ONYX PHARMACEUTICALS INC
Form 10-Q
November 09, 2005

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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 September 30, 2005

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.

þ Yes o No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

þ Yes o No

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

o Yes þ No

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 35,391,294 as of November 1, 2005.

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ONYX PHARMACEUTICALS, INC.

PART I: FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

CONDENSED BALANCE SHEETS

	September 30, 2005 (Unaudited)	December 31, 2004 (Note 1)
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 59,690	$ 74,243
Marketable securities	113,076	135,381
Receivable from collaboration partner	4,572	1,029
Other current assets	3,089	2,778
Total current assets	180,427	213,431
Property and equipment, net	1,647	1,623
Other assets	105	492
	$ 182,179	$ 215,546
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 3,279	$ 1,038
Payable to collaboration partner	18,609	11,520
Accrued liabilities	4,120	1,895
Accrued compensation	1,620	910
Accrued restructuring		195
Total current liabilities	27,628	15,558
Advance from collaboration partner	30,000	20,000
Commitments and contingencies		
Stockholders equity:		
Common stock	35	35
Additional paid-in capital	432,633	430,966
Accumulated other comprehensive loss	(659)	(377)
Accumulated deficit	(307,458)	(250,636)
Total stockholders equity	124,551	179,988
	$ 182,179	$ 215,546

See accompanying notes.

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ONYX PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands, except per share amounts)			
Revenue:				
License fee	$	$	$ 1,000	$
Operating expenses:				
Research and development	14,780	9,243	40,391	25,653
Marketing	6,839	859	14,155	2,619
General and administrative	2,429	2,072	7,753	6,151
Restructuring				258
Total operating expenses	24,048	12,174	62,299	34,681
Loss from operations	(24,048)	(12,174)	(61,299)	(34,681)
Interest income and (expense), net	1,467	910	4,102	2,130
Other income			375	
Net loss	$ (22,581)	$ (11,264)	$ (56,822)	$ (32,551)
Basic and diluted net loss per share	$ (0.64)	$ (0.32)	$ (1.61)	$ (0.96)
Shares used in computing basic and diluted net loss per share	35,367	34,905	35,300	34,064

See accompanying notes.

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

	Nine Months Ended September 30,	
	2005	2004
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (56,822)	$ (32,551)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	446	133
Gain on sale of investment	(375)	
Noncash restructuring charges		258
Gain on sale of fixed assets	(6)	
Stock-based compensation to consultants	603	1,323
Other		(34)
Changes in assets and liabilities:		
Receivable from collaboration partner	(3,543)	(919)
Other current assets	(311)	(1,028)
Other assets	12	(66)
Accounts payable	2,241	321
Accrued liabilities	2,225	52
Payable to collaboration partner	7,089	4,510
Accrued compensation	710	122
Accrued restructuring	(195)	
Net cash used in operating activities	(47,926)	(27,879)
Cash flows from investing activities:		
Purchases of marketable securities	(172,116)	(160,902)
Maturities of marketable securities	194,139	51,557
Proceeds from sale of Syrxx investment	750	
Capital expenditures	(470)	(130)
Proceeds from sale of fixed assets	6	581
Proceeds from repayment of note receivable		275
Net cash provided by (used in) investing activities	22,309	(108,619)
Cash flows from financing activities:		
Advance from collaboration partner	10,000	
Net proceeds from issuances of common stock	1,064	152,227
Net cash provided by financing activities	11,064	152,227
Net increase (decrease) in cash and cash equivalents	(14,553)	15,729
Cash and cash equivalents at beginning of period	74,243	55,312

Cash and cash equivalents at end of period	$ 59,690	$ 71,041

See accompanying notes.

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NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 2005
(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 nine months ended September 30, 2005 are not necessarily indicative of the results that may be expected for the year ending December 31, 2005, or for any other future operating periods.

The condensed balance sheet at December 31, 2004 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, as amended, for the year ended December 31, 2004.

Note 2. Stock-Based Compensation

The Company has elected to continue to follow Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), to account for employee stock options, and comply with the disclosure provisions of Statement of Financial Accounting Standards (SFAS) 123, *Accounting for Stock-Based Compensation* and SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. Under APB 25, no compensation expense is recognized when the exercise price of employee stock options equals the market price of the underlying stock on the date of grant.

