VICURON PHARMACEUTICALS INC
Form 10-Q
August 05, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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: June 30, 2005

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 reports) 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 July 14, 2005, there were 61,172,779 shares outstanding of the registrant s common stock.

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VICURON PHARMACEUTICALS INC.

Quarterly Report on Form 10-Q

For the Six Months Ended June 30, 2005

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

VICURON PHARMACEUTICALS INC.

CONSOLIDATED BALANCE SHEETS

(in thousands)

	(unaudited) June 30, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 93,681	$ 121,144
Marketable securities	21,612	34,127
Accounts receivable, net	6,536	6,232
Prepaid expenses and other current assets	2,980	8,310
Total current assets	124,809	169,813
Property and equipment, net	52,224	58,668
Intangible assets, net	19,770	24,230
Long-term receivables	12,087	12,222
Long-term marketable securities restricted	2,775	3,256
Other assets	2,709	1,837
Total assets	$ 214,374	$ 270,026
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,189	$ 12,473
Accrued liabilities	7,351	9,747
Current portion of long-term debt	1,120	1,225
Deferred revenue	215	550
Total current liabilities	13,875	23,995
Long-term debt, less current portion	8,404	10,066
Deferred revenue, less current portion	1,750	1,750
Other long-term liabilities	5,030	4,624
Total liabilities	29,059	40,435
Stockholders equity:		
Common stock	61	60
Additional paid-in capital	608,113	602,011
Deferred stock compensation	(171)	(179)

Accumulated other comprehensive income	16,798	32,945
Accumulated deficit	(439,486)	(405,246)
Total stockholders equity	185,315	229,591
Total liabilities and stockholders equity	$ 214,374	$ 270,026

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

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VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2005	June 30, 2004	June 30, 2005	June 30, 2004
Revenues:				
Collaborative research and development, contract services and government grants	$ 921	$ 1,778	$ 2,548	$ 3,570
License fees and milestones	198	139	341	275
Total revenues	1,119	1,917	2,889	3,845
Operating expenses:				
Research and development	12,870	19,355	26,150	41,390
General and administrative	7,735	7,192	12,393	11,263
Total operating expenses	20,605	26,547	38,543	52,653
Loss from operations	(19,486)	(24,630)	(35,654)	(48,808)
Other income (expense):				
Interest income	731	545	1,582	1,231
Interest expense	(5)	(25)	(12)	(53)
Net loss before income tax expense	(18,760)	(24,110)	(34,084)	(47,630)
Income tax expense	64		156	
Net loss	(18,824)	(24,110)	(34,240)	(47,630)
Net loss per share:				
Basic and diluted	$ (0.31)	$ (0.44)	$ (0.56)	$ (0.88)
Weighted average shares	61,108	54,616	60,841	54,323

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

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VICURON PHARMACEUTICALS INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Six Months Ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (34,240)	$ (47,630)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,515	2,801
Non-cash stock compensation expense	458	146
Amortization of bond discounts and premiums	(32)	578
Deferred tax expense	156	
Changes in operating assets and liabilities:		
Accounts receivable	(946)	421
Prepaid expenses and other current assets	4,946	277
Long-term receivables	(1,271)	(1,277)
Other assets	133	
Accounts payable	(6,582)	945
Accrued liabilities	(2,424)	2,943
Deferred revenue	(280)	(270)
Other long-term liabilities	(87)	(653)
Net cash used in operating activities	(37,654)	(41,719)
Cash flows from investing activities:		
Purchases of marketable securities	(17,382)	(14,048)
Sales/maturities of marketable securities	29,848	30,083
Additions to property and equipment	(1,565)	(8,353)
Disposals of property and equipment	5	
Net cash provided by investing activities	10,906	7,682
Cash flows from financing activities:		
Proceeds from issuance of common stock, net	5,653	6,155
Proceeds from long-term debt		
Repayments of long-term debt	(574)	(1,216)
Net cash provided by financing activities	5,079	4,939
Effect of exchange rate changes on cash and cash equivalents	(5,794)	(2,827)
Net change in cash and cash equivalents	(27,643)	(31,925)

Cash and cash equivalents at beginning of period	121,144	113,361
Cash and cash equivalents at end of period	$ 93,681	$ 81,436
Supplemental cash flow information:		
Cash paid during the period for interest	$ 12	$ 52

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

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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 June 30, 2005.

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, 2004, which are included in Vicuron Pharmaceuticals Inc. s, or the Company s, Annual Report on Form 10-K for the year ended December 31, 2004.

On June 15, 2005, we, Pfizer Inc. and a subsidiary of Pfizer (Merger Sub) entered into a definitive merger agreement pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into us and we will become a wholly-owned subsidiary of Pfizer. Under the terms of the merger agreement, upon consummation of the merger, holders of our common stock issued and outstanding immediately prior to the consummation of the merger (other than holders who exercise appraisal rights under Delaware law) will receive $29.10 per share in cash. In addition, each option to acquire our common stock outstanding immediately prior to the consummation of the merger will, upon consummation of the merger, be converted into the right to receive an amount in cash equal to the excess of $29.10 minus the exercise price of the option. Consummation of the merger is subject to the satisfaction of closing conditions, including the approval of our stockholders and the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. We cannot assure you that the merger will be approved by the Federal Trade Commission, that the other conditions to the merger will be satisfied or that the merger will close in the expected time frame or at all.

