ONYX PHARMACEUTICALS INC
Form 10-Q
August 09, 2006

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

þ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2006

or

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 0-28298

ONYX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	94-3154463
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer ID Number)

2100 Powell Street
Emeryville, California 94608
(Address of principal executive offices)
(510) 597-6500
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the proceeding 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 þ No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Act).

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No þ

Indicate the number of shares outstanding of each of the issuer s classes of Common Stock, as of the latest practicable date. The number of outstanding shares of the registrant s Common Stock, $0.001 par value, was 41,527,182 as of August 3, 2006.

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

ONYX PHARMACEUTICALS, INC.
CONDENSED BALANCE SHEETS
(In thousands)

	June 30, 2006 (Unaudited)	December 31, 2005 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,923	$ 46,064
Marketable securities	209,544	228,754
Receivable from collaboration partner	4,612	4,350
Other current assets	4,366	3,935
Total current assets	252,445	283,103
Long-term marketable securities		9,862
Property and equipment, net	1,296	1,617
Other assets	70	83
	$ 253,811	$ 294,665
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 278	$ 581
Payable to collaboration partner	17,101	30,823
Accrued liabilities	3,105	1,343
Accrued clinical trials and related expenses	10,251	5,567
Accrued compensation	2,859	3,111
Total current liabilities	33,594	41,425
Advance from collaboration partner	40,000	30,000
Commitments and contingencies		
Stockholders equity:		
Common stock	41	41
Additional paid-in capital	578,867	569,800
Receivable from stock option exercises	(27)	(24)
Accumulated other comprehensive loss	(1,028)	(767)
Accumulated deficit	(397,636)	(345,810)
Total stockholders equity	180,217	223,240

	$ 253,811	$ 294,665

See accompanying notes.

ONYX PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
Revenue:				
License fee	$ 150	$	$ 150	$ 1,000
Operating expenses:				
Net expense from unconsolidated joint business	12,449		16,551	
Research and development	8,693	12,079	16,493	25,611
Selling, general and administrative	13,421	7,840	25,044	12,640
Total operating expenses	34,563	19,919	58,088	38,251
Loss from operations	(34,413)	(19,919)	(57,938)	(37,251)
Interest income, net	2,939	1,403	6,112	2,635
Other income		375		375
Net loss	$ (31,474)	$ (18,141)	$ (51,826)	$ (34,241)
Basic and diluted net loss per share	$ (0.76)	$ (0.51)	$ (1.25)	$ (0.97)
Shares used in computing basic and diluted net loss per share	41,422	35,313	41,357	35,293

See accompanying notes.

ONYX PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	$ (51,826)	$ (34,241)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	379	278
Gain on sale of fixed assets		(6)
Gain on sale of investment		(375)
Stock-based compensation	7,493	355
Changes in assets and liabilities:		
Receivable from collaboration partner	(262)	(2,382)
Prepaid expenses and other current assets	(431)	(954)
Other assets	13	402
Accounts payable	(303)	(188)
Accrued liabilities	1,762	(590)
Accrued clinical trials and related expenses	4,684	2,787
Payable to collaboration partner	(13,722)	2,216
Accrued compensation	(252)	(4)
Net cash used in operating activities	(52,465)	(32,702)
Cash flows from investing activities:		
Purchases of marketable securities	(153,606)	(160,261)
Maturities of marketable securities	182,417	136,204
Capital expenditures	(58)	(232)
Proceeds from sale of fixed assets		6
Net cash provided by (used in) investing activities	28,753	(24,283)
Cash flows from financing activities:		
Advance from collaboration partner	10,000	
Net proceeds from issuances of common stock	1,571	813
Net cash provided by financing activities	11,571	813
Net decrease in cash and cash equivalents	(12,141)	(56,172)
Cash and cash equivalents at beginning of period	46,064	74,243
Cash and cash equivalents at end of period	$ 33,923	$ 18,071

See accompanying notes.

NOTES TO CONDENSED FINANCIAL STATEMENTS
June 30, 2006
(Unaudited)

Note 1. Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and six months ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006, or for any other future operating periods.

The condensed balance sheet at December 31, 2005 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

For further information, refer to the financial statements and footnotes thereto included in the Onyx Pharmaceuticals, Inc. (the Company or Onyx) Annual Report on Form 10-K for the year ended December 31, 2005.

Note 2. Net Expense from Unconsolidated Joint Business

Nexavar is currently marketed and sold primarily in the United States for the treatment of advanced kidney cancer. In July 2006, Nexavar received approval to treat patients in the European Union with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. Nexavar also has regulatory applications pending in other territories internationally. Onyx co-promotes Nexavar in the United States with Bayer Pharmaceuticals Corporation, or Bayer, under collaboration and co-promotion agreements. On March 6, 2006, Onyx and Bayer entered into a Co-Promotion Agreement to co-promote Nexavar in the United States. This agreement amends the original 1994 Collaboration Agreement and supersedes the provisions of that agreement that relate to the co-promotion of Nexavar in the United States. Outside of the United States, the terms of the Collaboration Agreement continue to govern. Under the terms of the Co-Promotion Agreement and consistent with the Collaboration Agreement, Onyx and Bayer will share equally in the profits or losses of Nexavar, if any, in the United States, subject only to the Company s continued co-funding of the development costs of Nexavar worldwide, excluding Japan. The collaboration was created through a contractual arrangement, not through a joint venture or other legal entity.

Bayer provides all product distribution and all marketing support services for Nexavar in the United States, including managed care, customer service, order entry and billing. Bayer is compensated for distribution expenses based on a fixed percent of gross sales of Nexavar in the United States. Bayer is reimbursed for half of its expenses for marketing services provided by Bayer for the sale of Nexavar in the United States. The parties share equally in any other out-of-pocket marketing expenses (other than expenses for sales force and medical science liaisons) that Onyx and Bayer incur in connection with the marketing and promotion of Nexavar in the United States. Bayer manufactures all Nexavar sold in the United States and is reimbursed at an agreed transfer price per unit for the cost of goods sold.

In the United States, Onyx contributes half of the overall number of sales force personnel required to market and promote Nexavar and half of the medical science liaisons to support Nexavar. Each of Onyx and Bayer bears its own sales force and medical science liaison expenses. These expenses are not included in the calculation of the profits or losses of the collaboration.

Outside of the United States, except in Japan, Bayer incurs all of the sales and marketing expenditures, and Onyx reimburses Bayer for half of those expenditures. In addition, upon approval of Nexavar in countries other than the United States, except Japan, Onyx will reimburse Bayer a fixed percentage of net sales to reimburse them for their marketing infrastructure. Research and development expenditures on a worldwide basis, except in Japan, are equally shared by both companies regardless of whether Onyx or Bayer incurs the expense. In Japan, Bayer is responsible for all development and marketing costs, and Onyx will receive a royalty on any net sales of Nexavar.

Net expense from the unconsolidated joint business consists of Onyx s share of the pretax collaboration loss generated from its collaboration with Bayer net of the reimbursement of Onyx s marketing and research and development costs related to Nexavar. Under the collaboration, Bayer recognizes net product revenue of Nexavar worldwide. Onyx records its share of the collaboration pre-tax loss on a quarterly basis. Collaboration loss is derived by calculating United States sales of Nexavar to third-party customers and deducting the cost of goods sold, distribution costs, marketing costs (including without limitation, advertising and education expenses, selling and promotion expenses, marketing personnel expenses, and Bayer marketing services expenses), Phase IV clinical trial costs, allocable overhead costs and research and development costs. As noted above, United States sales force and medical science liaison expenditures incurred by both companies are borne by each company separately and are not included in the calculation. Some of the revenue and expenses recorded to derive the net expense from unconsolidated joint business during the period presented are estimates of both parties and are subject to further adjustment based on each party s final review should actual results differ from these estimates.

For the three and six months ended June 30, 2006, net expense from unconsolidated joint business was $12.4 million and $16.6 million, respectively, calculated as follows:

	Three Months Ended June 30, 2006 (in thousands)	Six Months Ended June 30, 2006 (in thousands)
Product revenue, net	$ 32,190	$ 55,937
Combined cost of goods sold, distribution, selling, general and administrative	26,175	43,883
Combined research and development	49,362	79,393
Combined collaboration loss	$ (43,347)	$ (67,339)
Onyx s 50% share of collaboration loss	$ (21,674)	$ (33,670)
Reimbursement of Onyx s direct development and marketing expenses	9,225	17,119
Onyx s net expense from unconsolidated joint business	$ (12,449)	$ (16,551)

Note 3. Stock-Based Compensation

Effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards, or FAS, No. 123(R), Share-Based Payment , (FAS 123(R)), which requires the measurement and recognition of compensation expense for all stock-based payment made to employees and directors including employee stock option awards and employee stock purchases made under the Employee Stock Purchase Plan, or ESPP, based on estimated fair value. The Company previously applied the provisions of Accounting Principles Board Opinion, or APB, No. 25, Accounting for Stock Issued to Employees (APB 25) and related Interpretations and provided the required pro forma disclosures under FAS 123, Accounting for Stock-Based Compensation , or FAS 123.

All stock option awards to non-employees are accounted for at the fair value of the consideration received or the fair value of the equity instrument issued, as calculated using the Black-Scholes model, in accordance with FAS 123(R) and Emerging Issues Task Force Consensus No. 96-18, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The option arrangements are subject to periodic remeasurement over their vesting terms. The Company recorded compensation expense related to option grants to non-employees of $37,000 and $119,000 for the three months ended June 30, 2006 and 2005, respectively, and $160,000 and $355,000 for the six months ended June 30, 2006 and 2005, respectively.

Employee Stock Plans

In March 1996, the Board amended and restated the 1992 Incentive Stock Plan, renamed it as the 1996 Equity Incentive Plan (the Incentive Plan) and reserved 1,725,000 shares of common stock for issuance under the Incentive Plan. At the Company s annual meetings of stockholders in subsequent years, stockholders approved reserving an additional 4,100,000 shares of common stock for issuance under the Incentive Plan. The Incentive Plan provides for grants to employees of either nonqualified or incentive options and provides for the grant to consultants of the Company of nonqualified options. The exercise price of options granted under the Incentive Plan is determined by the Board of Directors, but cannot be less than 100 percent of the fair market value of the common stock on the date of grant.

In March 1996, the Board adopted the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan) and reserved 175,000 shares for issuance to provide for the automatic grant of nonqualified options to purchase shares of common stock to non-employee directors of the Company. At the Company s annual meetings of stockholders in subsequent years, stockholders approved reserving an additional 250,000 shares of common stock for issuance under the Directors Plan.

In June 2005, the 2005 Equity Incentive Plan was approved at the Company s annual meeting of stockholders to supersede and replace prior plans and reserved 7,560,045 shares of common stock for issuance under the Plan, consisting of (a) the number of shares remaining available for grant under the Incentive Plan and the Directors Plan, including shares subject to outstanding stock awards under those plans, and (b) an additional 3,990,000 shares. As of June 30, 2006, 4,738,880 shares of stock options and 40,000 shares of stock bonus awards were outstanding under the Plan.

In March 1996, the Board of Directors adopted the Employee Stock Purchase Plan, or the Purchase Plan. The number of shares available for issuance over the term of the Purchase Plan is limited to 400,000 shares. The Purchase Plan is designed to allow eligible employees of the Company to purchase shares of common stock through periodic payroll deductions. The price of common stock purchased under the Purchase Plan will be equal to 85 percent of the lower of the fair market value of the common stock on the commencement date of each offering period or the specified purchase date. Since inception, a total of 286,412 shares have been issued under the Purchase Plan, leaving a total of 113,588 shares available for issuance.