The pro forma information regarding net loss and loss per share prepared in accordance with SFAS 123, as amended by SFAS 148, has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method prescribed by SFAS 123. The fair value of options was estimated at the date of grant using the Black-Scholes option-valuation model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Risk-free interest rate	3.97%	3.12%	3.78%	2.90%
Expected life	3.8 years	3.8 years	3.8 years	3.7 years
Expected volatility	0.72	0.55	0.74	0.58
Expected dividends	None	None	None	None
Weighted average option fair value	$ 11.55	$ 17.20	$ 13.55	$ 17.51

The following table illustrates the pro forma effects on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands, except per share amounts)			
Net loss as reported	$ (22,581)	$ (11,264)	$ (56,822)	$ (32,551)
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards, net of related tax effects	(3,724)	(1,501)	(9,535)	(3,145)

Pro forma net loss		$ (26,305)	$ (12,765)	$ (66,357)	$ (35,696)
Net loss per share:					
Basic and diluted net loss per share	as reported	$ (0.64)	$ (0.32)	$ (1.61)	$ (0.96)
Basic and diluted net loss per share	pro forma	$ (0.74)	$ (0.37)	$ (1.88)	$ (1.05)

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Note 3. Revenue

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 4. 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 3,824,872 stock options and warrants as of September 30, 2005 and 2,745,088 stock options and warrants as of September 30, 2004 were not included in the computation of diluted net loss per share because their effect would have been antidilutive.

Note 5. 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 September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
	(In thousands)			
Net loss as reported	$ (22,581)	$ (11,264)	$ (56,822)	$ (32,551)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities	(125)	85	(282)	(268)
Comprehensive loss	$ (22,706)	$ (11,179)	$ (57,104)	$ (32,819)

Note 6. Restructuring

In June 2003, the Company restructured its operations and discontinued its therapeutic virus program in order to place an increased priority on the development of Nexavar® (sorafenib tosylate) Tablets, Onyx s lead product candidate that is being developed jointly with Bayer Pharmaceuticals Corporation. During 2003, the Company recorded an aggregate charge of $5.5 million associated with the restructuring. In the second quarter of 2004, the Company recorded an additional restructuring charge of $258,000 due to a change in estimate related to the discontinued use and inability to sublet a portion of the Company s former leased facility in Richmond, California. As of September 30, 2005, all restructuring costs have been fully paid.

Note 7. Recent Accounting Development

In December 2004, the Financial Accounting Standards Board, (FASB) issued SFAS No. 123(R), *Share-Based Payment*, (SFAS 123(R)), a revision to SFAS No. 123 *Accounting for Stock-Based Compensation*, effective for reporting periods beginning after June 15, 2005. SFAS 123(R) supersedes APB No. 25 and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options and employee stock purchase

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plans to be recognized in the income statement based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. In April 2005, the Securities and Exchange Commission adopted a rule amendment that delayed the compliance dates for SFAS 123(R) such that the Company is now allowed to adopt the new standard no later than January 1, 2006. SFAS 123(R) permits public companies to adopt its requirements using one of two methods:

1. A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date.

2. A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

Although the Company has not determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, the Company is evaluating the requirements under SFAS 123(R) and expects the adoption to have a material impact on the Company s statements of operations and net loss per share.

Note 8. Investment in Syrrx, Inc.

In April 2005, the Company redeemed its investment in Syrrx, Inc. as a result of the acquisition of Syrrx by Takeda Pharmaceutical Company Limited. The Company received cash of $750,000 as a result of the redemption, which resulted in a gain of $375,000, which was recorded as other income in the accompanying statements of operations.

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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 our 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 Business Risks.

Overview

We are a biopharmaceutical company dedicated to developing innovative therapies that target the molecular mechanisms that cause cancer. With our collaborators, we are developing small molecule, orally available anticancer therapies with the goal of *changing the way cancer is treated.*™

With our collaborator, Bayer Pharmaceuticals Corporation, in July 2005, we completed the filing of a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, for our lead drug candidate, Nexavar® (sorafenib tosylate) Tablets, for the treatment of patients with advanced renal cell carcinoma, also known as kidney cancer. The FDA advised us in September 2005 that the NDA has been accepted for review and granted priority review status. The July filing is based on the progression-free survival data that resulted from the March 2005 independent data monitoring committee, or DMC, review of the safety and efficacy data from the Phase III kidney cancer trial. Based on its analysis, the DMC concluded that the trial met its secondary endpoint resulting in statistically significant longer progression-free survival in those patients administered Nexavar versus those patients administered a placebo. Progression-free survival, or PFS, is a measure of the time that a patient lives without meaningful tumor growth. In November 2005, we and Bayer announced that an investigator-reported interim analysis of 220 patient deaths showed a favorable overall survival trend for patients who received Nexavar, although it did not reach the requirement for statistical significance.