Stock Options Fair Value Disclosures

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(unaudited)			

	(in thousands, except per share data)			
Net Loss, as reported	$ (18,824)	$ (24,110)	$ (34,240)	$ (47,630)
Add: stock-based employee compensation expense included in net loss		18		69
Less: total stock-based employee compensation, determined under fair value based method for all awards	(967)	(3,497)	(984)	(5,497)
Net loss pro forma	$ (19,791)	$ (27,589)	$ (35,224)	$ (53,058)
Basic and diluted net loss per share: As reported	$ (0.31)	$ (0.44)	$ (0.56)	$ (0.88)
Pro forma	$ (0.32)	$ (0.51)	$ (0.58)	$ (0.98)

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2. Basic and Diluted Net Loss per Share

Basic net loss per share is computed using the weighted-average number of shares of common stock outstanding. Diluted net loss per share does not differ from basic net loss per share since potential shares of common stock are anti-dilutive for all periods presented and therefore are excluded from the calculation of diluted net loss per share. The following potentially dilutive shares of common stock were excluded from the computation of net loss per share because their effect was anti-dilutive (in thousands):

	June 30,	
	2005	2004
Shares issuable upon exercise of stock options	7,332	8,508
Shares issuable upon exercise of warrants	39	112
	7,371	8,620

3. Comprehensive Loss

For the three month and six month periods ended June 30, 2005 and 2004, the components of total comprehensive loss are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
	(in thousands) (unaudited)			
Net loss (as reported)	$ (18,824)	$ (24,110)	$ (34,240)	$ (47,630)
Foreign currency translation adjustment	(9,170)	(1,464)	(16,208)	(5,358)
Unrealized gain/(loss) on investments	128	(107)	61	(133)
Other comprehensive loss	(9,042)	(1,571)	(16,147)	(5,491)
Pro forma	$ (27,866)	$ (25,681)	$ (50,387)	$ (53,121)

4. Restructuring Charge

On May 25, 2004, the Company received an approvable letter from the U.S. Food and Drug Administration, or FDA, indicating 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 has pursued two paths for approval of anidulafungin, as follows:

amended its existing NDA in May 2005 for the potential treatment of esophageal candidiasis; and

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

The Company reduced its expenses in light of this delay. From May 31, 2004 to July 2, 2004, the Company reduced its workforce in the United States. The severance charge was $864,000, of which $778,000 was paid in 2004 and $86,000, which was paid in January 2005. The Company also reduced its Italian workforce in September 2004. The related severance charge was $1.8 million, of which $1.1 million was paid in 2004 and $0.7 million was paid in January 2005. The severance charge was included in research and development and general and administrative expense in the consolidated statements of operations for the year ended December 31, 2004.

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5. Recent Accounting Pronouncements

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151, Inventory Costs an amendment of ARB 43, chapter 4 (FAS 151). FAS 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage) in the determination of inventory carrying costs. The statement requires that such costs be recognized as a current-period expense. FAS 151 also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for fiscal years beginning after July 15, 2005. The Company does not expect the adoption of this standard to have a material impact on its financial condition or results of operations.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123R (revised 2004), Share-Based Payment (FAS 123R). In summary, FAS 123R requires companies to expense the fair value of employee stock options and similar awards as of the date the Company grants the awards to employees. The expense would be recognized over the vesting period for each option and adjusted for actual forfeitures that occur before vesting. The effective date for this standard is the annual period beginning after June 15, 2005, and applies to all outstanding and unvested share-based payment awards at a company s adoption date. The Company is currently assessing each of the three transition methods offered by FAS 123R and believes adoption of FAS 123R will have a material impact on its consolidated financial statements, regardless of the method selected. The Company will adopt FAS 123R on January 1, 2006.

In December 2004, the FASB issued FASB Staff Position (FSP) FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004 . This FSP provides guidance on the application of Statement 109 to the provisions within the American Jobs Creation Act of 2005 (the Act), which provides tax relief to U.S. domestic manufacturers. The FSP states that a manufacturer s deduction provided for under the Act should be accounted for as a special deduction in accordance with Statement 109 and not as a tax rate reduction. The FSP also reminds preparers that the special deduction should be considered by an enterprise in (a) measuring deferred taxes when the enterprise is subjected to graduated tax rates, and (b) assessing whether a valuation allowance is necessary as required by Statement 109. This statement is effective immediately. The Company has adopted this statement and it did not have a material impact on the Company s financial position or results of operations.

6. 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 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.

The Company s revenue for the six month periods ended June 30, 2005 consisted primarily of collaborative research and development fees from Pfizer and Novartis of $1.9 million and $0.6 million, respectively.

The table below presents geographic information about reported segments for the six months ended June 30, 2005:

	(in thousands) (unaudited)		
	United States	Italy	Consolidated
Net revenue	$ 2,538	$ 351	$ 2,889
Long lived assets	$ 3,488	$ 86,077	$ 89,565

7. Legal Proceedings

Between June 15, 2004 and July 19, 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 alleged 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 sought 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 sought compensatory damages, interest, attorneys fees, and injunctive and equitable relief. The Company is vigorously defending this litigation.

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On August 23, 2004, the Court issued an order consolidating the six actions. On October 7, 2004, the Court entered an order appointing a 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.

The plaintiffs filed an Amended Complaint on December 6, 2004. The Amended Complaint alleges violations of Section 10(b) of the Securities Exchange Act of 1934, and violations of Section 11 of the Securities Act of 1933, against all of the defendants, including: the Company, three of the Company s senior officers and seven of the Company s directors. The Amended Complaint also alleges violations of Section 20(a) of the Securities Exchange Act of 1934 against the three officers. The Amended Complaint alleges a putative class period from January 6, 2003 through May 24, 2004, and seeks compensatory damages, interest, attorneys fees, and injunctive and equitable relief.

On January 20, 2005, in response to the plaintiffs Amended Complaint, defendants filed a motion to dismiss plaintiffs action. On July 1, 2005, the Court issued an order denying the defendants motion to dismiss.

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 filed 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.

The Company intends to defend this litigation vigorously. However, the outcome is currently not determinable and accordingly no amounts have been recorded in the accompanying consolidated financial statements.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and notes to those statements included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements for the year-ended December 31, 2004 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 materially from those anticipated in such forward-looking statements. References to the Company, Vicuron, and we throughout this Quarterly Report on Form 10-Q refer to Vicuron Pharmaceuticals Inc. and its subsidiaries.