Pro forma Information for Periods prior to the Adoption of FAS 123(R)

Prior to the adoption of FAS 123(R), the Company elected to follow APB 25 to account for employee stock options and complied with the disclosure provisions of FAS 123 and FAS 148, Accounting for Stock-Based Compensation-Transition and Disclosure. No employee stock-based compensation expense was reflected in the Company s results of operations for the three and six-month periods ended June 30, 2005 for employee stock option awards as all options were granted with an exercise price equal to the market value of the underlying common stock on the date of grant. Our ESPP was deemed non-compensatory under the provisions of APB 25. Previously reported amounts have not been restated.

The pro forma information for the three and six months ended June 30, 2005 was as follows:

	Three Months Ended June 30, 2005	Six Months Ended June 30, 2005
	(in thousands except per share data)	
Net loss, as reported	$ (18,141)	$ (34,241)
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards, net of related tax effects	(3,297)	(5,845)
Net loss pro forma	$ (21,438)	$ (40,086)
Loss per share:		
Basic and diluted net loss per share as reported	$ (0.51)	$ (0.97)
Basic and diluted net loss per share pro forma	$ (0.61)	$ (1.14)

Impact of the Adoption of FAS 123(R)

The Company adopted FAS 123(R) using the modified prospective transition method beginning January 1, 2006. Accordingly, during the three and six-month period ended June 30, 2006, the Company recorded stock-based compensation expense for awards granted prior to but not yet vested as of January 1, 2006 as if the fair value method required for pro forma disclosure under FAS 123 has been followed for expense recognition purposes adjusted for estimated forfeitures. For these awards, the Company has continued to recognize compensation expense using the accelerated amortization method under FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans. For stock-based awards granted after January 1, 2006, the Company recognized compensation expense based on the estimated grant date fair value method required under FAS 123(R). The compensation expense for these awards was recognized using a straight-line amortization method. As FAS 123(R) requires that stock-based compensation expense be based on awards that are ultimately expected to vest, estimated stock-based compensation for the three and six-month period ended June 30, 2006 has been reduced for estimated forfeitures. Compensation expense for stock bonus awards is based on the market price of our stock on the date of grant. In the Company s pro forma information required under FAS 123 for periods prior to January 1, 2006, the Company accounted for forfeitures as they occurred. FAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The impact on the results of operations of recording stock-based compensation for the three and six-month period ended June 30, 2006 were as follows:

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
	(in thousands except per share data)	
Research and development	$ 695	$ 1,381
Selling, general and administrative	3,008	5,952

Total share-based compensation expense	$ 3,703	$ 7,333
Impact on basic and diluted net loss per share	$ (0.09)	$ (0.18)

	Three Months Ended June 30, 2006	Six Months Ended June 30, 2006
Stock options plans:		
Weighted average grant date fair value	$ 7.95	$ 12.88
Total fair value vested (in thousands)	2,694	5,486
Stock bonus awards:		
Weighted average grant date fair value	$21.04	$ 21.04
Total fair value vested		

As of June 30, 2006, the total unrecorded stock-based compensation balance for unvested stock options shares, net of expected forfeitures, was $24.9 million which is expected to be amortized over a weighted-average period of 22 months. As of June 30, 2006, the total unrecorded stock-based compensation balance for unvested stock bonus awards, net of expected forfeitures, was $773,000 which is expected to be amortized over a weighted-average period of 34 months. Cash received during the three and six-month periods ended June 30, 2006 for stock options exercised under all stock-based compensation arrangements were $397,000 and $1.6 million, respectively.

Valuation Assumptions

As of June 30, 2006 and 2005, the fair value of stock-based awards for employee stock option awards, restricted stock awards and employee stock purchases made under the ESPP was estimated using the Black-Scholes option pricing model. The following weighted average assumptions were used:

	Three Months Ended June 30		Six Months Ended June 30	
	2006	2005	2006	2005
Stock Option Plans:				
Risk-free interest rate	4.57%	3.92%	4.57%	3.61%
Expected life	4.2 years	3.9 years	4.2 years	3.8 years
Expected volatility	60%	73%	60%	76%
Expected dividends	None	None	None	None
Weighted average option fair value	$ 7.95	$16.88	$12.88	$15.36
Stock bonus awards:				
Expected life	3 years		3 years	
Expected dividends	None		None	
Weighted average shares fair value	$21.04		$21.04	
ESPP:				
Risk-free interest rate	4.33%	2.50%	4.33%	2.50%
Expected life	6 months	6 months	6 months	6 months
Expected volatility	60%	80%	60%	80%
Expected dividends	None	None	None	None
Weighted average shares fair value	$ 9.32	$16.92	$ 9.32	$16.92

Stock-Based Payment Award Activity

The following table summarizes stock option and award activity under all option plans for the six-month periods ended June 30, 2006 and 2005:

	Shares Available for Grant	Number of Shares Outstanding	Weighted Average Exercise Price
Employee stock options:			
Balance at December 31, 2004	1,282,193	2,296,442	$ 17.99
Shares authorized	3,990,000		
Granted	(895,500)	895,500	$ 27.04
Exercised		(78,590)	$ 9.19
Cancelled/expired/forfeited	38,834	(38,834)	$ 30.46
Balance at June 30, 2005	4,415,527	3,074,518	$ 20.70
Balance at December 31, 2005	3,610,461	3,806,081	$ 21.17
Granted	(1,218,950)	1,218,950	$ 25.34
Exercised		(240,464)	$ 6.72
Expired	(9,083)		$ 48.74
Cancelled/forfeited	45,687	(45,687)	$ 33.70
Balance at June 30, 2006	2,428,115	4,738,880	$ 22.86

	Shares	Weighted Average Grant Date Fair Value
Stock bonus awards:		
Balance at December 31, 2005		
Granted	40,000	$21.04
Vested		
Cancelled		
Balance at June 30, 2006	40,000	$21.04

The following table summarizes nonvested stock option activity under all option plans for the six-month period ended June 30, 2006.

	Shares	Weighted Average Grant Date Fair Value
Nonvested at December 31, 2005	2,209,027	$ 14.68
Granted	1,218,950	$ 12.88
Vested	(389,354)	$ 14.11

Cancelled/expired/forfeited	(36,604)	$	17.66
Nonvested at June 30, 2006	3,002,019	$	13.99

The options outstanding and exercisable for stock-based payment awards as of June 30, 2006 were in the following exercise price ranges:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	**Number Outstanding**	**Weighted Average Contractual Life Remaining (In years)**	**Weighted Average Exercise Price**	**Number Exercisable**	**Weighted Average Exercise Price**
$3.82 - $12.00	1,033,931	4.7	$ 7.22	966,565	$ 7.30
$12.11 - $24.04	1,129,552	9.0	$ 19.44	102,491	$ 17.37
$24.14 - $36.13	1,952,297	9.2	$ 27.97	342,300	$ 28.04
$38.08 - $48.19	623,100	7.9	$ 38.98	325,505	$ 38.87
Total	4,738,880	8.0	$ 22.86	1,736,861	$ 17.90

As of June 30, 2006, weighted average contractual life remaining for exercisable shares is 6 years. The total number of in-the-money awards exercisable as of June 30, 2006 was approximately 1,042,408. The aggregate intrinsic value of awards exercised were $992,000 and $1.4 million for the three-months ended June 30, 2006 and 2005, respectively. The aggregate intrinsic value of awards exercised were $4.7 million and $1.6 million for the six-months ended June 30, 2006 and 2005, respectively. The aggregate intrinsic value of in-the-money outstanding and exercisable awards were $10.4 million and $9.3 million, respectively as of June 30, 2006. The aggregate intrinsic value of options represents the total pretax intrinsic value, based on the Company s closing stock price of $16.83 at June 30, 2006, which would have been received by award holders had all award holders exercised their awards that were in-the-money as of that date.

During the three and six-month periods ended June 30, 2006, no purchase was made under our ESPP. As of June 30, 2006, securities authorized and available for issuance in connection with the Company s ESPP were 113,588 shares.

Note 4. Revenue

In accordance with the Collaboration Agreement Bayer recognizes all revenue from the sale of Nexavar. As such, for the three and six months ended June 30, 2006, Onyx reported no revenue related to Nexavar.

In April 2006, Onyx licensed cytopathic viruses for therapy and prophylaxis of neoplasia to DNAtriX, headquartered in Houston, Texas. According to the agreement, DNAtriX is granted certain worldwide semi-exclusive research licenses and exclusive worldwide development and commercialization license. Onyx has no further obligations under the license agreement, as such, the $150,000 was recognized as license fee revenue in the accompanying statement of operations.

Effective January 2005, the Company licensed exclusive rights to its p53-selective virus, ONYX-015, to Shanghai Sunway Biotech Co., Ltd. headquartered in Shanghai, People s Republic of China. Under this agreement, Shanghai Sunway is responsible for the research, development, manufacture and commercialization of ONYX-015 worldwide. During the quarter ended March 31, 2005, the Company received a cash payment of $1.0 million in exchange for the license to Shanghai Sunway of the intellectual property and know-how to ONYX-015. As the Company has no further obligations under the license agreement, the $1.0 million payment was recorded as license fee revenue in the accompanying statement of operations.

Note 5. Net Loss Per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during each period. Potentially dilutive outstanding securities consisting of 4,788,143 stock awards and warrants as of June 30, 2006 and 3,101,558 stock options and warrants as of June 30, 2005 were not included in the computation of diluted net loss per share because their effect would have been antidilutive.

Note 6. Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) is comprised of unrealized holding gains and losses on the Company s available-for-sale securities that are excluded from net loss and reported separately in stockholders equity. Comprehensive loss and its components are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2006	2005	2006	2005
	(In thousands)		(In thousands)	
Net loss - as reported	$ (31,474)	$ (18,141)	$ (51,826)	$ (34,241)
Other comprehensive loss:				
Change in unrealized gain (loss) on available-for-sale securities	20	218	(261)	(157)
Comprehensive loss	$ (31,454)	$ (17,923)	$ (52,087)	$ (34,398)

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

The following Management s Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements that involve risks and uncertainties. We use words such as may, will, expect, anticipate, estimate, intend, plan, predict, potential, believe, should and similar expressions to identify forward-looking statements. These statements appearing throughout this Quarter Report on Form 10-Q are statements regarding our intent, belief, or current expectations, primarily regarding our operations. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-Q. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including those set forth under Item 1A Risk Factors in this Form 10-Q.

Overview

We are a biopharmaceutical company building an oncology business by developing innovative therapies that target the molecular mechanisms implicated in cancer. With our collaborators, we are developing small molecule drugs with the goal of *changing the way cancer is treated*. A common feature of cancer cells is the excessive activation of signaling pathways that cause abnormal cell proliferation. In addition, tumors require oxygen and nutrients from newly formed blood vessels to support their growth. The formation of these new blood vessels is a process called angiogenesis. We are applying our expertise to develop oral anticancer therapies designed to prevent cancer cell proliferation and angiogenesis by inhibiting proteins that signal or support tumor growth. By exploiting the genetic differences between cancer cells and normal cells, we aim to create novel anticancer agents that minimize damage to healthy tissue.

Our product, Nexavar® (sorafenib) tablets, being developed with our collaborator, Bayer Pharmaceuticals Corporation, or Bayer, was approved by the U.S. Food and Drug Administration, or FDA, in December 2005 for the treatment of individuals with advanced kidney cancer. This approval marked the first newly approved drug for patients with this disease in over a decade. In July 2006, Nexavar received approval to treat patients in the European Union with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. Nexavar is a novel, orally available multi-kinase inhibitor and is one of a new class of anticancer treatments that target growth signaling.

On March 6, 2006, we and Bayer entered into a Co-Promotion Agreement to co-promote Nexavar in the United States. This agreement amends the original 1994 Collaboration Agreement and supersedes the provisions of that agreement that relate to the co-promotion of Nexavar in the United States. Outside of the United States, the terms of the Collaboration Agreement continue to govern. Under the terms of the Co-Promotion Agreement and consistent with the Collaboration Agreement, we will share equally in the profits or losses of Nexavar, if any, in the United States, subject only to our continued co-funding of the development costs of Nexavar worldwide, excluding Japan. Please refer to Note 2 of the Notes to Financial Statements included in Item I of this Form 10-Q for further information.