In September 2005, we and Bayer also announced that Bayer submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for the approval to market Nexavar within the European Union for the treatment of advanced kidney cancer.

Together with Bayer, we are conducting multiple clinical trials of Nexavar. To date, we have treated over 3,000 patients. In October 2003, we initiated a pivotal Phase III clinical trial in patients with advanced kidney cancer. In April 2005, we and Bayer recommended that all patients in this Phase III trial be offered access to Nexavar. As a result, patients who were previously administered placebo in the trial could elect to receive Nexavar. Nexavar is also being studied in two ongoing Phase III clinical trials for the treatment of patients with metastatic melanoma and one ongoing Phase III trial in patients with advanced liver cancer. In addition, Nexavar is being investigated in earlier stage Phase II studies for lung, breast and other cancers, as well as in multiple Phase Ib trials evaluating its use in combination with standard chemotherapy drugs, as well as other anticancer agents.

In August 2005, we received the third milestone advance from Bayer for $10.0 million in connection with the filing of the NDA for Nexavar.

In a previous collaboration with Warner-Lambert Company, now a subsidiary of Pfizer Inc, we identified a number of lead compounds that modulate the activity of key enzymes that regulate the process whereby a single cell replicates itself and divides into two identical new cells, a process known as the cell cycle. Mutations in genes that regulate the cell cycle are present in a majority of human cancers. Warner-Lambert is currently advancing a lead candidate from that collaboration, PD 332991, a small molecule cell cycle inhibitor targeting a cyclin-dependent kinase, or CDK. In September 2004, we announced that Pfizer initiated Phase I clinical testing of this CDK4 inhibitor.

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In 2003, we restructured our operations and discontinued our therapeutic virus program in order to place an increased priority on the development of Nexavar. Effective January 2005, Onyx licensed exclusive rights to our 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. We received a cash payment of $1.0 million that we recorded as license fee revenue for the license of the intellectual property and know-how of ONYX-015. We may receive additional payments if Shanghai Sunway achieves certain clinical, regulatory and commercial events. We will also receive royalties on net sales of ONYX-015, if any.

We have not been profitable since inception and expect to incur substantial and increasing losses for the foreseeable future, due to expenses associated with the development and commercialization of Nexavar. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. As of September 30, 2005, our accumulated deficit was approximately $307.5 million.

Our business is subject to significant risks, including the risks inherent in our development and commercialization efforts, the lengthy, expensive and uncertain regulatory approval process, the results of the Nexavar clinical trials, our dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents and competition from other products. For a discussion of these and some of the other risks and uncertainties affecting our business, see Business Risks. We currently have no products that have received marketing approval, and we have generated no revenues from the sale of products. We do not expect to generate revenues, if any, from the sale of proposed products until at least 2006 and expect that until that time all of our revenues, if any, will be generated from collaboration agreements.

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 and use of estimates to be critical policies. Significant estimations used in 2005 included assumptions used in the determination of stock-based compensation related to stock options granted to non-employees. Actual results could differ materially from these estimates. There have been no changes to our critical accounting policies since we filed our 2004 Annual Report on Form 10-K, as amended, for the year ended December 31, 2004, with the Securities and Exchange Commission, or SEC. For a description of our critical accounting policies, please refer to our 2004 Annual Report on Form 10-K, as amended.

Recent Accounting Development

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS 123(R), *Share-Based Payment*, a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123, effective for reporting periods beginning after June 15, 2005. SFAS 123(R) supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options and employee stock purchase plans to be recognized in the income statement based on their fair values. The pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. In April 2005, the SEC adopted a rule amendment that delayed the compliance dates for SFAS 123(R) such that we are now allowed to adopt the new standard no later than January 1, 2006. SFAS 123(R) permits public companies to adopt its requirements using one of two methods:

1. A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of

SFAS 123(R) that remain unvested on the effective date.

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2. A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

Although we have not determined whether the adoption of SFAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123(R) and expect the adoption to have a material impact on our statements of operations and net loss per share.

