l., our wholly-owned 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 $1.6 million as of September 30, 2004, and we may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of September 30, 2004 by the authorized bank in the amount of up to approximately $1.4 million (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 at 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.

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 Delaware corporate law and the rules and regulations of the SEC and the NASDAQ National Market), the EU legal system and the Republic of Italy (including the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or 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 resources 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, is time-consuming and expensive;
- under Italian employment law, our relations with our employees in Italy are governed by collective bargaining agreements negotiated at the national level (and over which we have no control), which reduce the methods customarily available in the United States to motivate and/or make changes to our Italian workforce;
- under EU 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.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud. As a result, current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the trading price of our stock.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning with our fiscal year ending December 31, 2004 to include in our annual report our assessment of the effectiveness of our internal control over financial reporting and our audited financial statements as of the end of fiscal 2004. Furthermore, our independent registered public accounting firm, PricewaterhouseCoopers LLP, will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004. If our independent registered public accounting firm cannot timely attest to our assessment, we could be subject to regulatory sanctions and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations. Any of these failures could have a negative effect on the trading price of our stock.

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 our 2003 merger with Biosearch, 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 balances and cash flows 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.

We are in the process of reducing the number of our employees in Italy, and could incur substantial costs while doing so.

In order to reduce the number of our employees in Italy, we must obtain the approval of the Italian labor unions. Because of the applicable rules and collective bargaining agreements, this process could be protracted and we could incur substantial costs, which have not been fully ascertained, in seeking to implement the reduction. The Italian labor unions may reject our request to reduce the number of our employees in Italy, and our labor force may decide to strike. Even if we obtain the approval of the Italian labor unions, such approval could require us to make severance payments to our former employees in Italy. Further, our former employees in Italy

may assert claims relating to the termination of their employment or their receipt or purchase of our securities in connection with such employment. These claims, regardless of their merits, could cause us to incur substantial costs in defending ourselves and could divert the attention of our management away from our operations, which could harm our business. Further, if any such claims were to result in a judgment against us, we could be required to pay damages, which could harm our business.

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 such as the delays we experienced as a result of receiving the approvable letter for anidulafungin 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 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.

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 the FDA s Good Manufacturing Practice regulations. Even facilities outside the United States, such as the manufacturing plant we are constructing in Italy, 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 our intellectual property rights do not adequately protect our product candidates or future products, others could compete against us more directly, which would harm our business.

Our success depends in part on our ability to protect our intellectual property from unauthorized use by third parties, which we will be able to do only to the extent that our intellectual property is covered by valid and enforceable patents or is effectively maintained as a trade secret. We have rights relating to a number of patents and patent applications in the United States and abroad.

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, circumvented or expired. 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, we periodically review our U.S. and foreign patent filings to determine whether their maintenance is commercially justified. As a result, we may determine from time to time to abandon certain patent applications or allow certain patents to lapse. Moreover, 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.

Our success depends in part on our ability to operate without infringing upon the intellectual property rights of others. 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. U.S. patent applications, which are not foreign filed, can be maintained in secrecy until issuance. U.S. patent applications which are also intended for foreign filing usually publish 18 months after the earliest priority date or within six months of the U.S. filing date, whichever is later. 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.

Our success also depends in part on our ability to prevent others from infringing our intellectual property rights. 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:

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 or other 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 $10.0 million per occurrence and $10.0 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 damages 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 face certain litigation risks that could harm our business.

We have been recently named as a defendant in a number of lawsuits which have asserted various claims. These lawsuits have included several securities class actions and a shareholder derivative lawsuit. The results of complex legal proceedings, such as these, are difficult to predict. Moreover, many of the complaints filed against us do not specify the amounts of damages that plaintiffs seek and, therefore, we are unable to estimate the possible range of damages that might be incurrent should these lawsuits be resolved against us. While we are unable to estimate the potential damages arising from such lawsuits, certain of them assert types of claims that, if resolved against us, could give rise to substantial damages. Thus, an unfavorable outcome or settlement of one or more of these lawsuits could harm our financial position, liquidity or results of operations. Even if these lawsuits are not resolved against us, the uncertainty and expense associated with unresolved lawsuits could seriously harm our business, financial condition and reputation. Litigation can be costly, time-consuming and disruptive to normal business operations. The costs of defending these lawsuits could be quite significant and may not be covered by our insurance policies. The defense of these lawsuits

could also result in continued diversion of our management s time and attention away from business operations, which could harm our business.