We have not been profitable since inception and expect to incur substantial and potentially increasing losses for the foreseeable future, due to expenses associated with the continuing development and commercialization of Nexavar. Since inception, we have relied on public and private financings, combined with milestone payments from our collaborators to fund our operations. In January 2006, we received the fourth and final $10.0 million milestone advance from Bayer as a result of the FDA approval of Nexavar. However, we expect that our losses will continue and will fluctuate from quarter to quarter and that such fluctuations may be substantial. As of June 30, 2006, our accumulated deficit was approximately $397.6 million.

Our business is subject to significant risks, including the risks inherent in our development efforts, the results of the Nexavar clinical trials, the marketing of Nexavar as a treatment for patients with advanced kidney cancer, our dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents, the lengthy and expensive regulatory approval process and competition from other products. For a discussion of these and some of the other risks and uncertainties affecting our business, see Item 1A Risk Factors of this Quarterly Report on Form 10-Q.

Critical Accounting Policies and the Use of Estimates

Critical accounting policies are those that require significant estimates, assumptions and judgments by management about matters that are inherently uncertain at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. These estimates form the basis for making judgments about the carrying values of assets and liabilities. We base our estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We consider certain accounting policies related to research and development expenses, stock-based compensation and use of estimates to be critical policies. Significant estimations used in 2006 included assumptions used in the determination of stock-based compensation related to stock options granted. Actual results could differ materially from these estimates. The changes to our critical accounting policies since we filed our Annual Report on Form 10-K, for the year ended December 31, 2005, with the Securities and Exchange Commission, or SEC, are described below. For a description of our other critical accounting policies, please refer to our 2005 Annual Report on Form 10-K for the fiscal year ended December 31, 2005.

Net Expense from Unconsolidated Joint Business: Net expense from unconsolidated joint business relates to our collaboration with Bayer for the development and marketing of Nexavar. It consists of our share of the net collaboration loss generated from our Collaboration Agreement with Bayer net of the reimbursement of our development and marketing expenses related to Nexavar. Under the collaboration, Bayer recognizes all revenue from the sale of Nexavar. The net expense from the unconsolidated joint business is, in effect, the net amount due to Bayer to balance the companies economics under the Nexavar collaboration. Under the terms of the collaboration, the companies share all research and development, marketing, and non-U.S. sales expenses, excluding Japan. Some of the revenue and expenses recorded to derive the net expense from unconsolidated joint business during the period presented are estimates of both parties and are subject to further adjustment based on each party s final review should actual results differ materially from these estimates. If the Company underestimates activity levels associated with the collaboration of Nexavar at a given point in time, the Company could record significant additional expenses in future periods.

Stock-Based Compensation: Effective January 1, 2006, we adopted the Statement of Financial Accounting Standards, or FAS, No. 123(R), Share-Based Payment , (FAS 123(R)), which requires the measurement and recognition of compensation expense for all stock-based payment made to our employees and directors including employee stock option awards and employee stock purchases made under our Employee Stock Purchase Plan, or ESPP, based on estimated fair value. We previously applied the provisions of Accounting Principles Board Opinion, or APB, No. 25, Accounting for Stock Issued to Employees (APB 25) and related Interpretations and provided the required pro forma disclosures under FAS 123, Accounting for Stock-Based Compensation , or FAS 123.

We adopted FAS 123(R) using the modified prospective transition method beginning January 1, 2006. Accordingly, during the three and six-month periods ended June, 2006, we recorded stock-based compensation expense for awards granted prior to but not yet vested as of January 1, 2006 as if the fair value method required for pro forma disclosure under FAS 123 were in effect for expense recognition purposes adjusted for estimated forfeitures. For stock-based awards granted after January 1, 2006, we recognized compensation expense based on the estimated grant date fair value method required under FAS 123(R). The compensation expense for these awards was recognized using a straight-line amortization method. The net loss for the three and six months ended June 30, 2006 includes stock-based compensation expense of $3.7 million and $7.3 million, or $0.09 and $0.18 per share, respectively, for the adoption of FAS 123(R). As of June 30, 2006, the total unrecorded stock-based compensation balance for unvested shares, net of expected forfeitures, was $24.9 million, which is expected to be amortized over a weighted-average period of 22 months.

While fair value may be readily determinable for awards of stock, market quotes are not available for long-term, nontransferable stock options because these instruments are not traded. We currently use the Black-Scholes option-pricing model to estimate the fair value of stock options. Option valuation models require the input of highly subjective assumptions, including but not limited to stock price volatility and stock option exercise behavior. We expect to continue to use the Black-Scholes model for valuing our stock-based compensation expense. However, our estimate of future stock-based compensation expense will be affected by a number of items including our stock price, the number of stock options our board of directors may grant in 2006, as well as a number of complex and subjective

valuation adjustments and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price, expected life and stock option exercise behaviors. Actual results could differ materially from these estimates.

Results of Operations

Three and six months ended June 30, 2006 and 2005

Revenue

Nexavar, our only marketed product, was approved in the U.S. in December 2005. In accordance with our collaboration agreement with Bayer, Bayer recognizes all revenue from the sale of Nexavar. As such, for the quarter ended June 30, 2006, we reported no revenue related to Nexavar. For the three and six months ended June 30, 2006, Nexavar net sales were $32.2 million and $55.9 million, respectively, primarily in the United States. This represents a 36% increase over revenue related to Nexavar recorded by Bayer for the quarter ended March 31, 2006.

In April 2006, Onyx licensed cytopathic viruses for therapy and prophylaxis of neoplasia to DNAtriX, headquartered in Houston, Texas. According to the agreement, DNAtriX is granted certain worldwide semi-exclusive research licenses and exclusive worldwide development and commercialization license. Onyx has no further obligations under the license agreement, as such, the $150,000 was recognized as license fee revenue for the three and six-month periods ended June 30, 2006.

There was no revenue recorded in the three months ended June 30, 2005. We recognized $1.0 million of license revenue for the six months ended June 30, 2005. The 2005 revenue represented a non-refundable payment received from Shanghai Sunway Biotech Co., Ltd. for exclusive rights to certain Onyx patents from the now discontinued therapeutic virus program.

Net Expense from Unconsolidated Joint Business

Nexavar is currently marketed and sold in the United States for the treatment of advanced kidney cancer. In July 2006, Nexavar received approval to treat patients in the European Union with advanced renal cell carcinoma who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. We co-promote Nexavar in the United States with Bayer under a collaboration agreement. Under the terms of the collaboration agreement, we share equally in the profits or losses of Nexavar, if any, in the United States, subject only to our continued co-funding of the development costs of Nexavar outside of Japan and its continued promotion of Nexavar in the United States. The collaboration was created through a contractual arrangement, not through a joint venture or other legal entity.

Bayer provides all product distribution and all marketing support services for Nexavar in the United States, including managed care, customer service, order entry and billing. Bayer is compensated for distribution expenses based on a fixed percent of gross sales of Nexavar in the United States. Bayer is reimbursed for half of its expenses for marketing services provided by Bayer for the sale of Nexavar in the United States. The parties share equally in any other out-of-pocket marketing expenses (other than expenses for sales force and medical science liaisons) that we and Bayer incur in connection with the marketing and promotion of Nexavar in the United States. Bayer manufactures all Nexavar sold in the United States and is reimbursed at an agreed transfer price per unit for the cost of goods sold.

In the United States, we contribute half of the overall number of sales force personnel required to market and promote Nexavar and half of the medical science liaisons to support Nexavar. Each of Onyx and Bayer bears its own sales force and medical science liaison expenses. These expenses are not included in the calculation of the profits or losses of the collaboration.

Outside of the United States, except in Japan, Bayer incurs all of the sales and marketing expenditures, and we share equally in those expenditures. In addition, upon approval of Nexavar in countries outside the United States, except Japan, we will reimburse Bayer a fixed percentage of net sales to reimburse them for their marketing infrastructure. Research and development expenditures on a worldwide basis, except in Japan, are equally shared by both companies regardless of whether we or Bayer incurs the expense. In Japan, Bayer is responsible for all development and marketing costs and we will receive a royalty on net sales of Nexavar.

Net expense from unconsolidated joint business consists of our share of the pretax collaboration loss generated from our collaboration with Bayer net of the reimbursement of our marketing and research and development costs related to Nexavar. Under the collaboration, Bayer recognizes all sales of Nexavar worldwide. We record our share of the collaboration pre-tax loss on a quarterly basis. Collaboration loss is derived by calculating net sales of Nexavar to third-

party customers and deducting the cost of goods sold, distribution costs, marketing costs (including without limitation, advertising and education expenses, selling and promotion expenses, marketing personnel expenses, and Bayer marketing services expenses), Phase IV clinical trial costs, allocable overhead costs and research and development costs. The net expense from the unconsolidated joint business is, in effect, the net amount due to Bayer to balance the companies economics under the Nexavar collaboration. As noted above, United States sales force and medical science liaison expenditures incurred by both companies are borne by each company separately and are not included in the calculation. Some of the revenue and expenses recorded to derive the net expense from unconsolidated joint business during the period presented are estimates of both parties and are subject to further adjustment based on each party s final review should actual results differ from these estimates. If we underestimate activity levels associated with the co-promotion and collaboration of Nexavar at a given point in time, we could record significant additional expense in future periods.

Net expense from unconsolidated joint business decreases with increased net Nexavar revenue and as the differential between Bayer s and our shared Nexavar expenses declines. If net Nexavar revenue is greater than the differential between Bayer s and our shared Nexavar expenses, we will report a net profit from unconsolidated joint business. Conversely, if Nexavar revenue declines or if the differential between Bayer s and our shared Nexavar expenses increases, net expense from unconsolidated joint business will increase. Due to the uncertainty in Bayer s revenue from the sale of Nexavar and the relative expenses of Bayer s and our shared Nexavar expenses, it is not possible to predict our net expense from unconsolidated joint business for future periods. We expect Bayer s and our shared Nexavar research and development expenses to increase in future periods as the companies develop Nexavar for indications beyond advanced kidney cancer. We also expect Bayer s and our shared cost of goods sold, distribution, selling and general administrative expense to increase as the companies prepare to market and sell Nexavar outside of the United States.

For the three months and six months ended June 30, 2006, net expense from unconsolidated joint business was $12.4 million and $16.6 million, respectively, calculated as follows:

	Three Months Ended June 30, 2006 (in thousands)	Six Months Ended June 30, 2006 (in thousands)
Product revenue, net	$ 32,190	$ 55,937
Combined cost of goods sold, distribution, selling, general and administrative	26,175	43,883
Combined research and development	49,362	79,393
Combined collaboration loss	$ (43,347)	$ (67,339)
Onyx s 50% share of collaboration loss	$ (21,674)	$ (33,670)
Reimbursement of Onyx s direct development and marketing expenses	9,225	17,119
Onyx s net expense from unconsolidated joint business	$ (12,449)	$ (16,551)

Research and Development Expenses

Research and development expenses were $8.7 million, including stock-based compensation expense of $694,000 for the three months ended June 30, 2006, a net decrease of $3.4 million, or 28 percent, from $12.1 million in the same period in 2005. For the six months ended June 30, 2006, research and development expenses were $16.5 million, including stock-based compensation expense of $1.4 million, a net decrease of $9.1 million, or 36 percent, from $25.6 million in the same period in 2005. We did not expense employee stock-based compensation prior to our adoption of FAS 123(R) on January 1, 2006. The decrease was primarily due to the change in presentation of our

Statement of Operation to include the net expense from unconsolidated joint business line item. Our share of Bayer s Nexavar product development expenses are included in net expense in unconsolidated joint business for the three and six months ended June 30, 2006. In periods prior to 2006, Bayer s Nexavar product development expense was included in research and development expense. In the new

presentation, beginning with the three months ended March 31, 2006, only our direct research and development expenses are included in the research and development line item. Onyx and Bayer are continuing to expand their investment in the development of Nexavar for additional indications including Phase III trials for Nexavar in melanoma, liver cancer, and lung cancer.