Results of Operations

Three and nine months ended September 30, 2005 and 2004

Revenue

We recorded no product revenue for the three month periods ended September 30, 2005 and 2004. Effective January 2005, we licensed exclusive rights to our 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. We received a cash payment of $1.0 million, which was recorded as license fee revenue during the nine months ended September 30, 2005. We may receive additional payments if Shanghai Sunway achieves certain clinical, regulatory and commercial events and may also receive royalties on net sales of ONYX-015, if any. We recorded no revenue for the nine months ended September 30, 2004.

Research and Development Expenses

Research and development expenses were $14.8 million for the three months ended September 30, 2005, a net increase of $5.5 million, or 60 percent, from $9.2 million in the same period in 2004. In the three months ended September 30, 2005, expenses related to Onyx s share of the codevelopment costs with Bayer for Nexavar increased by $5.8 million as compared to the same period in 2004. Nexavar development costs reflect the pivotal Phase III kidney cancer trial including the expanded access program in the United States, a Phase III trial in liver cancer initiated in the first quarter of 2005 and a Phase III trial in metastatic melanoma initiated in May 2005, as well as multiple ongoing Phase Ib and II clinical trials. The increase in expenses related to Onyx s share of the codevelopment costs with Bayer for Nexavar was partially offset by a $303,000 decrease in expenses related to our therapeutic virus program which was discontinued in 2003. These continuing virus program costs relate to the monitoring, maintenance and storage of viral assets.

Research and development expenses were $40.4 million for the nine months ended September 30, 2005, a net increase of $14.7 million, or 57 percent, from $25.7 million in the same period in 2004. In the nine months ended September 30, 2005, expenses for Onyx s share of the codevelopment costs with Bayer for Nexavar increased by $16.2 million as compared to the same period in 2004 due to the ongoing codevelopment costs associated with Nexavar as well as the new liver and metastatic melanoma Phase III trials initiated in the first half of 2005. The increase in Nexavar program expenses was partially offset by a $1.5 million decrease in expenses for the therapeutic virus program which was terminated in 2003. It is anticipated that research and development expenses may increase in future periods as the clinical trial program of Nexavar advances and additional trials are initiated.

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.

The following table summarizes our principal product development initiatives, including the related stages of development for each product in development and the research and development expenses recognized in connection with each product. The information in the column labeled Phase of Development Estimated Completion is only our estimate of the timing of completion of the current in-process development phases based on current information. The actual timing of

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completion of those phases could differ materially from the estimates provided in the table. We cannot reasonably estimate the timing of completion of each clinical phase of our development programs due to the risks and uncertainties associated with developing pharmaceutical product candidates. The clinical development portion of these programs may span as many as seven to ten years, and estimation of completion dates or costs to complete would be highly speculative and subjective due to the numerous risks and uncertainties associated with developing biopharmaceutical products, including significant and changing government regulation, the uncertainty of future preclinical and clinical study results and uncertainties associated with process development and manufacturing as well as marketing. For a discussion of the risks and uncertainties associated with the timing and cost of completing a product development phase, see our Business Risks section below.

				Research and Development Expenses			
				For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
Product	Description	Collaborator	Phase of Development -Estimated Completion	2005	2004	2005	2004
				(In thousands)			
Nexavar® (sorafenib tosylate) Tablets	Small molecule multi-kinase inhibitor of tumor cell proliferation and angiogenesis, targeting RAF kinase, VEGFR-2, PDGFR-ß, KIT, and FLT-3	Bayer	Phase I - 2004 Phase II-Unknown Phase III-Unknown	$14,551	$8,711	$39,715	$23,503
Therapeutic Virus Programs	Programs discontinued during the second quarter of 2003.			229	532	676	2,150
		Total Research and Development Costs		$14,780	$9,243	$40,391	$25,653

Marketing Expenses

Marketing expenses consist primarily of salaries and employee benefits, consulting and other third-party costs, and allocations for overhead and occupancy costs. Marketing expenses were $6.8 million for the three months ended September 30, 2005, a net increase of $6.0 million, from $859,000 in the same period in 2004. Marketing expenses were $14.2 million for the nine months ended September 30, 2005, a net increase of $11.5 million, from $2.6 million in the same period in 2004. The increase was due to employee related costs for hiring of sales and marketing personnel as well as third-party costs incurred by Onyx and Bayer as we establish a commercial infrastructure in anticipation of our expected product launch of Nexavar in the U.S. in early 2006. It is anticipated that sales and marketing expenses will increase in future periods as we prepare with Bayer for potential product launches in the United States, Europe, and other parts of the world.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee benefits, and corporate functional expenses. General and administrative expenses were $2.4 million for the three months ended September 30, 2005, a net increase of $357,000, or 17 percent, from $2.1 million in the same period in 2004. General and administrative expenses were $7.8 million for the nine months ended September 30, 2005, a net increase of $1.6 million, or 26 percent, from $6.2 million in the same period in 2004. The increase was due primarily to employee-related costs as a result of headcount increases to support our planned commercialization of Nexavar. We anticipate that general and administrative expenses may continue to increase in future periods to support the continued infrastructure growth.