Overview

We are a transatlantic biopharmaceutical company focused on the discovery, development, manufacturing and marketing of pharmaceutical products for the treatment of seriously ill patients. Since our inception in 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 5.29 million shares of our common stock at $11.00 per share in an initial public offering and we received total net proceeds of approximately $52.7 million.

In April 2002, we completed a private placement of 2.99 million shares of our common stock to selected institutional investors at a purchase price of $15.00 per share. We received net proceeds from the private placement of approximately $41.9 million.

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In February 2003, we acquired all of the outstanding shares of Biosearch Italia S.p.A., a publicly-listed company in Italy. In connection with that transaction we issued 1.77 shares of our common stock for each outstanding share of Biosearch stock, or approximately 21.4 million shares.

In June 2003, we contributed the former assets, liabilities and business of Biosearch to our wholly-owned subsidiary in Italy, Vicuron Pharmaceuticals Italy S.r.1.

In July 2003, we sold 6 million 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 allows us to offer up to $200 million of our common stock, preferred stock, warrants and/or debt securities from time to time in one or more public offerings. In October 2004, we sold 5.05 million shares of our common stock at $14.75 per share in a public offering. We received net proceeds of approximately $71.5 million.

On June 15, 2005, we, Pfizer Inc. and a subsidiary of Pfizer (Merger Sub) entered into a definitive merger agreement pursuant to which, subject to the satisfaction or waiver of the conditions therein, Merger Sub will merge with and into us and we will become a wholly-owned subsidiary of Pfizer. Under the terms of the merger agreement, upon consummation of the merger, holders of our common stock issued and outstanding immediately prior to the consummation of the merger (other than holders who exercise appraisal rights under Delaware law) will receive $29.10 per share in cash. In addition, each option to acquire our common stock outstanding immediately prior to the consummation of the merger will, upon consummation of the merger, be converted into the right to receive an amount in cash equal to the excess of $29.10 minus the exercise price of the option.

Since we began our operations in 1995, we have not generated any revenues from product sales. In early 2003, we completed a Phase 3 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 U.S. Food and Drug Administration, or FDA, in June 2003. In January 2004, we received notification from the FDA that the agency would complete its review of our anidulafungin NDA in May 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. In May 2004, we received an approvable letter from the FDA. Based on the approvable letter and discussions with the FDA, the Company pursued two paths for approval of anidulafungin, as follows:

- amended our existing NDA in May 2005 for the treatment of esophageal candidiasis; and
- will submit an additional NDA for the treatment of invasive candidiasis/candidemia.

On May 27, 2005 we filed an amendment to our existing anidulafungin NDA with the FDA for the treatment of esophageal candidiasis. The amendment provides supplemental clinical data including data on the 100 mg dose of anidulafungin from the previously announced Phase 3 trial demonstrating the superiority of anidulafungin versus fluconazole in invasive candidiasis/candidemia. This amendment was subsequently accepted by the FDA as a complete class two response, so the current Prescription Drug User Fee Act date is November 27, 2005.

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 the EMEA was requested by us and granted by the EMEA. In the first quarter, we requested the withdrawal of the anidulafungin MAA for esophageal candidiasis from the EMEA. We intend to submit a new MAA for anidulafungin in invasive candidiasis.

In December 2004, we submitted an NDA for dalbavancin, a novel antibiotic for the treatment of complicated skin and soft tissue infections (cSSTIs). Dalbavancin is a unique, once weekly IV lipoglycopeptide for the treatment of cSSTIs caused by Gram-positive bacteria, including methicillin-resistant *Staphylococus aureus* (MRSA s). Dalbavancin is a second-generation lipoglycopeptide antibiotic belonging to the same class as vancomycin, the most widely-used injectable antibiotic for Staphylococcal infections. In February 2005, we received notice from the FDA that our file would receive priority review. In May 2005, we received notification from the FDA that the agency expects to complete the priority review of the dalbavancin NDA on or before September 21, 2005, which is a three-month extension from the original Prescription Drug User Fee Act action date of June 21, 2005.

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The extension is a result of the agency classifying recent responses to questions in the chemistry, manufacturing and controls (CMC) section of the NDA as a major amendment to the NDA. The agency has reset the action date to give itself additional time to review this information.

We also completed a Phase 1 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 achievement of specified milestones. We expect these revenues to decrease in 2005. 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 in research and development of new product candidates, when in-licensing existing 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 we expect our research and development expenses to continue as we develop our product candidates. We expect to incur sales and marketing expenses during 2005 as we establish our sales and marketing organization.

Since our inception, we have incurred significant losses. As of June 30, 2005, we had an accumulated deficit of $439.5 million. We anticipate incurring additional losses, which may increase for the foreseeable future, including at least through December 31, 2006.

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. The fluctuating nature of these factors makes predictions of our 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 24% and 20%, respectively, of our total research and development expenses since our inception.

Anidulafungin

Anidulafungin is our lead antifungal product candidate. We in-licensed anidulafungin from Eli Lilly pursuant to an agreement dated as of May 1999, which is described below. In April 2003, we submitted an NDA for anidulafungin for the treatment of esophageal candidiasis with the FDA. In May 2004, we received an approvable letter from the FDA for anidulafungin. Based on the approvable letter and our discussions with

the FDA, we pursued two paths for approval of anidulafungin, as follows:

- amended our existing NDA in May 2005 for the treatment of esophageal candidiasis; and
- will submit an additional NDA for the potential treatment of invasive candidiasis/candidemia.

We kept open the initial NDA for anidulafungin for the treatment of esophageal candidiasis that we filed in April 2003. We filed an amendment to that NDA in May 2005, which provided supplemental efficacy and safety data largely at the 100 mg dose, including data from our completed invasive candidiasis/candidemia Phase 3 clinical trial. This amendment was subsequently accepted by the FDA as a complete class two response, so the current PDUFA date is November 27, 2005.

We intend to file a new NDA for anidulafungin for the treatment of invasive candidiasis/candidemia with additional efficacy and integrated safety data, including data from our completed Phase 3 clinical trial, the headline results of which were released in February 2005.