The major components of research and development costs include clinical manufacturing costs, clinical trial expenses, consulting and other third-party costs, salaries and employee benefits, supplies and materials, and allocations of various overhead and occupancy costs. The scope and magnitude of future research and development expenses are difficult to predict at this time given the number of studies that will need to be conducted for any of our potential product candidates. In general, biopharmaceutical development involves a series of steps beginning with identification of a potential target and includes proof of concept in animals and Phase I, II and III clinical studies in humans, each of which is typically more expensive than the previous step.

We manage the ongoing development program of Nexavar, together with our partner Bayer, through a joint development committee under the Collaboration Agreement between the parties. Together with Bayer, we have implemented a broad-based global development strategy for Nexavar that implements simultaneous clinical programs currently designed to expand the number of approved indications of Nexavar and evaluate the use of Nexavar in new and/or novel combinations. Our global development plan has included major Phase III studies in advanced kidney and liver cancer, and currently includes additional major Phase III clinical trials in metastatic melanoma comparing the administration of Nexavar in combination with the chemotherapeutics carboplatin and paclitaxel, as well as Nexavar with standard chemotherapeutic agents in non-small cell lung cancer. The completion dates of these trials are currently unknown. As of June 30, 2006, we have invested $174.5 million in the development of Nexavar, representing our share of the costs incurred to date under the collaboration.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $13.4 million, including stock-based compensation expense of $3.0 million, for the three months ended June 30, 2006, a net increase of $5.6 million, or 71 percent, from $7.8 million in the same period in 2005. For the six months ended June 30, 2006, selling, general and administrative expenses were $25.0 million, including stock-based compensation expense of $6.0 million, a net increase of $12.4 million, or 98 percent, from $12.6 million in the same period in 2005. We did not expense employee stock-based compensation prior to our adoption of FAS 123(R) on January 1, 2006. In addition to the stock-based compensation expense, the increase was primarily due to the establishment of our U.S. Nexavar sales force in the second half of 2005 and our marketing expenses relating to the Nexavar launch. In addition, with the change in accounting presentation to reflect net expense from unconsolidated joint business, our share of Bayer s Nexavar-related marketing expenses is included in the net expense from unconsolidated joint business line item. In periods prior to 2006, our share of Nexavar-related marketing expenses was included in the Company s selling, general and administrative line item. Under the new presentation only our direct selling, general and administrative expenses are included in the selling, general and administrative expense line item. Our direct selling, general and administrative expenses increased significantly for the three and six months end June 30, 2006 over the same period in the prior year due to the adoption of FAS 123(R), as well as the payroll-related costs of our sales force and medical science liaisons who were hired in the second half of 2005.

Interest Income, net

We had net interest income of $2.9 million for the three months ended June 30, 2006, an increase of $1.5 million from $1.4 million in the same period in 2005. For the six months ended June 30, 2006, we recorded interest income of $6.1 million, an increase of $3.5 million from $2.6 million in the same period in 2005. The increase was primarily due to higher interest rates as well as higher average investment balances for the three and six months ended June 30, 2006 resulting from our November 2005 sale of equity securities from which we received $136.2 million in net cash proceeds.

Other Income

In April 2005, we redeemed our investment in Syrrx, Inc. as a result of the acquisition of Syrrx by Takeda Pharmaceutical Company Limited. We received cash of $750,000 as a result of the redemption, which resulted in a gain of $375,000. This amount was recorded as Other income. No similar items were recorded in 2006.

Liquidity and Capital Resources

Since our inception, we have incurred losses, and we have relied primarily on public and private financing, combined with milestone payments we have received from our collaborators to fund our operations.

At June 30, 2006, we had cash, cash equivalents and short and long-term marketable securities of $243.5 million, compared to $284.7 million at December 31, 2005. The decrease of $41.2 million was attributable to net cash used in operations of $52.5 million, primarily related to the year-to-date net loss and the payment of the year-end and first quarter payable to Bayer, our collaboration partner. The decrease was offset by our $10.0 million receipt of the final milestone-based advance from Bayer in January 2006 for the approval of Nexavar by the FDA. The cash was used primarily for co-funding the clinical development program for Nexavar. In addition, we received proceeds of $1.6 million from the exercise of stock options during the six-month period ended June 30, 2006.

Our collaboration agreement with Bayer calls for creditable milestone-based payments. These amounts are interest-free and will be repayable to Bayer from a portion of any of our future profits and royalties. We received a $5.0 million in the third quarter of 2002 upon initiation of Phase II clinical studies and $15.0 million in the fourth quarter of 2003 based upon the initiation of a Phase III study. Based on the July 2005 NDA filing, we received the third milestone advance for $10.0 million in the third quarter of 2005. In addition, in January 2006, we received the final $10.0 million milestone advance as a result of the U.S. approval of Nexavar in December 2005. We received a total of $40.0 million of milestone advances from Bayer in connection with the development and approval of Nexavar. These advances will be repayable to Bayer from a portion of any of our future profits and royalties. If we do not receive any profits or royalties on any products, we will not have to repay Bayer any creditable milestone-based payments.

Total capital expenditures for equipment and leasehold improvements for the six-month period ended June 30, 2006, were $58,000. We currently expect to make expenditures for capital equipment and leasehold improvements of approximately $821,000 for the remainder of 2006.

We believe that our existing capital resources and interest thereon will be sufficient to fund our current and planned operations into 2008. However, if we change our development plans, we may need additional funds sooner than we expect. In addition, we anticipate that our co-development costs for the Nexavar program may increase over the next several years as we continue our share of funding the clinical development program and prepare for the potential product launches throughout the world. While these costs are unknown at the current time, we may need to raise additional capital to continue the co-funding of the program in future periods through and beyond 2008. We intend to seek any required additional funding through collaborations, public and private equity or debt financings, capital lease transactions or other available financing sources. Additional financing may not be available on acceptable terms, if at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders may result. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or to obtain funds through collaborations with others that are on unfavorable terms or that may require us to relinquish rights to certain of our technologies, product candidates or products that we would otherwise seek to develop on our own.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The primary objective of our investment activities is to preserve principal while at the same time maximize the income we receive from our investments without significantly increasing risk. Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. This means that a change in prevailing interest rates may cause the principal amount of the investments to fluctuate. By policy, we minimize risk by placing our investments with high quality debt security issuers, limit the amount of credit exposure to any one issuer, limit duration by restricting the term, and hold investments to maturity except under rare circumstances. We maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, money market funds, and investment grade government and non-government debt securities. Through our money managers, we maintain risk management control systems to monitor interest rate risk. The risk management control systems use analytical techniques, including sensitivity analysis. If market interest rates were to increase by 100 basis points, or 1%, as of June 30, 2006, the fair value of our portfolio would decline by approximately $936,000.

The table below presents the amounts and related weighted interest rates of our cash equivalents and marketable securities at:

	June 30, 2006			December 31, 2005		
	Maturity	Fair Value (In millions)	Average Interest Rate	Maturity	Fair Value (In millions)	Average Interest Rate
Cash equivalents, fixed rate	0 2 months	$ 33.9	4.96%	0 2 months	$ 45.4	3.97%
Marketable securities, fixed rate	0 19 months	$ 209.5	5.42%	0 23 months	$ 238.6	4.66%

We did not hold any derivative instruments as of June 30, 2006, and we have not held derivative instruments in the past. However, our investment policy does allow us to use derivative financial instruments for the purposes of hedging foreign currency denominated obligations. Our cash flows are denominated in U.S. dollars.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures: The Company s chief executive officer and chief financial officer reviewed and evaluated the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on that evaluation, the Company s chief executive officer and chief financial officer concluded that the Company s disclosure controls and procedures were effective as of June 30, 2006 to ensure the information required to be disclosed by the Company in this Quarterly Report on Form 10-Q is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and forms.

Changes in Internal Control over Financial Reporting: There were no changes in the Company s internal control over financial reporting during the quarter ended June 30, 2006 that have materially affected, or are reasonably likely to materially affect the Company s internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls: Internal control over financial reporting may not prevent or detect all errors and all fraud. Also, projections of any evaluation of effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

We are not a party to any material legal proceedings.

Item IA. Risk Factors

You should carefully consider the risks described below, together with all of the other information included in this report, in considering our business and prospects. The risks and uncertainties described below contain forward-looking statements, and our actual results may differ materially from those discussed here. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. Each of these risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our common stock and/or contingent value rights.

We have marked with an asterisk (*) those risk factors below that reflect material changes from the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2006.

Nexavar® (sorafenib) tablets is our only product, and we do not have any other product candidates in Phase II or Phase III clinical development. If Nexavar is not commercially successful, we may be unable to identify and promote alternative product candidates and our business would fail.

Nexavar is our only product. In June 2003, following an unsuccessful search for new collaboration partners for our therapeutic virus product candidates, including ONYX-015 and ONYX-411, we announced that we were discontinuing the development of all therapeutic virus product candidates, eliminating all employee positions related to these candidates and terminating all related research and manufacturing capabilities. As a result, we do not have internal research and preclinical development capabilities. Our scientific and administrative employees are dedicated to the development and commercialization of Nexavar and managing our relationship with Bayer, but are not actively discovering or developing new product candidates. As a result of the termination of our therapeutic virus program and drug discovery programs, we do not have a clinical development pipeline beyond Nexavar. If Nexavar is not commercially successful, we may be unable to identify and promote alternative product candidates to later stage clinical development, which would cause our business to fail.

If our clinical trials fail to demonstrate that Nexavar is safe and effective for cancer types other than kidney cancer, we will be unable to broadly commercialize Nexavar as a treatment for cancer, and our business may fail.

In collaboration with Bayer, we are conducting multiple clinical trials of Nexavar. We have completed Phase I single-agent clinical trials of Nexavar. We are currently conducting a number of Phase Ib clinical trials of Nexavar in combination with other anticancer agents. Phase I trials are not designed to test the efficacy of a drug candidate but rather to test safety; to study pharmacokinetics, or how drug concentrations in the body change over time; to study pharmacodynamics, or how the drug candidate acts on the body over a period of time; and to understand the drug candidate s side effects at various doses and schedules.

With Bayer, we have completed Phase II clinical trials of Nexavar in kidney and liver cancer and are conducting Phase II clinical trials in breast, non-small cell lung, melanoma and other cancers. Phase II trials are designed to explore the efficacy of a product candidate in several different types of cancers and may be randomized and double-blinded to ensure that the results are due to the effects of the drug.

In addition, we and Bayer are conducting a number of Phase III trials of Nexavar. Phase III trials are designed to more rigorously test the efficacy of a product candidate and are normally randomized and double-blinded. In May 2006, we and Bayer completed enrollment of a Phase III clinical trial of Nexavar in patients with liver cancer. In May 2006, we and Bayer completed enrollment of a Phase III clinical trial of Nexavar in combination with the chemotherapeutic agents carboplatin and paclitaxel in patients with malignant melanoma. In February 2006, we and Bayer initiated a Phase III clinical trial of Nexavar in combination with carboplatin and paclitaxel in patients with non-small cell lung cancer, or NSCLC.

Although we have received approvals for the use of Nexavar in the treatment of patients with advanced kidney cancer, the efficacy of Nexavar has not been proven in other types of cancer. Historically, many companies have failed to demonstrate the effectiveness of pharmaceutical product candidates in Phase III clinical trials notwithstanding favorable results in Phase I or Phase II clinical trials. Even though we have obtained fast track designation for Nexavar in metastatic liver and skin cancer, we and Bayer may not obtain marketing approval for the use of Nexavar in these indications from the FDA or other regulatory authorities. In addition, if previously unforeseen and unacceptable side effects are observed, we may not proceed with further clinical trials of Nexavar. In our clinical trials, we treat patients who have failed conventional treatments and who are in advanced stages of cancer. During the course of treatment, these patients may die or suffer adverse medical effects for reasons unrelated to Nexavar. These adverse effects may impact the interpretation of clinical trial results, which could lead to an erroneous conclusion regarding the toxicity or efficacy of Nexavar.