Restructuring

In June 2003, we restructured our operations and discontinued our therapeutic virus program in order to place an increased priority on the development of Nexavar, our lead product candidate that is being developed jointly with Bayer. During 2003, the Company recorded an aggregate charge of $5.5 million associated with the restructuring. In the second quarter of 2004, the Company recorded an additional restructuring charge of $258,000 due to a change in estimate related to the discontinued use and inability to sublet a portion of our former leased facility in Richmond, California. As of September

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30, 2005, all restructuring costs have been fully paid. We did not record any restructuring charges during the three and nine months ended September 30, 2005.

Interest Income and (Expense), net

We had net interest income of $1.5 million for the three months ended September 30, 2005, an increase of $557,000 from $910,000 in the same period in 2004, and net interest income of $4.1 million for the nine months ended September 30, 2005, an increase of $2.0 million, from $2.1 million, in the same period in 2004. The increases were primarily due to higher interest rates as well as higher average investment balances for the nine months ended September 30, 2005 resulting from our February 2004 sale of equity securities from which we received $148.3 million in net cash proceeds.

Other Income

No other income was recorded for the three months ended September 30, 2005. 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, which was recorded as other income for the nine months ended September 30, 2005. No other income was recorded for the three and nine months ended September 30, 2004.

Liquidity and Capital Resources

Since our inception, we have incurred losses, and we have relied primarily on the proceeds from the sale of equity securities to fund our operations.

At September 30, 2005, we had cash, cash equivalents and marketable securities of $172.8 million, compared to $209.6 million at December 31, 2004. The decrease of $36.8 million was attributable to net cash used in operations of $47.9 million offset by the $10.0 million milestone advance payment received from Bayer in August 2005. The cash was used primarily for cofunding the clinical development program for Nexavar and the development of a commercial infrastructure, including hiring of the Nexavar sales force.

Total capital expenditures for equipment and leasehold improvements for the nine-month period ended September 30, 2005, were $470,000. We currently expect to make expenditures for capital equipment and leasehold improvements of approximately $300,000 for the remainder of 2005.

We believe that our existing capital resources and interest thereon will be sufficient to fund our current and planned operations into 2007. However, if we change our development plans, we may need additional funds sooner than we expect. In addition, we anticipate that our codevelopment 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 cofunding of the program in future periods through and beyond 2007. 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 research or 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.

Business Risks

Nexavar® (sorafenib tosylate) is our only product candidate currently in Phase II and Phase III clinical development, and our ability to promote additional candidates to clinical development is constrained. If Nexavar is not successfully commercialized, we may be unable to identify and promote alternative product candidates and our business would fail.

Nexavar is our only product candidate in Phase II and Phase III clinical development. In June 2003, following an unsuccessful search for new collaboration partners for our therapeutic virus product candidates, including ONYX-015 and

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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 managing our relationship with Bayer, and the development of Nexavar, 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 successful in clinical trials, does not receive marketing approval or is not successfully commercialized, we may be unable to identify and promote alternative product candidates to later stage clinical development, which would cause our business to fail.

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

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 surrogate endpoint, resulting in statistically significant longer progression-free survival in those patients administered Nexavar versus those patients administered placebo. As a result, in July 2005, we and Bayer filed a New Drug Application, or NDA, seeking approval of Nexavar to treat patients with kidney cancer in the United States. 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 Food and Drug Administration, or FDA. As a result, patients who were previously administered placebo in the trial could have elected 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 (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 soon after we and Bayer offered access to Nexavar to all patients in the trial, including those that had been receiving placebo. The investigator reported there was a 39% improvement in survival 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 trial specifications. 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. 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 get statistically significant overall survival data.