As of June 30, 2005, anidulafungin has been evaluated in a:

- Phase 3 clinical trial for the treatment of esophageal candidiasis, patient enrollment completed, top-line data released and data published;
- Phase 3 clinical trial for the treatment of invasive candidiasis/candidemia, patient enrollment completed and top-line data released; and
- Phase 2/3 clinical trial for the treatment of aspergillosis, patient enrollment completed and top-line data released.

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In May 1999, we obtained from Eli Lilly an exclusive worldwide license for the development and commercialization of anidulafungin. We paid $11.0 million for the license and an additional $3.0 million for product inventory (which we have received). 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 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 $21.0 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 2 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:

- 11% for the six months ended June 30, 2005 compared to 11% for the six months ended June 30, 2004; and
- 24% in the aggregate from our inception through June 30, 2005.

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

The goal of our anidulafungin project is to obtain marketing approval from the FDA and analogous international agencies; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. 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 the total estimated cost to complete, the anticipated completion date or when material cash inflows from our anidulafungin project will commence, if ever.

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

because our research and development projects are independent, a failure to obtain marketing approval for anidulafungin would not necessarily interrupt our development programs for dalbavancin or our pre-clinical compounds; however, we might reduce our development staff (unless one or more of our other product candidates is then entering in 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;

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we would not earn any sales revenue from anidulafungin, which would increase the likelihood that we would need to obtain additional financing for our other development efforts; and

our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all.

Dalbavancin

Dalbavancin is our lead antibiotic product candidate. We filed an NDA for dalbavancin for the treatment of complicated skin and skin structure infections with the FDA in December 2004. In February 2005, we received the acceptance to file notification from the FDA and were granted priority review status by the FDA for the NDA. In May 2005, we received notification from the FDA that the agency expects to complete the priority review of the dalbavancin NDA on or before September 21, 2005, which is a three-month extension from the original Prescription Drug User Fee Act action date of June 21, 2005. The extension is a result of the agency classifying recent responses to questions in the chemistry, manufacturing and controls section of the NDA as a major amendment to the NDA. The agency has reset the action date to give itself additional time to review this information.

As of June 30, 2005 dalbavancin has been evaluated in:

three Phase 3 clinical trials for the treatment of skin and soft tissue infections (completed and top-line data released); and

a Phase 2 clinical trial for the treatment of catheter-related blood stream infections (completed, top-line data released and published).

a Phase 2 trial in skin and soft tissue infections (completed, top-line data released and published).

In February 1998, we entered into a license agreement and a collaborative agreement with Biosearch. Under the license agreement, Biosearch granted us an exclusive license to develop and commercialize dalbavancin in the United States and Canada. In exchange for the license and upon the receipt of favorable results in pre-clinical studies, we paid an initial license fee of $2.0 million and issued 250,000 shares of our common stock to Biosearch. In May 2001 and December 2002, we paid Biosearch additional milestone payments for the start of Phase 2 and Phase 3 clinical trials, respectively. As a result of the Biosearch merger, we no longer owe any milestones or royalties on dalbavancin.

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

6% for the six months ended June 30, 2005 compared to 31% for the six months ended June 30, 2004; and

20% in the aggregate from our inception through June 30, 2005.

Our development administration overhead costs are included in total research and development expense for each period, but 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; and we will consider the project substantially complete if we obtain those approvals even though subsequent to that time we might incur additional expenses in conducting additional clinical trials and follow-up studies. Before we can obtain such marketing approvals we will need to obtain approval from the FDA. 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 the total estimated cost to complete, the anticipated completion date or when material cash inflows from our anidulafungin project will commence, if ever.

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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 in late-stage clinical trials, in which case we might be able to re-assign dalbavancin researchers to those projects);

- we would not earn any sales revenue from dalbavancin, which would increase the likelihood that we would need to obtain additional financing for our other development efforts; and

- our reputation among investors might be harmed, which might make it more difficult for us to obtain equity capital on attractive terms or at all.

Risks relating to our major research and development projects

We face many risks that could prevent or delay the completion of our 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:

- 18% for the six months ended June 30, 2005, compared to 10% for the six months ended June 30, 2004; and

- 10% in the aggregate from our inception through June 30, 2005.

We do not allocate our development administration 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 46% of our total research and development expenses from our inception through June 30, 2005 were generated by various pre-clinical studies and drug discovery programs, including our collaborations with Pfizer and Novartis described below.

Oxazolidinones collaboration with Pfizer.

In March 1999, we entered into a collaboration agreement with Pharmacia Corporation, now Pfizer, pursuant to which we are collaborating to discover, synthesize and develop second and third generation oxazolidinone product candidates. In connection with the collaboration, Pfizer made an equity investment in us of $3.8 million and paid us research support and license fee payments. Under the terms of the agreement and in consideration of 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. In October 2000, Pfizer increased its funding for this collaboration by 30%, and in June 2001, we received a milestone payment for the initiation of clinical development of one of the compounds. In July 2002, we amended our arrangement with Pfizer by extending the collaboration for an additional three years through March 2005. In March 2005, we announced that the collaboration had been extended until March 2006. Through June 30, 2005, Pfizer has made aggregate payments to us under this collaboration agreement (excluding equity investments) of $21.2 million.

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

6% for the six months ended June 30, 2005, compared to 4% for the six months ended June 30, 2004; and

10% in the aggregate from January 1, 1999 through June 30, 2005.

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

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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 1 clinical trials. In order to obtain marketing approval, Pfizer will need to complete Phase 1, 2 and 3 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, receipt of marketing approvals and acceptance in the marketplace, we cannot predict the total estimated costs to complete, the anticipated completion date or when material cash inflows from our collaboration with Pfizer will commence, if ever.

Deformylase inhibitors collaboration with Novartis.