Our clinical trials may fail to demonstrate that Nexavar is safe and effective as a treatment for types of cancer other than kidney cancer, which would prevent us from marketing Nexavar as a treatment for those other types of cancer, limiting the potential market for the product, which may cause our business to fail.

There is a competing therapy approved for the treatment of advanced kidney cancer, and we expect the number of approved therapies to rapidly increase, which could harm the prospects for Nexavar in this indication.

Historically, the most commonly used therapeutic agents for patients suffering from metastatic kidney cancer were interleukin-2, or IL-2 and interferon-alpha, or IFN. With the development and approval of new anticancer therapies, it is anticipated that the first-line treatment for many of these patients could shift to the new therapeutic products.

Pfizer s drug, Sutent, a multi-kinase inhibitor, was recently approved by the FDA and the European Union for treating patients with kidney cancer and Gleevec-resistant gastrointestinal stromal tumors, or GIST. In June 2006, results of a randomized Phase III trial comparing Sutent to IFN in treatment-naive patients with advanced kidney cancer were reported. The primary endpoint of the study was progression-free survival with a median progression-free survival of 11 months for patients receiving Sutent compared to five months for patients receiving IFN. Moreover, Genentech s Avastin has been reported to have activity in kidney cancer, and Genentech has indicated that Avastin is now being used off-label for treatment of some kidney cancer patients. In June 2006, results from a randomized Phase II trial comparing Avastin with or without erlotinib in treatment-naive advanced renal cancer patients were reported. The median progression-free survival for the Avastin-treated patients was 8.5 months. A Phase III randomized trial in treatment-naïve advanced kidney cancer patients is underway comparing Avastin and IFN that may produce superior progression-free survival or overall survival data than Nexavar.

In addition, Wyeth is conducting a Phase III study of temsirolimus (CCI-779), an mTOR inhibitor, in patients with advanced kidney cancer. In June 2006, results of a randomized Phase III trial comparing temsirolimus to interferon to both agents combined in treatment-naïve, poor-risk advanced kidney cancer patients were reported. The primary endpoint of the study was overall survival. The reported median overall survival was 10.9 months for temsirolimus alone as compared to 7.3 months for interferon.

Pfizer also has an earlier stage compound, AG-013736, a multi-kinase inhibitor, which is in clinical development and being evaluated in kidney cancer patients.

It is not currently known which of Nexavar and these potential new kidney cancer products, if any, will be accepted by the medical community as the standard of care. The use of any particular therapy may limit the use of a competing therapy with a similar mechanism of action. The FDA approval of Nexavar permits Nexavar to be used as an initial, or first-line, therapy for the treatment of advanced kidney cancer, but the Swiss and European Union approvals do not. The successful introduction of other new therapies could significantly reduce the potential market for Nexavar in this indication. Decreased demand or price for Nexavar would harm our ability to realize revenue and profits from Nexavar which could cause our stock price to fall.

We are dependent upon our collaborative relationship with Bayer to manufacture and to further develop and commercialize Nexavar. There may be circumstances that delay or prevent the development and commercialization of Nexavar.

Our strategy for manufacturing and further developing and commercializing Nexavar depends in large part upon our relationship with Bayer. If we are unable to maintain our collaborative relationship with Bayer, we would need to undertake development, manufacturing and marketing activities at our own expense, which would significantly increase our capital requirements and limit the indications we are able to pursue and could prevent us from further commercializing Nexavar.

Under the terms of the collaboration agreement, we and Bayer are conducting multiple clinical trials of Nexavar. We and Bayer must agree on the development plan for Nexavar. If we and Bayer cannot agree, clinical trial progress could be significantly delayed or halted.

Under our agreement with Bayer, we have the opportunity to fund 50 percent of clinical development costs worldwide except in Japan, where Bayer will fund 100 percent of development costs and pay us a royalty on net sales. We are currently funding 50 percent of development costs for Nexavar and depend on Bayer to fund the balance of these costs. Our collaboration agreement with Bayer does not, however, create an obligation for either us or Bayer to fund additional development of Nexavar, or any other product candidate. If a party declines to fund development or ceases to fund development of a product candidate under the collaboration agreement, then that party will be entitled to receive a royalty on any product that is ultimately commercialized, but not to share in profits. Bayer could, upon 60 days notice, elect at any time to terminate its co-funding of the development of Nexavar. If Bayer terminates its co-funding of Nexavar development, we may be unable to fund the development costs on our own and may be unable to find a new collaborator, which could cause our business to fail.

Bayer has been the sponsor for all regulatory filings with the FDA. As a result, we have been dependent on Bayer s experience in filing and pursuing applications necessary to gain regulatory approvals. Bayer has limited experience in developing drugs for the treatment of cancer.

Our collaboration agreement with Bayer provides for Bayer to advance us creditable milestone-based payments. Bayer advanced us a total of $40.0 million pursuant to this provision. These funds are repayable out of a portion of our future profits and royalties, if any, from any of our products.

Our collaboration agreement with Bayer terminates when patents expire that were issued in connection with product candidates discovered under that agreement, or upon the time when neither we nor Bayer are entitled to profit sharing under that agreement, whichever is later. Bayer holds the global patent applications related to Nexavar. We currently anticipate that, if issued, the United States patent related to Nexavar will expire in 2022, subject to possible patent-term extension, the entitlement to which and the term of which cannot presently be calculated.

We are subject to a number of additional risks associated with our dependence on our collaborative relationship with Bayer, including:

- the amount and timing of resource expenditures can vary because of decisions by Bayer;
- possible disagreements as to development plans, including clinical trials or regulatory approval strategy;
- the right of Bayer to terminate its collaboration agreement with us on limited notice and for reasons outside our control;
- loss of significant rights if we fail to meet our obligations under the collaboration agreement;
- withdrawal of support by Bayer following the development or acquisition by it of competing products; and
- possible disagreements with Bayer regarding the collaboration agreement or ownership of proprietary rights.

Due to these factors and other possible disagreements with Bayer, we may be delayed or prevented from further developing or commercializing Nexavar, or we may become involved in litigation or arbitration, which would be time consuming and expensive.

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Our clinical trials could take longer to complete than we project or may not be completed at all.

Although for planning purposes we project the commencement, continuation and completion of ongoing clinical trials for Nexavar, the actual timing of these events may be subject to significant delays relating to various causes, including actions by Bayer, scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria and shortages of available drug supply. We may not complete clinical trials involving Nexavar as projected or at all.

We rely on Bayer, academic institutions and clinical research organizations to conduct, supervise or monitor most clinical trials involving Nexavar. We have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own.

We are directly supervising and monitoring on our own certain Phase II and Phase III clinical trials of Nexavar for the treatment of malignant melanoma. Onyx has not conducted a clinical trial that has led to an NDA filing. Consequently, we may not have the necessary capabilities to successfully execute and complete these planned clinical trials in a way that leads to approval of Nexavar for the target indication. Failure to commence or complete, or delays in our planned clinical trials would prevent us from commercializing Nexavar in melanoma, and thus seriously harm our business.

If serious adverse side effects are associated with Nexavar, approval for Nexavar could be revoked, sales of Nexavar could decline, and we may be unable to develop Nexavar as a treatment for other types of cancer.

The approved package insert for Nexavar for the treatment of patients with advanced kidney cancer includes the following warnings relating to observed adverse side effects:

> Hypertension may occur early in the course of therapy and blood pressure should be monitored weekly during the first six weeks of therapy and treated as needed.
>
> Incidence of bleeding, regardless of causality, was 15 percent for Nexavar vs. 8 percent for placebo and the incidence of treatment-emergent cardiac ischemia/infarction was 2.9 percent for Nexavar vs. 0.4 percent for placebo.
>
> Most common treatment-emergent adverse events with Nexavar were diarrhea, rash/desquamation, fatigue, hand-foot skin reaction, alopecia and nausea. Grade 3 / 4 adverse events were 38 percent for Nexavar vs. 28 percent for placebo.
>
> Women of child-bearing potential should be advised to avoid becoming pregnant and advised against breast-feeding.
>
> In cases of any severe or persistent side effects, temporary treatment interruption, dose modification or permanent discontinuation should be considered.

As Nexavar becomes more widely available worldwide, we and Bayer anticipate that newly discovered information regarding adverse events may be added to the package insert to reflect any new data resulting from additional patient exposures. Such updated and expanded information about the adverse event profile of the drug may have an adverse effect on Nexavar sales.

If additional adverse side effects emerge, or a pattern of severe or persistent previously observed side effects is observed in the Nexavar patient population, the FDA or other international regulatory agencies could modify or revoke approval of Nexavar or we may choose to withdraw it from the market. If this were to occur, we may be unable to obtain approval of Nexavar in additional indications and foreign regulatory agencies may decline to approve Nexavar for use in any indication. Any of these outcomes would have a material adverse impact on our business. In addition, if patients receiving Nexavar were to suffer harm as a result of their use of Nexavar, these patients or their representatives may bring claims against us. These claims, or the mere threat of these claims, could have a material adverse effect on our business and results of operations.

Our operating results are unpredictable and may fluctuate. If our operating results are below the expectations of securities analysts or investors, the trading price of our stock could decline.

Our operating results will likely fluctuate from fiscal quarter to fiscal quarter, and from year to year, and are difficult to predict. Sales of Nexavar commenced in late December 2005. Due to a highly competitive environment with existing and emerging products, Nexavar sales will be difficult to predict from period to period. Our operating expenses are largely independent of Nexavar sales in any particular period. We believe that our quarterly and annual results of operations may be negatively affected by a variety of factors. These factors include, but are not limited to, the level of patient demand for Nexavar, the ability of Bayer s distribution network to process and ship product on a timely basis, fluctuations in foreign exchange rates, investments in sales and marketing efforts to support the sales of Nexavar, Bayer and our investments in the research and development and commercialization of Nexavar, and expenditures we may incur to acquire additional products.

In addition, as a result of our adoption of FAS 123(R), we must measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award, and recognize the cost as an expense over the employee s requisite service period. As the variables that we use as a basis for valuing these awards change over time, the magnitude of the expense that we must recognize may vary significantly. Any such variance from one period to the next could cause a significant fluctuation in our operating results.

It is, therefore, difficult for us to accurately forecast profits or losses. As a result, it is possible that in some quarters our operating results could be below the expectations of securities analysts or investors, which could cause the trading price of our common stock to decline, perhaps substantially.

We have a history of losses, and we expect to continue to incur losses.

Our net loss for the year ended December 31, 2003 was $45.0 million, for the year ended December 31, 2004 was $46.8 million and for the year ended December 31, 2005 was $95.2 million. Our net loss for the six months ended June 30, 2006 was $51.8 million. As of June 30, 2006, we had an accumulated deficit of approximately $397.6 million. We have incurred these losses principally from costs incurred in our research and development programs, from our general and administrative costs and the development of our commercialization infrastructure. It is not unusual for patients to be offered access to investigational compounds in late-stage clinical development. Such programs involve substantial costs. We expect to incur significant and increasing operating losses over the next several years as we continue our clinical trial activities and, with Bayer, establish commercial infrastructure in Europe and other parts of the world. We expect our operating losses to increase with our co-funding of ongoing Nexavar clinical and commercial activities under our collaboration agreement with Bayer.