In July 2005, we and Bayer filed for approval of Nexavar based on the progression-free survival data. We and Bayer do not know whether regulatory authorities, including the FDA and its foreign counterparts, will grant full approval to Nexavar as a treatment for kidney cancer on the basis of the progression-free survival endpoint and without statistically significant overall survival data. It is possible that in the absence of statistically significant overall survival data, Nexavar will not receive full marketing approval, or will not receive approval in some countries. Lack of marketing approval in a particular country would prevent us from selling Nexavar in that country, which could harm our business. If Nexavar is approved as a treatment for advanced kidney cancer based on statistically significant longer progression-free survival data, it may be at a competitive disadvantage to third parties drugs if they are approved based on overall patient survival, which could impair our ability to successfully market Nexavar.

We expect the number of therapies available for the treatment of kidney cancer could rapidly increase, which could harm the prospects for Nexavar in this indication.

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

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For example, 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 addition, Avastin is currently in a Phase III trial for kidney cancer, which, if successful, could result in marketing approval in this indication.

Pfizer announced that its investigational drug, Sutent, a multi-kinase inhibitor, has proven effective in treating Gleevec-resistant gastrointestinal stromal tumors, or GIST. Sutent is also being tested to treat other tumor types, including Phase II and Phase III trials in kidney cancer patients, some of whom are second-line patients, or have been previously treated, and some of whom are first-line patients. It is possible that Sutent will receive FDA marketing approval for treatment of GIST and/or kidney cancer before Nexavar receives FDA marketing approval in any indication. Pfizer recently announced that it filed an NDA for Sutent in both GIST and kidney cancer and was granted priority review status. Even if only approved for treatment of GIST, medical practitioners may use Sutent off-label to treat other tumor types, including kidney cancer, even if the compound has not yet received marketing approval for use in these other indications. In addition, Wyeth is conducting a Phase III study of CCI-779, an mTOR inhibitor, in patients with advanced kidney cancer. 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.

As a result of these and other developments, a number of new therapeutic products may become available to treat metastatic kidney cancer, either on an off-label or approved basis, within a short period of time. With the potential availability of multiple drugs, the price and usage of these agents may be impacted, which could affect our potential revenues and profits. In addition, it is not currently known which of these potential new kidney cancer products will be used as first-line therapy. The use of any first-line agent may limit the use of an agent with a similar mechanism of action in second-line patients. While Nexavar has not been approved as either a first or second-line therapy, our Phase III trial of Nexavar in kidney cancer was for the treatment of patients having previously received systemic therapy. Both Genentech and Pfizer have pivotal Phase III kidney cancer studies underway in first-line patients that may include survival data and may lead to approvals in this indication. If Nexavar is approved only as a second-line therapy for kidney cancer, the successful introduction of new first-line 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 from Nexavar, should it be approved, which could cause our stock price to fall.

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 currently 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 October 2003 we and Bayer initiated a Phase III clinical trial to treat patients with advanced kidney cancer. In addition, in March 2005, we and Bayer initiated a Phase III clinical trial of Nexavar in patients with liver cancer. In May 2005, we and Bayer initiated a Phase III clinical trial of Nexavar in combination with the chemotherapeutic agents carboplatin and pactitaxel in patients with malignant melanoma. Phase III trials are designed to more rigorously test the efficacy of a product candidate and are normally randomized and double-blinded.

Although we believe we have demonstrated the efficacy and tolerability of Nexavar in patients with advanced kidney cancer, in other types of cancer the efficacy of Nexavar has not been proven. 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. 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

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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.

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

Our strategy for developing, manufacturing and commercializing Nexavar and obtaining regulatory approval 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 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 the 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 cofunding of the development of Nexavar. If Bayer terminates its cofunding 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 calls for Bayer to advance us creditable milestone-based payments. To date, Bayer has advanced us $30.0 million for achievement of specific milestones. Any funds advanced under the agreement 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. At present, it is anticipated that, if issued, the last of the United States patents 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;

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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 developing or commercializing Nexavar, or we may become involved in litigation or arbitration, which would be time consuming and expensive.

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

Bayer may change its business strategy. 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.

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 codevelopment and copromotion rights under the collaboration agreement. If Bayer were to exercise this right, Bayer would gain exclusive development and marketing rights to the product candidates being 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 cofunding 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.

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 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 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.