Insurance coverage is increasingly difficult to obtain or maintain.

While we currently have insurance for our business, directors and officers, and property and products, first- and third-party insurance is increasingly more costly and narrower in scope, and we may be required to assume more risk in the future. If we are subject to third-party claims or suffer a loss or damage in excess of our insurance coverage, we may be required to share that risk in excess of our insurance limits. Furthermore, any first- or third-party claims made on our insurance policies may impact our future ability to obtain or maintain insurance coverage at reasonable costs, if at all.

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:

- the results of our clinical trials and those of our competitors, and any significant delays or unexpected complications in our clinical trials;
- decisions by regulatory authorities with respect to our development efforts and product candidates;
- public concern regarding the safety and efficacy of drugs we develop;
- new products or services introduced or announced by us or our competitors;
- our ability to successfully commercialize and market any products;
- 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;
- general economic conditions;
- changes in, or failure to achieve, financial estimates by securities analysts;
- new regulatory legislation adopted in the United States or abroad;
- future sales of equity or debt securities by us;
- sales of our common stock by our directors, officers or significant stockholders; and

litigation against us and our directors and officers.

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 October 20, 2004, the market price of our common stock as reported on the NASDAQ National Market ranged from a high of $24.54 to a low of $8.76 and our average daily trading volume was 513,016 shares. 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, as occurred with us in May 2004. Any additional securities class action suits against us could result in substantial costs, potential liabilities and the diversion of management s attention and resources.

We have implemented anti-takeover provisions that could discourage or prevent a takeover, even if an acquisition would be beneficial to our stockholders.

Provisions of our restated certificate of incorporation, our amended and restated bylaws and our shareholder rights plan, or poison pill, increase the likelihood that any third party would need to negotiate with our board prior to initiating a takeover proposal for us and could have the effect of delaying or preventing a change of control of our company. For example, our board of directors, without further stockholder approval, may issue preferred stock (or, in the face of a potential acquirer s increased ownership, rights to purchase our common stock for a nominal price) that could delay or prevent a change of control, as well as reduce the voting power of holders of our common stock. These provisions could delay or prevent an attempt to replace or remove our management. The foregoing factors could also limit the price that investors or an acquirer might be willing to pay in the future for shares of our common stock.

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):

	September 30, 2004
Cash and cash equivalents	$ 79,576
Average interest rate	1.75%
Marketable securities	$ 16,730
Average interest rate	1.85%

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

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

Inflation

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

Exchange Rates

As a result of our 2003 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.

ITEM 4 . CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 each of 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.

As of September 30, 2004, our principal executive officer and our principal financial officer have performed an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act,) and concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC rules and forms. These officers have also concluded that there were no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Beginning on June 15, 2004, six shareholder securities class action complaints were filed against the Company and certain of the Company s senior officers in the U. S. District Court for the Eastern District of Pennsylvania. Those actions are styled: *Perry Paragamian vs. Vicuron Pharmaceuticals, Inc., et al.* (Case No. 04cv2627); *John H Taylor vs. Vicuron Pharmaceuticals, Inc. et al*. (Case No. 04cv2685); *Security Police-Fire Professionals of America vs. Vicuron Pharmaceuticals, Inc. et al.* (Case No. 04cv2708); *Fred Zucker vs. Vicuron Pharmaceuticals, Inc. et al.* (Case No. 04cv2745); *Brian B. Steketee vs. Vicuron Pharmaceuticals, Inc. et al.* (Case No. 04cv3365); and *Brad Staton vs. Vicuron Pharmaceuticals, Inc.* (Case No. 04cv3422), collectively the Federal Class

Actions. Each complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 arising from our May 24, 2004 press release announcing the approvable letter from the FDA indicating anidulafungin does not currently support a labeling for initial treatment of esophageal candidiasis. Each plaintiff seeks to represent a class of Vicuron securities purchasers from January 6, 2003, through May 24, 2004, (except *Zucker*, whose putative class period begins March 17, 2003). The complaints seek compensatory damages, interest, attorneys fees, and injunctive and equitable relief. The Company intends to defend this litigation vigorously.