In March 1999, we entered into a collaboration agreement with Novartis Pharma AG pursuant to which we are collaborating to discover and develop novel deformylase inhibitors. In connection with the collaboration, Novartis made an initial equity investment in us of $3.0 million. We have also received a number of milestone payments from Novartis and are entitled to receive additional payments of up to $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. In February 2003, we amended the original agreement in order to extend the research term through March 31, 2005. In September 2003, we announced achievement of a late-stage pre-clinical milestone for which we received a milestone payment from Novartis, and in December 2003 we announced that we received an additional milestone payment from Novartis as a result of entering into Phase 1 work on our research collaboration with Novartis. Through March 31, 2005, Novartis has made aggregate payments to us under this agreement (excluding equity investments) of $19.6 million. The Company received its final collaboration payment of $0.7 million in the first quarter of 2005, which was recognized as revenue. In March 2005, the Company announced that Novartis has opted to suspend the Phase 1 compound and will advance a second compound. The Company received a milestone for the designation of this second compound as a late stage preclinical compound. This milestone was recognized as revenue in 2004 and received in 2005. The Company terminated research associated with this collaboration on March 31, 2005 and is no longer incurring expenses with respect to this collaboration. Novartis continues preclinical development of deformylase inhibitors from the collaboration.

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 six months ended June 30, 2005, compared to 3% for the six months ended June 30, 2004; and

8% in the aggregate from January 1, 1999 through June 30, 2005.

The goal of our agreement with Novartis is to discover, synthesize and obtain marketing approval for deformylase inhibitor product candidates. We were responsible for supplying research to the collaboration, according to a research plan developed by a joint research committee. Our research obligations ended March 31, 2005. Novartis provided us with funding to support some of our researchers on this project. The future success of this research effort 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 1 clinical trials. In order to obtain marketing approval, Novartis will need to initiate and complete Phase 1, 2 and 3 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, receipt of marketing approvals and acceptance in the marketplace, we cannot predict the total estimated costs to complete, the anticipated completion date or 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 payment, 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.

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

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

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while we do not rely on any particular external development collaboration to produce marketable products (and, ultimately, royalty revenues), the failure of all of our external development collaborations would increase the likelihood that we would need to obtain additional financing for our internal research and development efforts.

Results of Operations

Three Months Ended June 30, 2005 Compared to Three Months Ended June 30, 2004

Revenues

Revenues were $1.1 million and $1.9 million in the three months ended June 30, 2005 and 2004, respectively. Revenues in the second quarter of 2005 consisted of $0.9 million of collaborative research and development fees from Pfizer and $0.2 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in the second quarter of 2004 consisted of $1.6 million of collaborative research and development fees from Pfizer and Novartis and $0.3 million of collaborative research and development and grant revenues from our research operations in Italy. The decrease in revenue was primarily due to the suspension of the Novartis collaboration in March 2005.

Research and Development Expenses

Research and development expenses were $12.9 million and $19.4 million in the three months ended June 30, 2005 and 2004, respectively. The decrease in these expenditures was due to the completion of clinical trials associated with dalbavancin and anidulafungin combined with a reduction in expenses at our two research facilities. These decreases were partially offset by increases in costs associated with our nearly completed manufacturing facility in Italy.

General and Administrative Expenses

General and administrative expenses were $7.7 million and $7.2 million in the three months ended June 30, 2005 and 2004, respectively. The majority of this increase in expenses in the quarter was due to a $1.5 million increase in legal fees of which $1.5 million was due to merger related activity. This increase was partially offset by a decrease in expenses related to our sales department and our European operations. The decrease in our sales department was due to the ramp up in 2004 of our sales infrastructure in the second quarter of 2004.

Interest Income

Interest income was $731,000 and $545,000 in the three months ended June 30, 2005 and 2004, respectively. The increased income in the second quarter of 2005 was due to an increase in the average yield and partially offset by a decrease in interest-bearing cash and marketable securities.

Interest Expense

Interest expense was $5,000 and $25,000 in the three months ended June 30, 2005 and 2004, respectively. The decrease was due to a decrease in interest-bearing debt.

Income Taxes

Income tax expense was $64,000 and $0 in the three months ended June 30, 2005 and 2004, respectively. The increase was due to taxable interest income at the Vicuron Italy branch.

Six Months Ended June 30, 2005 Compared to Six Months Ended June 30, 2004

Revenues

Revenues were $2.9 million and $3.8 million in the six months ended June 30, 2005 and 2004, respectively. Revenues in 2005 consisted of $2.6 million of collaborative research and development fees from Pfizer and Novartis and $0.3 million of collaborative research and development and grant revenue from our research operations in Italy. Revenues in 2004 consisted of $3.1 million of collaborative research and development fees from Pfizer and Novartis and $0.7 million of collaborative research and grant revenue from our research operations in Italy. The decrease in revenue was primarily due to the suspension of the Novartis collaboration in March 2005.

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Research and Development Fees

Research and development expenses were $26.2 million and $41.4 million in the six months ended June 30, 2005 and 2004 respectively. The decrease in these expenditures was due to the completion of clinical trials associated with dalbavancin and anidulafungin combined with a reduction in expenses at our two research facilities. These decreases were partially offset by costs associated with our recently completed manufacturing facility in Italy and a $0.9 million severance payment to our former Chief Medical Officer.

General and Administrative Expenses

General and administrative expenses were $12.4 million and $11.3 million in the six months ended June 30, 2005 and 2004 respectively. The increase in expenses in 2005 results from $1.5 million in legal fees associated with the merger with Pfizer. This increase was partially offset by decreases in expenses related to our Italian operations and the development of a sales force in 2004.

Interest Income

Interest income was $1.6 million and $1.2 million in the six months ended June 30, 2005 and 2004, respectively. The increased interest income in 2005 was due to an increase in the average yield. This increase was partially offset by a decrease in interest-bearing cash and marketable securities.

Interest Expense

Interest expense was $12,000 and $53,000 in the six months ended June 30, 2005 and 2004, respectively. The decrease was due to a decrease in interest bearing-debt.

Income Taxes

Income tax expense was $156,000 and $0 in the six months ended June 30, 2005 and 2004, respectively. The increase was due to taxable income at the Vicuron Italy branch.