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

We are engaged in a rapidly changing and highly competitive field. We are seeking to develop and market product candidates that will 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

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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, Novartis International AG, AstraZeneca PLC, OSI Pharmaceuticals, Inc., Genentech, Inc., Chiron Corporation, and Abgenix, Inc., among others. A number of companies have small molecules 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 tyrosine kinase, has been approved in the United States for treatment of non-small cell lung cancer. Companies working on developing antibody approaches include Abgenix and ImClone Systems, Inc. ImClone has developed Erbitux, which is an antibody targeting EGF receptors. Erbitux has been approved in the United States and the European Union for treatment of colorectal 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. In addition, many other pharmaceutical companies are developing novel cancer therapies that, if successful, would also provide competition for Nexavar.

Our Phase III trial of Nexavar in kidney cancer was conducted to treat second-line patients. Our competitors may seek approval of their drugs to treat first-line patients, or to treat both first-line and second-line patients. If our competitors are successful and succeed in obtaining approval to treat first-line patients, this could put us at a competitive disadvantage. 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 in anticipation of a potential launch of Nexavar. If Nexavar receives regulatory approval but 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.

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

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We will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to develop Nexavar, pursue regulatory approval and commercialize this product candidate. 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;

our receipt of milestone-based payments;

the ability to manufacture sufficient drug supply to complete clinical trials;

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

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 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 2007. However, if we change our development plans, we may need additional funds sooner than we expect. In addition, we anticipate that our codevelopment 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 cofunding of the Nexavar program in future periods through and beyond 2007. We may have to curtail our funding of Nexavar if we cannot raise sufficient capital. If we do not cofund development of Nexavar, we will receive a royalty on future sales of any product that is ultimately commercialized, instead of a share of profits.

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

Our net loss for the year ended December 31, 2002 was $45.8 million, for the year ended December 31, 2003 was $45.0 million, and for the year ended December 31, 2004 was $46.8 million. Our net loss for the nine months ended September 30, 2005 was $56.8 million. As of September 30, 2005, we had an accumulated deficit of approximately $307.5 million. We have incurred these losses principally from costs incurred in our research and development programs and from our general and administrative costs. In addition, we are incurring precommercial marketing expenses in anticipation of our commercial launch. It is not unusual for patients to be offered access to investigational compounds in late-stage clinical development. Such programs involve substantial costs. To date, we have derived no revenues from product sales or royalties. 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 cofunding of ongoing Nexavar clinical and commercial activities under our collaboration agreement with Bayer.

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We do not expect to generate revenues from the sale of proposed products until at least 2006, and we must repay the milestone-based advances we receive from Bayer from our future profits and royalties, if any. We have made significant expenditures towards the development and anticipated commercialization of Nexavar, and may never realize any revenues from product sales. Any product sales revenue we do realize may be insufficient to offset our 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.

We do not have manufacturing expertise or capabilities and are dependent on Bayer to fulfill our manufacturing needs, which could result in 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 any commercial requirements. However, should Bayer give up its right to codevelop 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, if any. 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, if any, or product candidates on a timely basis and at commercially reasonable prices. Failure by these third parties 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 have the right to copromote Nexavar in the United States, but we do not have proven sales or marketing expertise.

We have the right under our collaboration agreement with Bayer to copromote Nexavar in the United States in conjunction with Bayer. In anticipation of copromoting Nexavar, we are in the process of developing commercial capabilities. While we intend to continue investing in our commercialization infrastructure, we may not successfully establish marketing and sales capabilities or have sufficient resources to do so.

If we do not further develop marketing and sales capabilities, we will be unable to meet our copromotion obligations under our collaboration agreement, which could result in the loss of our copromotion rights. If we do develop such capabilities, we will compete with other companies that have experienced and well-funded marketing and sales operations, and we will incur additional expenses. We will receive no return on our investment in sales and marketing capabilities if Nexavar does not receive marketing approval. If Nexavar is not approved, none of the sales and marketing capabilities we have developed will be utilized, and we will be unable to recoup the expense of developing these capabilities.

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, and 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

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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.

We have rapidly expanded our sales and marketing operations, and any difficulties managing this growth could disrupt our operations.

In anticipation of a potential commercial launch of Nexavar in the United States, we have rapidly expanded and developed our sales and marketing operations. We increased expenditures in these areas, hired additional employees and expanded the scope of our operations. As we have not, to date, had any products approved for sale, our sales and marketing operations, and our ability to manage them, are untested. We do not have any history of managing sales and marketing operations, and may be unable to do so. If we are unable to effectively manage our newly expanded sales and marketing capacity, or if this capacity proves inadequate, we may not be able to implement our business plan.

Even if our product candidates are approved, the market may not accept these products.