On August 18, 2004, counsel for all parties involved in the Federal Class Actions stipulated to consolidation of the six actions. Under the stipulation, defendants are not required to respond to the six individual complaints. Rather, defendants will respond to an amended, consolidated class action complaint that will be filed by the court-appointed lead plaintiff and lead plaintiff counsel, or the Consolidated Complaint. The District Court approved the Consolidation Stipulation on August 23, 2004. The Court s order provides that:

- the designated lead plaintiff will have 60 days to file the Consolidated Complaint once appointed by the District Court;
- defendants will file a responsive pleading within 60 days of service of the Consolidated Complaint; and
- in the event defendants responsive pleading is a motion to dismiss, plaintiffs opposition papers will be due 60 days from the filing of the motion, and any reply papers by defendants will be due 30 days thereafter.

Three motions were filed with the District Court pursuant to 15 U.S.C. 78u-4(a)(3)(A)(i)(II) proposing a lead plaintiff and lead plaintiff counsel. On October 7, 2004, the Court entered an order appointing the group of institutional investors (Massachusetts State Guaranteed Annuity Fund, Massachusetts State Carpenters Pension Fund, and Greater Pennsylvania Carpenters Pension Fund) as lead plaintiffs, the law firm of Lerach Coughlin Stoia Geller Rudman & Robbins as lead plaintiffs counsel, and the law offices of Marc S. Henzel as liaison counsel. Based on the Court s order of August 23, 2004, plaintiffs must file a consolidated amended complaint by December 6, 2004. The Court has ordered a status conference in the Federal Class Actions for November 1, 2004.

On July 2, 2004, a shareholder derivative complaint styled *Jonathan Meyers vs. George F. Horner, III et al.* was filed against certain of the Company s officers and directors in the Court of Common Pleas of the State of Pennsylvania, Montgomery County (Case no. 04-19595). The complaint purports to allege claims of insider selling, breach of fiduciary duty, abuse of control, gross mismanagement, waste of corporate assets, and unjust enrichment. The complaint seeks compensatory damages, disgorgement of profits, imposition of a constructive trust, equitable and injunctive relief, attorneys fees and costs. On August 11, 2004, counsel for the parties entered a stipulation to stay all proceedings in the state court derivative action, pending the District Court s resolution of the motion to dismiss that defendants expect to file in the Federal Class Actions. Under the stipulation to stay, defendants time to respond to the derivative complaint is extended until 60 days after the stay expires. The Court approved the stipulation, and stayed the derivative action, on August 17, 2004.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In October 2004, we closed our public offering of 5,051,000 shares of common stock at $14.75 per share. We received net proceeds of approximately $71.4 million.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

The Annual Meeting of the Stockholders of Vicuron Pharmaceuticals Inc. was held on October 28, 2004 at the Villanova Conference Center for the purposes of acting upon the following matters:

1. The election of two directors to the board of directors to hold office until the 2007 annual meeting of stockholders or until their successors are duly elected and qualified.

	For	Withhold
Christopher T. Walsh, Ph.D.	30,631,392	3,930,284
Cheryl A. Wenzinger, CPA	34,461,604	100,072

2. To ratify the appointment of PricewaterhouseCoopers LLP as independent auditors for the fiscal year ending December 31, 2004.

For	Against	Abstain
34,400,929	137,687	23,060

ITEM 5. OTHER INFORMATION

In July 2004, our board of directors amended certain provisions of our bylaws relating to the compositions of our board of directors which were adopted in connection with our merger with Biosearch in 2003.

We have been in discussions with the Italian labor unions regarding the possibility of reducing our work force in Italy.

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.