We and Bayer only began to generate revenues from the sale of Nexavar in December 2005, and we must repay the milestone-based advances we received from Bayer from any future profits and royalties. We have made significant expenditures towards the development and commercialization of Nexavar, and may never realize sufficient product sales to offset these expenditures. Our ability to achieve profitability depends upon success by us and Bayer in completing development of Nexavar, obtaining required regulatory approvals and manufacturing and marketing the approved product.

Our clinical trial of Nexavar in kidney cancer may not yield statistically significant overall survival data, which may negatively impact the commercialization of Nexavar.í

In March 2005, an independent data monitoring committee reviewed the safety and efficacy data from our ongoing Phase III trial of Nexavar in kidney cancer and concluded that the trial met its co-primary endpoint, resulting in statistically significant longer progression-free survival in those patients administered Nexavar versus those patients administered placebo. In July 2005, we and Bayer filed an NDA seeking approval of Nexavar to treat patients with kidney cancer in the United States based on the results. In September 2005, Bayer also filed a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for the approval to market Nexavar within the European Union to treat patients with kidney cancer.

In April 2005, we and Bayer recommended that all patients in our ongoing Phase III kidney cancer trial be offered access to Nexavar. This decision followed further review of the progression-free survival data, as well as additional discussions with the principal investigators, an independent data monitoring committee, and the FDA. As a result in April 2005, patients who were previously administered placebo in the trial were given the opportunity to elect to receive Nexavar. This action has reduced the number of patients in the trial receiving placebo and is expected to negatively impact our ability to obtain statistically significant data on overall survival of patients with kidney cancer participating in this clinical trial.

In November 2005, an investigator-reported interim analysis on overall survival of patients in the Phase III kidney cancer trial was presented at the thirteenth European Cancer Conference, or ECCO. The analysis, which was based on the 220 deaths that had occurred by May 31, 2005, was conducted while the Phase III kidney cancer study was ongoing and as described above, in April 2005 we and Bayer offered access to Nexavar to all patients in the trial, including those who had been receiving placebo. The investigator reported there was a 28% reduction in rate of death within the measurement period for patients receiving Nexavar compared to those who were not. While this represents a positive trend, with a p-value of 0.018, the data was not sufficient to be considered statistically significant according to the predefined specifications for this interim analysis. P-values are used to indicate the probability that results observed in two different samples are different due to chance alone, as opposed to a benefit due to the intervention, such as treatment with Nexavar. In order for the interim analysis of survival data reported by the investigator to be considered statistically significant, the p-value would have had to be less than 0.0005. A second investigator-reported interim analysis was presented at the American Society of Clinical Oncology, or ASCO, meeting in June 2006. This second analysis indicated that overall survival was longer for patients receiving Nexavar than for placebo patients. The updated data showed a continued improvement in overall survival of 19.3 months for Nexavar patients versus 15.9 months for placebo patients, with a p-value of 0.015, despite the fact that 48% of placebo patients crossed over to Nexavar. While suggesting a favorable survival trend for patients who received Nexavar, these data are not sufficient to be considered statistically significant according to the predefined specifications for this interim analysis.

The final survival analysis, which is planned when 540 deaths have occurred, is not expected for some time. Cross over of patients from placebo to Nexavar is likely to negatively impact our ability to obtain statistically significant overall survival data. Competitors with statistically significant overall survival data could impair our ability to successfully market Nexavar.

We are subject to extensive government regulation, which can be costly, time consuming and subject us to unanticipated delays.

Drug candidates under development are subject to extensive and rigorous domestic and foreign regulation. We have received regulatory approval only for the use of Nexavar in the treatment of advanced kidney cancer in the United States and a number of foreign markets.

We expect to rely on Bayer to manage communications with regulatory agencies, including filing new drug applications and generally directing the regulatory approval process for Nexavar. We and Bayer may not obtain necessary additional approvals from the FDA or other regulatory authorities. If we fail to obtain required governmental approvals, we will experience delays in or be precluded from marketing Nexavar in particular indications or countries. The FDA or other regulatory authorities may approve only limited label information for the product. The label information describes the indications and methods of use for which the product is authorized, and if overly restrictive, may limit our and Bayer s ability to successfully market any approved product. If we have disagreements as to ownership of clinical trial results or regulatory approvals, and the FDA refuses to recognize us as holding, or having access to, the regulatory approvals necessary to commercialize our product candidates, we may experience delays in or be precluded from marketing products.

The regulatory review and approval process takes many years, requires the expenditure of substantial resources, involves post-marketing surveillance and may involve ongoing requirements for post-marketing studies. Additional or more rigorous governmental regulations may be promulgated that could delay regulatory approval of Nexavar. Delays in obtaining regulatory approvals may:

adversely affect the successful commercialization of Nexavar;

impose costly procedures on us;

diminish any competitive advantages that we may attain; and

adversely affect our receipt of revenues or royalties.

Even after Nexavar and any other products we may develop are marketed, the products and their manufacturers are subject to continual review. Later discovery of previously unknown problems with Nexavar or manufacturing and production by Bayer or other third parties may result in restrictions on Nexavar, including withdrawal of Nexavar from the market. In addition, problems or failures with the products of others, before or after regulatory approval, including our competitors, could have an adverse effect on our ability to obtain or maintain regulatory approval for Nexavar. If we fail to comply with applicable regulatory requirements, we could be subject to penalties, including fines, suspensions of regulatory approval, product recall, seizure of products and criminal prosecution.

While Nexavar has received approvals for sale in a number of countries outside of the United States, it may never receive pricing approval in these foreign countries, and may not receive marketing approval in additional countries. [í]

In July 2005, we and Bayer filed for approval of Nexavar based on the progression-free survival data. While the FDA granted full approval in December 2005 for patients with advanced kidney cancer, we and Bayer do not know whether foreign regulatory authorities will broadly grant approval to Nexavar. In March 2006, the Swiss Agency for Therapeutic Products approved Nexavar as a treatment for patients with advanced kidney cancer, after nepherectomy and prior palliative or adjuvant therapy with cytokines. In April 2006 the Mexican Ministry of Health granted approval of Nexavar as a treatment for advanced kidney cancer. In July 2006, the European Commission granted marketing authorization for Nexavar for the treatment of patients with advanced kidney cancer who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy. Nexavar has also received approvals in Chile, Brazil, Korea, and Argentina. Other foreign regulatory authorities may not, however, be satisfied with the safety and efficacy data submitted in support of the foreign applications, which could result in non-approval, a requirement of additional clinical trials, further analysis of existing data or a restricted use of Nexavar. Lack of marketing approval in a particular country would prevent us from selling Nexavar in that country, which could harm our business. In addition, we and Bayer will be required to negotiate the price of Nexavar with European governmental authorities in order for Nexavar to be eligible for government reimbursement. In many European countries, patients will not use prescription drugs that are not reimbursable by their governments. European price negotiations could delay commercialization in a particular country by twelve months or more.

Nexavar was approved by the FDA for the treatment of advanced kidney cancer on the basis of the progression-free survival endpoint. Since we have not yet performed the final analysis on overall survival, we do not know whether we will achieve a statistically significant outcome on this endpoint. We expect that our ability to obtain statistically significant overall survival data will be negatively impacted by our April 2005 decision to allow patients that had been receiving placebo to elect to receive Nexavar. Regulatory authorities may have concerns or require further analysis of the manner in which tumor progression was determined. It is possible that in the absence of statistically significant overall survival data, Nexavar will not receive marketing approval in some countries, or will receive more limited approval than that granted by the FDA. For example, neither the European Union nor the Swiss Agency for Therapeutic Products approved Nexavar as an initial or first-line therapy, and it is possible that other foreign regulatory agencies will take a similar approach. In addition to the question of whether Nexavar has demonstrated sufficient efficacy in the treatment of kidney cancer, regulatory authorities may have questions about the safety of the drug. For example, there were instances of greater adverse events in the treatment arm relative to the placebo arm of the Phase III trial, and physicians have reported some incidents of additional adverse events in patients receiving Nexavar. In addition, as an element of the foreign approval process, the applicable regulatory authority must be satisfied with the processes and facilities for drug manufacture, which includes a physical inspection of those facilities. Any conclusion that there are shortcomings in the processes, facilities, or quality control procedures related to manufacture of the drug could result in a significant delay in foreign approval. For these or other reasons, there is no assurance that Nexavar will receive any additional foreign approvals on the basis of the current application without amendment, if it is approved at all.

We face intense competition and rapid technological change, and many of our competitors have substantially greater resources than we have.

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market Nexavar to compete with other products and therapies that currently exist or are being developed. Many other companies are actively seeking to develop products that have disease targets similar to those we are pursuing. Some of these competitive product candidates are in clinical trials, and others are approved. Competitors that target the same tumor types as our Nexavar program and that have commercial products or product candidates in clinical development include Pfizer, Wyeth, Novartis International AG, Amgen, AstraZeneca PLC, OSI Pharmaceuticals, Inc. and Genentech, Inc. among others. A number of companies have agents targeting Vascular Endothelial Growth Factor, or VEGF; VEGF receptors; Epidermal Growth Factor, or EGF; EGF receptors; and other enzymes. These agents include antibodies and small molecules. OSI Pharmaceuticals with Tarceva , a small molecule inhibitor of the EGF receptor has been approved in the United States for treatment of NSCLC and pancreatic cancer in combination with gemcitabine. Companies working on developing antibody approaches include Amgen and ImClone Systems, Inc. ImClone has developed Erbitux, which is an antibody targeting the EGF receptor. Erbitux has been approved in the United States and the European Union for treatment of colorectal cancer, as well as in the United States for the treatment of most types of head and neck cancer. Genentech has developed Avastin , an antibody targeting VEGF, which has received approvals in the United States and the European Union for treatment of colorectal cancer and is in clinical development for kidney cancer. In addition, many other pharmaceutical companies are developing novel cancer therapies that, if successful, would also provide competition for Nexavar.

Many of our competitors, either alone or together with collaborators, have substantially greater financial resources and research and development staffs. In addition, many of these competitors, either alone or together with their collaborators, have significantly greater experience than we do in:

developing products;

undertaking preclinical testing and human clinical trials;

obtaining FDA and other regulatory approvals of products; and

manufacturing and marketing products.

Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or commercializing product candidates before we do. If we receive FDA approval and commence commercial product sales, we will compete against companies with greater marketing and manufacturing capabilities, areas in which we have limited or no experience.

We also face, and will continue to face, competition from academic institutions, government agencies and research institutions. Further, we face numerous competitors working on product candidates to treat each of the diseases for which we are seeking to develop therapeutic products. In addition, our product candidates, if approved, will compete with existing therapies that have long histories of safe and effective use. We may also face competition from other drug development technologies and methods of preventing or reducing the incidence of disease and other classes of therapeutic agents.

Developments by competitors may render our product candidates obsolete or noncompetitive. We face and will continue to face intense competition from other companies for collaborations with pharmaceutical and biotechnology companies, for establishing relationships with academic and research institutions, and for licenses to proprietary technology. These competitors, either alone or with collaborative parties, may succeed with technologies or products that are more effective than ours.

We anticipate that we will face increased competition in the future as new companies enter our markets and as scientific developments surrounding other cancer therapies continue to accelerate. We have made significant expenditures towards the development of Nexavar and the establishment of a commercialization infrastructure. If Nexavar cannot compete effectively in the marketplace, we may be unable to realize revenue from Nexavar sufficient to offset our expenditures towards its development and commercialization, and our business will suffer.

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We will need substantial additional funds, and our future access to capital is uncertain.

We will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to develop Nexavar for additional indications, pursue regulatory approval and commercialize this product in Europe and the rest of the world. Our future capital requirements will depend upon a number of factors, including:

the size and complexity of our Nexavar program;

decisions made by Bayer and Onyx to alter the size, scope and schedule of clinical development;

repayment of our of milestone-based advances;

progress with clinical trials;

the time and costs involved in obtaining regulatory approvals;

the cost involved in enforcing patent claims against third parties and defending claims by third parties (both of which are shared with Bayer);

the costs associated with acquisitions or licenses of additional products;

competing technological and market developments; and

global product commercialization activities.