Financial Condition

Assets

As of June 30, 2005 and December 31, 2004, we held total assets of $214.4 million and $270.0 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 combined with a decline in the value of the euro during 2005.

Liabilities

As of June 30, 2005 and December 31, 2004, our total liabilities equaled $29.1million and $40.4 million, respectively. The decrease in total liabilities was primarily due to the decrease in accounts payable and accrued liabilities associated with several large clinical trials, which have now been completed.

Stockholders Equity

As of June 30, 2005 and December 31, 2004, our total stockholders equity equaled $185.3 million and $229.6 million, respectively. The decrease in our stockholders equity was primarily due to our year-to-date loss of $34.2 million and decline in accumulated other comprehensive income associated with the decline in the value of the euro. These decreases were partially offset by $5.7 million in cash received from the exercise of stock options.

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Liquidity and Capital Resources

We have funded our operations principally with the proceeds of $78.5 million from a series of six preferred stock offerings over the period 1995 through 1999, and net proceeds of $52.7 million from our initial public offering received in August 2000. In addition, in April 2002, we completed a private placement of 2.99 million shares of our common stock to selected institutional investors at a purchase price of $15.00 per share, from which we received net proceeds of approximately $41.9 million. In July 2003, we sold 6.0 million shares of our common stock at $13.85 per share in a public offering and received net proceeds of $77.8 million. In addition, in February 2004, we filed a universal shelf registration statement on Form S-3, which allows us to offer up to $200 million of our common stock, preferred stock, warrants and/or debt securities from time to time in one or more public offerings. In October 2004, we sold 5.05 million shares of our common stock at $14.75 per share in a public offering and received net proceeds of $71.5 million.

In addition, we have also received approximately $40.8 million in payments for collaborative research, contract services and milestone payments, as well as license fees from our collaborators, including Sepracor through June 30, 2005, which we have used to fund our operations.

As of June 30, 2005, we had cash, cash equivalents and marketable securities of $115.3 million. Our short-term investments as of such date consisted of U.S. Treasury and government agency obligations and investment grade corporate obligations. Historically, we have funded our capital equipment purchases through available cash, capital leases and equipment financing line of credit agreements. During the period from March 2003 through December 2004, Biosearch Manufacturing S.r.l. received proceeds of 7.5 million euros from a loan facility entered into by Biosearch Manufacturing S.r.l. with Basilicata Region of Italy for the construction of Biosearch Manufacturing S.r.l. s manufacturing plant in Pisticci. Under the loan agreement, Biosearch Manufacturing S.r.l. has a total loan facility of 7.5 million euro repayable in 10 years. The term loan bears interest at 6 months LIBOR rate plus a 1.65% spread less a 4% interest rate which is charged to the Basilicata Region. The loan matures in 2012. As of June 30, 2005, the outstanding loan balance was $8.6 million.

Our operating activities used cash of $37.7 million for the six months ended June 30, 2005. Our cash used by operating activities consisted primarily of cash used to fund our net loss of $34.2 million and payments against accounts payable and accrued liabilities of $9.0 million. These amounts were partially offset by a decrease in prepaid expenses and other current assets of $4.9 million and non-cash depreciation and amortization of $2.5 million.

Our investing activities provided cash of $10.9 million for the six months ended June 30, 2005. Our investing activities consisted primarily of a net decrease in marketable securities of $12.5 million to fund operations. This was partially offset by purchases of equipment of $1.6 million.

Our financing activities provided cash of $5.1 million for the six months ended June 30, 2005. Our financing activities consist primarily of proceeds from the exercise of stock options of $5.7 million.

We expect that our current cash and cash equivalents and marketable securities will be sufficient to fund our operations for the foreseeable future.

Recent Accounting Pronouncements

In November 2004, the FASB issued Statement of Financial Accounting Standards No. 151, Inventory Costs an amendment of ARB 43, chapter 4 (FAS 151). FAS 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage) in the determination of inventory carrying costs. The statement requires such costs be recognized as a current-period expense. FAS 151 also requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. This statement is effective for fiscal years beginning after July 15, 2005. We do not expect the adoption of this standard to have a material impact on our financial condition or results of operations.

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123R (revised 2004), Share-Based Payment (FAS 123R). In summary, FAS 123R requires companies to expense the fair value of employee stock options and similar awards as of the date the Company grants the awards to employees. The expense would be recognized over the vesting period for each option and adjusted for actual forfeitures that occur before vesting. The effective date for this standard is the annual period beginning after June 15, 2005, and applies to all outstanding and unvested share-based payment awards at a company s adoption date. We are currently assessing each of the three transition methods offered by FAS 123R and believe adoption of FAS 123R will have a material impact on our consolidated financial statements, regardless of the method selected. The Company will adopt FAS 123R on January 1, 2006.

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In December 2004, the FASB issued FASB Staff Position (FSP) FAS 109-1, Application of FASB Statement No. 109, Accounting for Income Taxes, to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004. This FSP provides guidance on the application of Statement 109 to the provisions within the American Jobs Creation Act of 2005 (the Act), which provides tax relief to U.S. domestic manufacturers. The FSP states that a manufacturer s deduction provided for under the Act should be accounted for as a special deduction in accordance with Statement 109 and not as a tax rate reduction. The FSP also reminds preparers that the special deduction should be considered by an enterprise in (a) measuring deferred taxes when the enterprise is subjected to graduated tax rates, and (b) assessing whether a valuation allowance is necessary as required by Statement 109. This statement is effective immediately.

The Company has adopted this statement and it did not have a material impact on the Company s financial position or results of operations.

Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations is based on our consolidated 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 revenues as they are earned. Revenue from license fees and contract services are recognized over the initial license or contract service term as the related work is performed, which generally is on a straight-line basis. Collaborative research and development payments are recognized as the related work is performed.

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.

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 using enacted tax rates in effect for the year in which the differences are expected to affect taxable

income.

Intangible Assets

The identifiable intangible assets resulted from the merger, after allocation of negative goodwill. 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.