Even if our product development efforts are successful and even if the requisite regulatory approvals are obtained, 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 our product candidates 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 our product candidates. In addition, the market for our product candidates may be limited by third-party payors who establish lists of approved products and do not provide reimbursement for products not listed. If our product candidates are not on the approved lists, the sales of our product candidates may suffer.

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 any revenues from product sales, which may cause our stock price to decline.

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 not received regulatory approval in the United States or any foreign market for Nexavar or any other product candidate.

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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 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. Even if Nexavar is approved, 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.

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.

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. At present, it is anticipated 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 September 30, 2005, we owned or had licensed rights to 52 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 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.

Our existing patent rights may not have a deterrent effect on competitors who are conducting or desire to commence competitive research programs with respect to the biological targets or fields of inquiry that we are

pursuing. Although third

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parties may challenge our rights to, or the scope or validity of our patents, to date, we have not received any communications from third parties challenging our patents or patent applications covering our product candidates.

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

The use of Nexavar in clinical trials, and the sale of any approved products, 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 for our clinical trials. We intend to expand our insurance coverage to include the commercial sale of Nexavar if marketing approval is obtained. 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 one of our product candidates 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.

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

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, 2002 and ending September 30, 2005, the closing sales price for one share of our common stock reached a high of $58.75 and a low of $3.59. Factors affecting our stock price include:

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

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.

Existing stockholders have significant influence over us.

Our executive officers, directors and five-percent stockholders own, in the aggregate, approximately 45 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.

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

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costs, could divert management s attention and resources, and could seriously harm our business, financial condition and results of operations.

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 13 months of a change in control of Onyx. On October 5, 2005, our board of directors approved a new form of executive change in control severance benefits agreement and authorized the company to enter into this new agreement with any present and future chief executive officer, executive vice president, senior vice president or vice president. The new form of agreement will provide for the payment of severance benefits and the acceleration of stock option vesting if the officer s employment is terminated within 24 months of a change in control of Onyx. These changes in control severance agreements may have the effect of preventing a change in control.

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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 September 30, 2005, the fair value of our portfolio would decline by approximately $743,000.

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

	September 30, 2005			December 31, 2004		
	Maturity	Fair Value (In millions)	Average Interest Rate	Maturity	Fair Value (In millions)	Average Interest Rate
Cash equivalents, fixed rate	0 2 months	$ 59.7	3.65%	0 2 months	$ 74.2	2.09%
Marketable securities, fixed rate	0 19 months	$ 113.1	4.30%	0 16 months	$ 135.4	2.18%

We did not hold any derivative instruments as of September 30, 2005, 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

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.

Evaluation of Disclosure Controls and Procedures: The Company s chief executive officer and principal 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 principal financial officer concluded that the Company s disclosure controls and procedures were effective as of September 30, 2005 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 September 30, 2005 that have materially affected, or are reasonably likely to materially affect the Company s internal control over financial reporting.

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PART II: OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

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

On September 6, 2005, Onyx issued an aggregate of 9,259 shares of its common stock to DKR Soundshore Strategic Holding Fund Ltd. pursuant to the cash exercise of a warrant dated May 7, 2002. The warrant was exercisable for 9,259 shares of common stock and had an exercise price of $9.59 per share. The issuance of the shares pursuant to this warrant was exempt from registration under the Securities Act of 1933 in reliance on Section 4(2) promulgated thereunder and, based upon the number of persons receiving shares of our common stock in the transaction, their financial position and sophistication and the absence of any general solicitation, the transaction was determined not to involve any public offering..

Item 3. Defaults Upon Senior Securities

Not applicable.

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

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

3.1	Restated Certificate of Incorporation of the Company. (1)
3.2	Bylaws of the Company. (1)
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation. (2)
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Specimen Stock Certificate. (1)
10.46	Form of Executive Change in Control Severance Benefits Agreement.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).
32.1	Certifications required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350). (3)

(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) 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

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ONYX PHARMACEUTICALS, INC.

before or after the date of the Quarterly Report on Form 10-Q), irrespective of any general incorporation language contained in such filing.

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SIGNATURES

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

ONYX PHARMACEUTICALS, INC.

Date: November 9, 2005

By: /s/ Hollings C. Renton

Hollings C. Renton
Chairman of the Board,
President and Chief Executive Officer
(Principal Executive and Financial Officer)

Date: November 9, 2005

By: /s/ Marilyn E. Wortzman

Marilyn E. Wortzman
Vice President, Finance and Administration
(Principal Accounting Officer)

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