We may not be able to raise additional financing on favorable terms, or at all. If we are unable to obtain additional funds, we may not be able to fund our share of commercialization expenses and clinical trials. We may also have to curtail operations or obtain funds through collaborative and licensing arrangements that may require us to relinquish commercial rights or potential markets or grant licenses that are unfavorable to us.

We believe that our existing capital resources and interest thereon will be sufficient to fund our current development plans into 2008. However, if we change our development plans, we may need additional funds sooner than we expect. Moreover, once a development program has been initiated, under our collaboration with Bayer we may have limited ability to control the expenditures made under that program, which we share equally with Bayer. In addition, we anticipate that our co-development costs for the Nexavar program may increase over the next several years as we continue our share of funding the clinical development program and prepare for the potential product launches of Nexavar throughout the world. While these costs are unknown at the current time, we expect that we will need to raise substantial additional capital to continue the co-funding of the Nexavar program in future periods through and beyond 2008. We may have to curtail our funding of Nexavar if we cannot raise sufficient capital. If we do not continue to co-fund the further development of Nexavar, we will receive a royalty on future sales of products, instead of a share of profits.

We do not have manufacturing expertise or capabilities and are dependent on Bayer to fulfill our manufacturing needs, which could result in lost sales and the delay of clinical trials or regulatory approval.

Under our collaboration agreement with Bayer, Bayer has the manufacturing responsibility to supply Nexavar for clinical trials and to support our commercial requirements. However, should Bayer give up its right to co-develop Nexavar, we would have to manufacture Nexavar, or contract with another third party to do so for us. We lack the resources, experience and capabilities to manufacture Nexavar or any future product candidates on our own and would require substantial funds to establish these capabilities. Consequently, we are, and expect to remain, dependent on third parties to manufacture our product candidates and products. These parties may encounter difficulties in production scale-up, including problems involving production yields, quality control and quality assurance and shortage of qualified personnel. These third parties may not perform as agreed or may not continue to manufacture our products for the time required by us to successfully market our products. These third parties may fail to deliver the required quantities of our products or product candidates on a timely basis and at commercially reasonable prices.

Failure by these third parties could impair our ability to meet the market demand for Nexavar, and could delay our ongoing clinical trials and our applications for regulatory approval. If these third parties do not adequately perform, we may be forced to incur additional expenses to pay for the manufacture of products or to develop our own manufacturing capabilities.

We are dependent on the efforts of Bayer to market and promote Nexavar in countries outside the United States where Nexavar has received approval.

Under our collaboration and co-promotion agreements with Bayer, we and Bayer are co-promoting Nexavar in the United States. If we continue to co-promote Nexavar, and continue to co-fund development in the United States, we will share equally in profits or losses, if any, in the United States.

We do not, however, have the right to co-promote Nexavar in any country outside the United States, and will be dependent solely on Bayer to promote Nexavar in foreign countries where Nexavar is approved. In all foreign countries, except Japan, Bayer would first receive a portion of the product revenues to repay Bayer for its foreign commercialization infrastructure, before determining our share of profits and losses. In Japan, we would receive a royalty on any sales of Nexavar.

We have limited ability to direct Bayer in its promotion of Nexavar in foreign countries where Nexavar is approved. Bayer may not have sufficient experience to promote oncology products in foreign countries and may fail to devote appropriate resources to this task. If Bayer fails to adequately promote Nexavar in foreign countries, we may be unable to obtain any remedy against Bayer. If this were to happen, sales of Nexavar in any foreign countries where Nexavar is approved may be harmed, which would negatively impact our business.

Similarly, Bayer may establish a sales and marketing infrastructure for Nexavar outside the United States that is too large and expensive in view of the magnitude of the Nexavar sales opportunity or establish this infrastructure too early in view of the ultimate timing of regulatory approval. Since we share in the profits and losses arising from sales of Nexavar outside of the United States, rather than receiving a royalty (except in Japan), we are at risk with respect to the success or failure of Bayer s commercial decisions related to Nexavar as well as the extent to which Bayer succeeds in the execution of its strategy.

We have the right to co-promote Nexavar in the United States, but we do not have proven sales or marketing expertise.

We have the right under our collaboration and co-promotion agreements with Bayer to co-promote Nexavar in the United States in conjunction with Bayer. While we have invested heavily in our commercialization infrastructure, we have only limited experience in selling and marketing Nexavar which was approved in December 2005. If we do not develop and maintain marketing and sales capabilities as required by the co-promotion agreement, we could lose our co-promotion rights. Further, we compete with other companies that have experienced and well-funded marketing and sales operations. If we are unable to compete successfully our business will be harmed.

If the specialty pharmacies and distributors that we and Bayer rely upon to sell our products fail to perform, our business may be adversely affected.

Our success depends on the continued customer support efforts of our network of specialty pharmacies and distributors. A specialty pharmacy is a pharmacy that specializes in the dispensing of medications for complex or chronic conditions, which often require a high level of patient education and ongoing management. The use of specialty pharmacies and distributors involves certain risks, including, but not limited to, risks that these specialty pharmacies and distributors will:

- not provide us with accurate or timely information regarding their inventories, the number of patients who are using Nexavar or complaints about Nexavar;
- not effectively sell or support Nexavar;
- reduce their efforts or discontinue to sell or support Nexavar;
- not devote the resources necessary to sell Nexavar in the volumes and within the time frames that we expect;

be unable to satisfy financial obligations to us or others; and

cease operations.

Any such failure may result in decreased product sales and profits, which would harm our business.

If we lose our key employees and consultants or are unable to attract or retain qualified personnel, our business could suffer.

Our future success will depend in large part on the continued services of our management personnel, including Hollings C. Renton, our Chairman, President and Chief Executive Officer, Laura A. Brege, our Executive Vice President and Chief Business Officer, Edward F. Kenney, our Executive Vice President and Chief Commercial Officer and Henry J. Fuchs, our Executive Vice President and Chief Medical Officer as well as each of our other executive officers. The loss of the services of one or more of these key employees could have an adverse impact on our business. We do not maintain key person life insurance on any of our officers, employees or consultants, other than for our chief executive officer. Any of our key personnel could terminate their employment with us at any time and without notice. We depend on our continued ability to attract, retain and motivate highly qualified personnel. We face competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities and other research institutions.

In 2003, we restructured our operations to reflect an increased priority on the development of Nexavar and discontinued our therapeutic virus program. As a result of the restructuring, we eliminated approximately 75 positions, including our entire scientific team associated with the therapeutic virus program. Our remaining scientific and administrative employees are engaged in managing our collaboration with Bayer to develop Nexavar, but are not actively involved in new product candidate discovery. If we resume our research and development of other product candidates, we will need to hire individuals with the appropriate scientific skills. If we cannot hire these individuals in a timely fashion, we will be unable to engage in new product candidate discovery activities.

The market may not accept our products and pharmaceutical pricing and reimbursement pressures may reduce profitability.

Nexavar or any future product candidates that we may develop may not gain market acceptance among physicians, patients, healthcare payors and the medical community or the market may not be as large as forecasted. One factor that may affect market acceptance of Nexavar or any future products we may develop is the availability of third-party reimbursement. Our commercial success may depend, in part, on the availability of adequate reimbursement for patients from third-party healthcare payors, such as government and private health insurers and managed care organizations. Third-party payors are increasingly challenging the pricing of medical products and services and their reimbursement practices may affect the price levels for Nexavar. Changes in government legislation or regulation, such as the Medicare Act, including Medicare Part D, or changes in private third-party payers policies towards reimbursement for our products may reduce reimbursement of our products costs to physicians. In addition, the market for Nexavar may be limited by third-party payors who establish lists of approved products and do not provide reimbursement for products not listed. If Nexavar is not on the approved lists, our sales may suffer.

Nexavar s success in Europe will also depend largely on obtaining and maintaining government reimbursement because in many European countries patients will not use prescription drugs that are not reimbursed by their governments. In addition, negotiating prices with governmental authorities can delay commercialization by twelve months or more. Even if reimbursement is available, reimbursement policies may adversely affect our ability to sell our products on a profitable basis. For example, in Europe as in many international markets, governments control the prices of prescription pharmaceuticals and expect prices of prescription pharmaceuticals to decline over the life of the product or as volumes increase. We believe that this will continue into the foreseeable future as governments struggle with escalating health care spending.

A number of additional factors may limit the market acceptance of products including the following:

rate of adoption by healthcare practitioners;

types of cancer for which the product is approved;

rate of a product s acceptance by the target population;

timing of market entry relative to competitive products;

availability of alternative therapies;

price of our product relative to alternative therapies;

extent of marketing efforts by us and third-party distributors or agents retained by us; and

side effects or unfavorable publicity concerning our products or similar products.

If Nexavar or any future product candidates that we may develop do not achieve market acceptance, we may not realize sufficient revenues from product sales, which may cause our stock price to decline.

If Bayer s business strategy changes, it may adversely affect our collaborative relationship.

Bayer may change its business strategy. Bayer recently completed a public takeover of Schering AG and the integration of the two companies will consume management resources at Bayer that may negatively impact our collaboration. Decisions by Bayer to either reduce or eliminate its participation in the oncology field, or to add competitive agents to its portfolio, could reduce its financial incentive to promote Nexavar. A change in Bayer s business strategy may adversely affect activities under its collaboration agreement with us, which could cause significant delays and funding shortfalls impacting the activities under the collaboration and seriously harming our business.

We may not be able to protect our intellectual property or operate our business without infringing upon the intellectual property rights of others.

We can protect our technology from unauthorized use by others only to the extent that our technology is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, we depend in part on our ability to:

obtain patents;

license technology rights from others;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

In the case of Nexavar, the global patent applications related to this product candidate are held by Bayer, but licensed to us in conjunction with our collaboration agreement with Bayer. We currently anticipate that, if issued, the United States patent related to Nexavar will expire in 2022, subject to possible patent-term extension, the entitlement to which and the term of which cannot presently be calculated. Patent applications for Nexavar are also pending throughout the world. As of June 30, 2006, we owned or had licensed rights to 51 United States patents and 34 United States patent applications and, generally, foreign counterparts of these filings. Most of these patents or patent applications cover protein targets used to identify product candidates during the research phase of our collaborative agreements with Warner-Lambert Company or Bayer, or aspects of our now discontinued virus program. Additionally, we have corresponding patents or patent applications pending or granted in certain foreign jurisdictions.

The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Our patents, or patents that we license from others, may not provide us with proprietary protection or

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competitive advantages against competitors with similar technologies. Competitors may challenge or circumvent our patents or patent applications. Courts may find our patents invalid. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization, which would reduce or eliminate any advantage the patents may give us.

We may not have been the first to make the inventions covered by each of our issued or pending patent applications, or we may not have been the first to file patent applications for these inventions. Competitors may have independently developed technologies similar to ours. We may need to license the right to use third-party patents and intellectual property to develop and market our product candidates. We may not acquire required licenses on acceptable terms, if at all. If we do not obtain these required licenses, we may need to design around other parties patents, or we may not be able to proceed with the development, manufacture or, if approved, sale of our product candidates. We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how, or determine the scope and validity of others proprietary rights. In addition, we may require interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. These activities, and especially patent litigation, are costly.

Bayer may have rights to publish data and information in which we have rights. In addition, we sometimes engage individuals, entities or consultants to conduct research that may be relevant to our business. The ability of these individuals, entities or consultants to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. The nature of the limitations depends on various factors, including the type of research being conducted, the ownership of the data and information and the nature of the individual, entity or consultant. In most cases, these individuals, entities or consultants are, at the least, precluded from publicly disclosing our confidential information and are only allowed to disclose other data or information generated during the course of the research after we have been afforded an opportunity to consider whether patent and/or other proprietary protection should be sought. If we do not apply for patent protection prior to publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information will be harmed.