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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 pursued two paths for approval of anidulafungin, as follows:

amended our existing NDA in May 2005 for the potential treatment of esophageal candidiasis; and

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

On May 27, 2005 we filed an amendment to our existing anidulafungin NDA with the U.S. Food and Drug Administration for the treatment of esophageal candidiasis. The amendment provides supplemental clinical data including data on the 100 mg dose of anidulafungin from the previously announced Phase 3 trial demonstrating superiority of anidulafungin versus fluconazole in invasive candidiasis/candidemia. This amendment was subsequently accepted by the FDA as a complete class two response, so the current PDUFA date is November 27, 2005.

In addition, we completed Phase 3 clinical trials with dalbavancin for the treatment of both complicated and uncomplicated skin and soft tissue infections and we completed a Phase 2 clinical trial of dalbavancin for catheter-related bloodstream infections. We filed an NDA for Dalbavancin for complicated skin and soft tissue infections in December 2004 and in February 2005, we received notice from the FDA that our file had been accepted for review and had received priority review. In May 2005 we received notification from the FDA that the agency expects to complete the priority review of the dalbavancin NDA on or before September 21, 2005, which is a three-month extension from the original Prescription Drug User Fee Act action date of June 21, 2005. The extension is a result of the agency classifying recent responses to questions in the chemistry, manufacturing and controls section of the NDA as a major amendment to the NDA. The agency has reset the action date to give itself additional time to review this information.

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 clinical trials for anidulafungin and dalbavancin; and
- negative or inconclusive results of our 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 international 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.

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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 NDAs might be denied by the FDA and analogous foreign regulators.

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

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

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

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

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

We have incurred net losses since our inception in 1995. As of June 30, 2005 our accumulated deficit was $439.5 million, including the $94.5 million write-off of acquired in-process research and development resulting from our merger with Biosearch.

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, clinical trials and sales and marketing, 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.

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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, micafungin 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 generic vancomycin, generic cefazolin, teicoplanin, trimethaprin/sulfamethoxazole, 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

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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 completed a Phase 3 clinical trial for anidulafungin for invasive candidiasis/candidemia. We expect to use the results of this Phase 3 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. We also filed an NDA for dalbavancin in December 2004. In addition, we have two other product candidates in clinical trials; ramoplanin, which has completed Phase 2; and VIC-Acne, which has completed Phase 1. We also had anidulafungin in Phase 2/3 for an additional indication and dalbavancin and ramoplanin in Phase 2, 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 June 30, 2005, we had 22 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 manufacturing facilities capable of manufacturing our products in quantities necessary for large-scale trials or marketing. Eli Lilly has supplied us with sufficient anidulafungin echinocandin-B nucleus to market the drug for a few years. We produce anidulafungin (active pharmaceutical ingredient) API at ChemSym Laboratories, a department of Eagle-Picher Pharmaceutical Services, LLC. Dalbavancin API is produced at the Aventis plant in Brindisi, Italy. The lyophilized sterile vials for both anidulafungin and dalbavancin are produced at Ben Venue Laboratories. We do not, however, have any long term agreements with any of these third parties. In the future, we intend to manufacture products at our own manufacturing plant in Pisticci, Italy, wherein the construction process is being completed.

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, VIC-Acne and VIC-5555, 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.

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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 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 two collaboration arrangements with third parties to develop product candidates, one of which expired by its terms on March 31, 2005. 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.

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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

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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 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 June 30, 2005 will be sufficient to fund our operating losses for the next 18 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.

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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. 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 June 30, 2005, plus accrued interest and applicable damages, and we may forfeit grants and subsidies awarded to Biosearch but not yet disbursed as of June 30, 2005 by the authorized bank in the amount of up to approximately $1.3 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.

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

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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 determining whether to reduce the number of our employees in Italy, and if we decide to do so, we could incur substantial costs.

In order to reduce the number of our employees in Italy, we would need to 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, if we seek to implement any such reduction. The Italian labor unions may reject any request we make 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 Our Merger with Pfizer

We cannot assure you that all conditions to the merger with Pfizer Inc. will be completed and the merger consummated.

On June 16, 2005, we announced that we had entered into a merger agreement with Pfizer and a wholly-owned subsidiary of Pfizer (Merger Sub) in a transaction where we would become a wholly-owned subsidiary of Merger Sub. The merger is subject to the satisfaction of closing conditions, including the approval of our stockholders and the expiration of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. We cannot assure you that the merger will be approved by the Federal Trade Commission, that the other conditions to the merger will be satisfied or that the merger will close in the expected time frame or at all.

You will receive $29.10 per share of our common stock in cash despite changes in market value of our common stock.

Under the terms of our merger agreement with Pfizer, holders of our common stock issued and outstanding immediately prior to the consummation of the merger (other than holders who exercise appraisal rights under Delaware law) will receive $29.10 per share in cash. In addition, each option to acquire our common stock outstanding immediately prior to the consummation of the merger will, upon consummation of the merger, be converted into the right to receive an amount in cash equal to the excess of $29.10 minus the exercise price of the option. This consideration will not be adjusted for changes in the market price of either our common stock or Pfizer common stock.

If the merger is not completed, the share price of our common stock and future business and operations could be harmed.

If the merger is not completed, the share price of our common stock and future business and operations could be harmed and may be subject to certain material risks, such as:

- the share price of our common stock may change to the extent that the current market price of our common stock reflects an assumption that the merger will be completed;
- our costs related to the merger, such as legal, accounting and some of the fees of our financial advisors, must be paid even if the merger is not completed; and
- under certain circumstances, we may be required to pay Pfizer a termination fee of $58 million.

Further, if the merger is terminated and our board of directors determines to seek another merger or business combination, we may not be able to find a merger prospect or enter into or consummate a new merger agreement. Any other merger prospect may not be willing to pay an equivalent, higher or more attractive merger consideration than that which is

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proposed to be paid by Pfizer in the merger. While the merger agreement is in effect, subject to specified exceptions, we may not take any action to solicit, initiate or knowingly encourage any takeover proposal or participate in negotiations or discussions regarding any takeover proposal or furnish any nonpublic information with respect to a takeover proposal.