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: November 4, 2004

/s/ GEORGE F. HORNER III

George F. Horner III

President and Chief Executive Officer

(Principal Executive Officer and Accounting Officer)

Date: November 4, 2004

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

Dov A. Goldstein, M.D.
Executive Vice President,

Finance and Chief Financial Officer

(Principal 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-Q for the period ended September 30, 2004 (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 Versicor Inc. and Biosearch Italia, S.p.A. (5)
2.2	First Amendment to Agreement and Plan of Merger entered into on August 14, 2002, by and between Versicor Inc. and Biosearch Italia S.p.A.(2)
2.3	Second Amendment to Agreement and Plan of Merger entered into on October 29, 2002, by and between Versicor Inc. and Biosearch Italia S.p.A.(2)
3.1	Fourth Amended and Restated Certificate of Incorporation(1)
3.2	Certificate of Amendment and Restatement of the Certificate of Designations of Versicor Inc. (6)
3.3	Certificate of Merger relating to the merger of Biosearch Italia S.p.A. with and into Versicor Inc.(3)
3.4	Certificate of Ownership and Merger Merging Vicuron Pharmaceuticals Inc. into Versicor Inc. (7)
3.5	Amended and Restated Bylaws, as currently in effect(11)
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 Versicor Inc.(1)

4.3	Form of Warrant for the Purchase of Shares of Series C Preferred Stock dated as of December 9, 1997(1)
4.4	Form of Warrant for the Purchase of Shares of Series F Preferred Stock dated as of June 25, 1999(1)
4.5	Second Amended and Restated Investors Rights Agreement(1)
4.6	Shareholder Rights Agreement by and between Versicor Inc. and American Stock Transfer & Trust Company, as Rights Agent, dated June 28, 2001 (6)
4.7	First Amendment to Shareholder Rights Agreement, dated as of July 30, 2002, by and between Versicor Inc. and American Stock Transfer & Trust Company, as Rights Agent (5)
4.8	Registration Rights Agreement dated as of April 8, 2002, by and among Versicor Inc. and the Purchasers listed on Schedule A attached thereto (8)
4.9	Form of Deposit Agreement and Depositary Receipt(4)
4.10	Form of Senior Debt Indenture(4)
4.11	Form of Subordinated Debt Indenture(4)
4.12	Form of Common Stock Warrant Agreement and Warrant Certificate(4)
4.13	Form of Preferred Stock Warrant Agreement and Warrant Certificate(4)
4.14	Form of Depository Share Warrant Agreement and Warrant Certificate(4)
4.15	Form of Debt Securities Warrant Agreement and Warrant Certificate(4)
4.16	Stockholders Agreement dated as of July 30, 2002, by and among George F. Horner, III, Dr. James H. Cavanaugh, Dr. Claudio Quarta and Dr. Francesco Parenti (9)
4.17	Amendment of Stockholders Agreement dated as of September 22, 2004, by and among George F. Horner, III, Dr. James H. Cavanaugh, Dr. Claudio Quarta and Dr. Francesco Parenti (10)
31.1	Rule 13a-14(a)/15d-14(a) Certification of George F. Horner III (11)
31.2	Rule 13a-14(a)/15d-14(a) Certification of Dov A. Goldstein, M.D.(11)
32.1	Section 1350 Certification(11)

(1) Filed as an exhibit to our 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 our Registration Statement on Form S-4 (File No. 333-98935) as amended, effective November 5, 2002, and incorporated herein by reference.
(3) Filed as an exhibit to our Annual Report on Form 10-K, which was filed with the SEC on March 3, 2003, and incorporated herein by reference.
(4) Filed as an exhibit to our Registration Statement on Form S-3 (File No. 333-112847), which was filed with the SEC on February 13, 2004, and incorporated herein by reference.
(5) Filed as an exhibit to our Current Report on Form 8-K, which was filed with the SEC on July 31, 2002 and is incorporated herein by reference.
(6) Filed as an exhibit to our Current Report on Form 8-K, which was filed with the SEC on July 11, 2001 and incorporated herein by reference.
(7) Filed as an exhibit to our Current Report on Form 8-K, which was filed with the SEC on March 26, 2003 and incorporated herein by reference.
(8) Filed as an exhibit to our Current Report on Form 8-K, which was filed with the SEC on April 10, 2002 and incorporated herein by reference.
(9) Filed as an exhibit to our Schedule 13D, which was filed with the SEC on August 9, 2002 and incorporated herein by reference.
(10) Filed as an exhibit to our Schedule 13D/A, which was filed with the SEC on October 4, 2004 and incorporated herein by reference.
(11) Filed herewith.