We may incur significant liability if it is determined that we are promoting the off-label use of drugs or are otherwise found in violation of federal and state regulations in the United States or elsewhere.

Physicians may prescribe drug products for uses that are not described in the product s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Physicians may prescribe Nexavar for the treatment of cancers other than advanced kidney cancer, although neither we nor Bayer are permitted to promote Nexavar for the treatment of any indication other than kidney cancer, and the FDA and other regulatory agencies have not approved the use of Nexavar for any other indication. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies may not promote drugs for off-label uses. Accordingly, prior to approval of Nexavar for use in any indications other than advanced kidney cancer, we may not promote Nexavar for these indications. The FDA and other regulatory agencies actively enforce regulations prohibiting promotion of off-label uses and the promotion of products for which marketing clearance has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. We engage in medical education activities and communicate with investigators and potential investigators regarding our clinical trials. Although we believe that all of our communications regarding Nexavar are in compliance with the relevant regulatory requirements, the FDA or another regulatory authority may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

We face product liability risks and may not be able to obtain adequate insurance.

The sale of Nexavar and its ongoing use in clinical trials exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Nexavar.

We believe that we have obtained reasonably adequate product liability insurance coverage that includes the commercial sale of Nexavar and our clinical trials. However, the cost of insurance coverage is rising. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise should a future product candidate receive marketing approval. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

injury to our reputation;

withdrawal of clinical trial volunteers; and

loss of revenues.

Thus, whether or not we are insured, a product liability claim or product recall may result in losses that could be material.

If we do not receive timely and accurate financial information from Bayer regarding the development and sale of Nexavar, we may be unable to accurately report our results of operations.*

As a result of our arrangements with Bayer, we are highly dependent on Bayer for timely and accurate information regarding the costs incurred in developing and selling Nexavar, and any revenues realized from its sale, in order to accurately report our results of operations. If we do not receive timely and accurate information, or underestimate activity levels associated with the co-promotion and development of Nexavar at a given point in time, we could record significant additional expense in future periods, and may be required to restate our results for prior periods. Such inaccuracies or restatements could cause a loss of investor confidence in our financial reporting or lead to claims against us, resulting in a decrease in the trading price of shares of our common stock.

Our stock price is volatile.

The market price of our common stock has been volatile and is likely to continue to be volatile. For example, during the period beginning January 1, 2003 and ending June 30, 2006, the closing sales price for one share of our common stock reached a high of $58.75 and a low of $4.65. Factors affecting our stock price include:

reported sales of Nexavar;

interim or final results of, or speculation about, clinical trials from Nexavar;

decisions by regulatory agencies;

changes in the regulatory approval requirements;

ability to accrue patients into clinical trials;

success or failure in, or speculation about, obtaining regulatory approval by us or our competitors;

public concern as to the safety and efficacy of our product candidates;

developments in our relationship with Bayer;

developments in patent or other proprietary rights;

additions or departures of key personnel;

announcements by us or our competitors of technological innovations or new commercial therapeutic products;

published reports by securities analysts;

statements of governmental officials; and

changes in healthcare reimbursement policies.

We are at risk of securities class action litigation due to our expected stock price volatility.

In the past, stockholders have often brought securities class action litigation against a company following a decline in the market price of its securities. This risk is especially acute for us, because biotechnology companies have experienced greater than average stock price volatility in recent years and, as a result, have been subject to, on average, a greater number of securities class action claims than companies in other industries. Following our announcement in October 2004 of Phase II clinical trial data in patients with advanced kidney cancer, our stock price declined significantly. Our closing stock price on the last trading day before the announcement was $40.81, and our closing stock price on the day of the announcement was $27.34. We may in the future be the target of securities class action litigation. Securities litigation could result in substantial costs, could divert management s attention and resources, and could seriously harm our business, financial condition and results of operations.

Existing stockholders have significant influence over us.

Our executive officers, directors and five-percent stockholders own, in the aggregate, approximately 27 percent of our outstanding common stock. As a result, these stockholders will be able to exercise substantial influence over all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This could have the effect of delaying or preventing a change in control of our company and will make some transactions difficult or impossible to accomplish without the support of these stockholders.

Bayer, a collaborative party, has the right, which it is not currently exercising, to have its nominee elected to our board of directors as long as we continue to collaborate on the development of a compound. Because of these rights, ownership and voting arrangements, our officers, directors, principal stockholders and collaborator may be able to effectively control the election of all members of the board of directors and determine all corporate actions.

Provisions in our collaboration agreement with Bayer may prevent or delay a change in control.

Our collaboration agreement with Bayer provides that if Onyx is acquired by another entity by reason of merger, consolidation or sale of all or substantially all of our assets, and Bayer does not consent to the transaction, then for 60 days following the transaction, Bayer may elect to terminate Onyx s co-development and co-promotion rights under the collaboration agreement. If Bayer were to exercise this right, Bayer would gain exclusive development and marketing rights to the product candidates developed under the collaboration agreement, including Nexavar. If this happened, Onyx, or the successor to Onyx, would receive a royalty based on any sales of Nexavar and other collaboration products, rather than a share of any profits. In this case, Onyx or its successor would be permitted to continue co-funding development, and the royalty rate would be adjusted to reflect this continued risk-sharing by Onyx or its successor. These provisions of our collaboration agreement with Bayer may have the effect of delaying or preventing a change in control, or a sale of all or substantially all of our assets, or may reduce the number of companies interested in acquiring Onyx.

Provisions in Delaware law, our charter and executive change of control agreements we have entered into may prevent or delay a change of control.

We are subject to the Delaware anti-takeover laws regulating corporate takeovers. These anti-takeover laws prevent Delaware corporations from engaging in a merger or sale of more than ten percent of its assets with any stockholder, including all affiliates and associates of the stockholder, who owns 15 percent or more of the corporation s outstanding voting stock, for three years following the date that the stockholder acquired 15 percent or more of the corporation s stock unless:

the board of directors approved the transaction where the stockholder acquired 15 percent or more of the corporation s stock;

after the transaction in which the stockholder acquired 15 percent or more of the corporation s stock, the stockholder owned at least 85 percent of the corporation s outstanding voting stock, excluding shares owned by directors, officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held under the plan will be tendered in a tender or exchange offer; or

on or after this date, the merger or sale is approved by the board of directors and the holders of at least two-thirds of the outstanding voting stock that is not owned by the stockholder.

As such, these laws could prohibit or delay mergers or a change of control of us and may discourage attempts by other companies to acquire us.

Our certificate of incorporation and bylaws include a number of provisions that may deter or impede hostile takeovers or changes of control or management. These provisions include:

our board is classified into three classes of directors as nearly equal in size as possible with staggered three-year terms;

the authority of our board to issue up to 5,000,000 shares of preferred stock and to determine the price, rights, preferences and privileges of these shares, without stockholder approval;

all stockholder actions must be effected at a duly called meeting of stockholders and not by written consent;

special meetings of the stockholders may be called only by the chairman of the board, the chief executive officer, the board or ten percent or more of the stockholders entitled to vote at the meeting; and

no cumulative voting.

These provisions may have the effect of delaying or preventing a change in control, even at stock prices higher than the then current stock price.

We have entered into change in control severance agreements with each of our executive officers. These agreements provide for the payment of severance benefits and the acceleration of stock option vesting if the executive officer s employment is terminated within 24 months of a change in control of Onyx. These change in control severance agreements may have the effect of preventing a change in control.

Accounting pronouncements may affect our future financial position and results of operations.

There may be new accounting pronouncements or regulatory rulings, which may have an effect on our future financial position and results of operations. In December 2004, the Financial Accounting Standards Board, or FASB, issued a revision of Statement of Financial Accounting Standards, or FAS, No. 123, Accounting for Stock-Based Compensation. The revision is referred to as FAS 123(R) Share-Based Payment , which supersedes Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and will require companies to recognize compensation expense, using a fair-value based method, for costs related to share-based payments including stock options and stock issued under our employee stock plans. We adopted FAS 123(R) using the modified prospective basis on January 1, 2006. We expect that the adoption of FAS 123(R) will have a material adverse impact on our results of operations and our net loss per share. For example, as a result of our adoption of FAS 123(R), for the quarter

ended March 31, 2006, our net loss increased

by $3.6 million, or $0.09 per share, and for the quarter ended June 30, 2006, our net loss increased by $3.7 million, or $0.09 per share over the corresponding periods in 2005. We expect that our 2006 results will continue to be adversely affected by the implementation of FAS 123(R) and that the FASB could issue new accounting pronouncements that could affect our future financial position and results of operations.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Submission of Matters to a Vote of Security Holders

Our Annual Meeting of Stockholders was held on May 25, 2006. The results of the matters voted upon at the meeting were:

(a) Each of the nominees of the Board of Directors was elected to serve until our annual meeting of stockholders in 2009. The nominees were: Paul Goddard, Ph.D; 32,700,103 common shares for and 1,989,707 withheld; Antonio J. Grillo-Lopez, M.D.; 34,285,260 common shares for and 404,550 withheld; and Wendell Wierenga, Ph.D.; 32,725,273 commons shares for and 1,964,537 withheld. The term of office of directors Corinne H. Lyle and Thomas G. Wiggans continues until our annual meeting of stockholders in 2007. The term of office of directors Magnus Lundberg and Hollings C. Renton continues until our annual meeting of stockholders in 2008.

(b) The stockholders approved the amendment to the Company s Certificate of Incorporation to increase the authorized number of shares of common stock from 50,000,000 to 100,000,000 shares: 31,950,614 common shares for, 2,438,752 against, 300,444 abstaining and zero broker non-votes.

(c) The stockholders approved the amendment to the Company s Employee Stock Purchase Plan to increase the aggregate number of shares of Common Stock authorized for issuance under that plan by 75,000 shares: 21,644,605 common shares for, 1,476,529 against, 291,701 abstaining and 11,276,975 broker non-votes.

(d) The stockholders ratified the selection by the Audit Committee of the Board of Directors of Ernst & Young LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2006: 34,133,204 common shares for, 264,927 against, 291,679 abstaining and zero broker non-votes.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

3.1 (1) Restated Certificate of Incorporation of the Company.

3.2 (1) Bylaws of the Company.

3.3 (2) Certificate of Amendment to Amended and Restated Certificate of Incorporation.

4.1 Reference is made to Exhibits 3.1, 3.2 and 3.3.

4.2 (1) Specimen Stock Certificate.

10.7 (3) 1996 Employee Stock Purchase Plan

10.30 (4) Letter Agreement between Gregory W. Schafer and the Company, dated April 12, 2006.

10.33 (5) Separation Agreement between the Company and Scott M. Freeman, M.D., dated May 3, 2006.

10.34 (6) Letter Agreement between Laura A. Brege and the Company, dated May 19, 2006.

31.1 (7) Certification of Chief Executive Officer as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

31.2 (7) Certification of Principal Financial Officer as required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended

32.1 (7) Certifications required by Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

(1) Filed as an exhibit to the registrant s Registration Statement on Form SB-2 (No. 333-3176-LA).

(2) Filed as an exhibit to the registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2000.

(3) Filed as an exhibit to the registrant s Registration Statement on Form S-8 (No. 333-134567).

(4) Filed as an exhibit to the registrant s Current Report on Form 8-K filed on April 18, 2006

(5) Filed as an exhibit to the registrant s Current Report on Form 8-K filed on May 12, 2006

(6) Filed as an exhibit to the registrant s Current Report on

Form 8-K filed on June 12, 2006

(7) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Onyx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

ONYX PHARMACEUTICALS, INC.

Date: August 9, 2006

By: /s/ Hollings C. Renton
Hollings C. Renton
Chairman of the Board,
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 9, 2006

By: /s/ Gregory W. Schafer
Gregory W. Schafer
Vice President and Chief Financial Officer
(Principal Financial Officer)

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