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.

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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 or expire at an inopportune time. 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;

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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 and certain of our directors and certain of our executive officers have been recently named as a defendant in a number of lawsuits which have asserted various claims. We have agreed to indemnify our directors and executive officers for any losses and other expenses that they may incur in connection with these lawsuits. 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

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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:

* prospects that the merger may not be consummated;

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 July 18, 2005 the market price of our common stock as reported on the NASDAQ National Market ranged from a high of $28.23 to a low of $8.76 and our average daily trading volume was 646,879 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.

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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. We have amended our shareholder rights agreement to permit the contemplated merger with Pfizer.

ITEM 3: Quantitative and Qualitative Disclosures about Market Risk

Interest Rates

Our exposure to market risk is limited to interest rate risk and, to a lesser extent, foreign currency risk. Our exposure to changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio and on the increase or decrease in the amount of interest expense we must pay with respect to our various outstanding debt instruments. Our risk associated with fluctuating interest expense is limited to our financings, and the interest rates which are expected to closely tied to market rates. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes. We ensure the safety and preservation of our invested principal funds by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities and limiting the amount invested in any single security. We mitigate market risk by maintaining an average maturity of less than one year for our investments. We mitigate reinvestment risk by investing in securities with varying maturity dates. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would have decreased the fair value of our interest sensitive financial instruments at June 30, 2005 by $0.1 million and December 31, 2004 by $0.2 million. Declines in interest rates over time will reduce our interest income, while increases in interest rates over time will increase our interest expense.

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 at June 30, 2005 (in thousands):

	2005
Cash and cash equivalents	$ 93,681
Average interest rate	2.58%
Marketable securities	$ 21,612
Average interest rate	2.83%

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 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

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of operations and financial condition, and fluctuations in exchange rates might introduce additional volatility in our reported results and accounts from period to period. 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 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.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Consequently, even effective internal controls can only provide reasonable assurances with respect to any disclosure controls and procedures and internal control over financial statement preparation and presentation.

As of June 30, 2005, 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

Between June 15, 2004 and July 19, 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 alleged 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 sought 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 sought compensatory damages, interest, attorneys fees, and injunctive and equitable relief. The Company is vigorously defending this litigation.

On August 23, 2004, the Court issued an order consolidating the six actions. On October 7, 2004, the Court entered an order appointing a 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.

The plaintiffs filed an Amended Complaint on December 6, 2004. The Amended Complaint alleges violations of Section 10(b) of the Securities Exchange Act of 1934, and violations of Section 11 of the Securities Act of 1933, against all of the defendants, including: the Company, three of the Company s senior officers and seven of the Company s directors. The Amended Complaint also alleges violations of Section 20(a) of the Securities Exchange Act of 1934 against the three officers. The Amended Complaint alleges a putative class period from January 6, 2003 through May 24, 2004, and seeks compensatory damages, interest, attorneys fees, and injunctive and equitable relief.

On January 20, 2005, in response to the plaintiffs Amended Complaint, defendants filed a motion to dismiss plaintiffs action. On July 1, 2005, the Court issued an order denying defendants motion to dismiss.

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

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derivative action, pending the District Court s resolution of the motion to dismiss that defendants filed 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

None.

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 May 20, 2005 at the Villanova Conference Center for the purposes of acting upon the following matters:

1. To elect two directors to the board of directors to hold office until the 2008 annual meeting of stockholders or until their successors are duly elected and qualified.

	For	Withhold
James H. Cavanaugh, Ph.D.	38,055,185	4,633,383
George F. Horner III	39,921,892	2,766,676

The terms of the following directors continued after the meeting: (i) Costantino Ambrosio; (ii) David V. Milligan, Ph.D.; (iii) Alan W. Dunton, M.D.; (iv) Christopher T. Walsh, Ph.D. and (v) Cheryl A. Wenzinger, CPA.

2. To approve an amendment to our 2001 Stock Option Plan to increase the number of shares of our common stock available for issuance thereunder by 3,000,000 shares to an aggregate of 9,600,737 shares.

For	Against	Abstain
28,296,926	7,193,605	26,761

2. To ratify the appointment of PricewaterhouseCoopers LLP as independent auditors for the fiscal year ending December 31, 2005.

For	Against	Abstain
42,471,588	216,280	700

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit List, which follows the signature page, are included or incorporated by reference in this Quarterly Report on Form 10-Q.

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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: August 5, 2005

/s/ GEORGE F. HORNER III

George F. Horner III

President and Chief Executive Officer

(Principal Executive Officer and Accounting Officer)

Date: August 5, 2005

/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 June 30, 2005 (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)
2.4	Agreement and Plan of Merger, dated as of June 15, 2005 among Pfizer Inc., Viper Acquisition Corp. and Vicuron Pharmaceuticals, Inc. (11)

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(3)
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)

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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	Second Amendment to Shareholder Rights Agreement, dated as of June 15, 2005, by and between Vicuron Pharmaceuticals Inc. and American Stock Transfer & Trust Company, as Rights Agent (11)
9.2	Letter agreement amending the Letter agreement dated February 28, 2003, by and between Monte Tetoli S.p.A. and Vicuron Pharmaceuticals Inc. (12)
31.1	Certification of George F. Horner III under Section 302 of the Sarbanes-Oxley Act of 2002 (12)
31.2	Certification of Dov A. Goldstein, M.D. under Section 302 of the Sarbanes-Oxley Act of 2002 (12)
32.1	Certification of George F. Horner III under Section 906 of the Sarbanes-Oxley Act of 2002 (12)
32.2	Certification of Dov A. Goldstein, M.D. under Section 906 of the Sarbanes-Oxley Act of 2002 (12)

(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 as an exhibit to our Current Report on From 8-K, which was filed with the SEC on June 16, 2005 and incorporated herein by reference.
(12) Filed herewith.