ONYX PHARMACEUTICALS INC
Form 10-Q
November 09, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2004

or

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

For the transition period from _____to_____

Commission File Number: 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)

3031 Research Drive
Richmond, California 94806
(Address of principal executive offices)

(510) 222-9700
(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.

[X] Yes [ ] No

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

[X] Yes [ ] 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 35,264,192 as of November 1, 2004.

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

CONDENSED BALANCE SHEETS

	September 30, 2004	December 31, 2003
	(Unaudited)	(Note 1)
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 71,041	$ 55,312
Marketable securities	159,165	50,088
Receivable from collaboration partner	1,503	584
Other current assets	2,667	2,461
Total current assets	234,376	108,445
Property and equipment, net	282	285
Other assets	474	408
	$ 235,132	$ 109,138
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 620	$ 299
Payable to collaboration partner	18,289	13,632
Accrued restructuring	306	325
Accrued clinical trials and related expenses.		147
Accrued compensation	844	722
Other accrued liabilities	823	494
Total current liabilities	20,882	15,619
Advance from collaboration partner	20,000	20,000
Commitments and contingencies		
Stockholders equity:		
Common stock	35	30

Additional paid-in capital	430,887	277,577
Receivable from stock option exercises		(235)
Accumulated other comprehensive (loss) income	(241)	27
Accumulated deficit	(236,431)	(203,880)
Total stockholders equity	194,250	73,519
	$ 235,132	$ 109,138

See accompanying notes.

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CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
	(In thousands, except per share amounts)			
Operating expenses:				
Research and development	$ 9,270	$ 8,841	$ 25,844	$ 24,593
Marketing	859	195	2,619	504
General and administrative	2,045	1,353	5,960	4,218
Restructuring		944	258	4,145
Total operating expenses	12,174	11,333	34,681	33,460
Loss from operations	(12,174)	(11,333)	(34,681)	(33,460)
Interest income, net	910	254	2,130	562
Other expense related party				(275)
Net loss	$(11,264)	$(11,079)	$(32,551)	$(33,173)
Basic and diluted net loss per share	$ (0.32)	$ (0.40)	$ (0.96)	$ (1.34)
Shares used in computing basic and diluted net loss per share	34,905	27,777	34,064	24,791

See accompanying notes.

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CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2004	**2003**
	(In thousands)	
Cash flows from operating activities:		
Net loss	$ (32,551)	$(33,173)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	133	1,083
Noncash restructuring charges	258	2,394
Stock-based compensation to consultants	1,323	716
Loss on impairment of investment		275
Other	(34)	3
Changes in assets and liabilities:		
Receivable from collaboration partner	(919)	(788)
Other current assets	(1,028)	(287)
Other assets	(66)	32
Accounts payable	321	(382)
Accrued liabilities	52	52
Accrued clinical trials and related expenses	4,510	416
Accrued compensation	122	(832)
Net cash used in operating activities	(27,879)	(30,491)
Cash flows from investing activities:		
Purchases of marketable securities	(160,902)	(50,491)
Maturities of marketable securities	51,557	26,873
Capital expenditures	(130)	(132)
Proceeds from sale of fixed assets	581	
Proceeds from repayment of note receivable	275	
Net cash used in investing activities	(108,619)	(23,750)
Cash flows from financing activities:		
Net proceeds from issuances of common stock	152,227	85,669

Net cash provided by financing activities	152,227	85,669
Net increase in cash and cash equivalents	15,729	31,428
Cash and cash equivalents at beginning of period	55,312	11,014
Cash and cash equivalents at end of period	$ 71,041	$ 42,442

See accompanying notes.

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NOTES TO CONDENSED FINANCIAL STATEMENTS
September 30, 2004
(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, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004, or for any other future operating periods.

The condensed balance sheet at December 31, 2003 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.

Certain amounts in the prior periods have been reclassified from research and development expenses to marketing expenses to conform to the current period presentation.

For further information, refer to the financial statements and footnotes thereto included in the Onyx Pharmaceuticals, Inc. (the Company or Onyx) Annual Report on Form 10-K for the year ended December 31, 2003.

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, because the alternative fair value method of accounting prescribed by Statement of Financial Accounting Standards No. (SFAS) 123, Accounting for Stock-Based Compensation, requires the use of option valuation models that were not developed for use in valuing employee stock options. 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, has been determined as if the Company had accounted for its employee stock options 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,	
	2004	2003	2004	2003
Risk-free interest rate	3.12%	1.77%	2.90%	2.34%
Expected life	3.8 years	2.5 years	3.7 years	3.0 years
Expected volatility	0.55	0.78	0.58	0.89

Expected dividends	None	None	None	None
Weighted average option fair value	$17.20	$7.62	$17.51	$3.39

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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,	
	2004	2003	2004	2003
	(In thousands, except per share amounts)			
Net loss as reported	$(11,264)	$(11,079)	$(32,551)	$(33,173)
Deduct: Total stock-based employee compensation determined under the fair value based method for all awards, net of related tax effects	(1,501)	(312)	(3,145)	(1,241)
Pro forma net loss	$(12,765)	$(11,391)	$(35,696)	$(34,414)
Net loss per share:				
Basic and diluted net loss per share as reported	$ (0.32)	$ (0.40)	$ (0.96)	$ (1.34)
Basic and diluted net loss per share pro forma	$ (0.37)	$ (0.41)	$ (1.05)	$ (1.39)

Note 3. 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 the period. Potentially dilutive outstanding securities consisting of 2,745,088 stock options and warrants as of September 30, 2004 and 3,384,417 stock options and warrants as of September 30, 2003 were not included in the computation of diluted net loss per share because their effect would have been antidilutive.

Note 4. 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,

	2004	2003	2004	2003
			(In thousands)	
Net loss as reported	$(11,264)	$(11,079)	$(32,551)	$(33,173)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities	85	45	(268)	31
Comprehensive loss	$(11,179)	$(11,034)	$(32,819)	$(33,142)

Note 5. Recent Accounting Pronouncements

On March 31, 2004, the Financial Accounting Standards Board (FASB) issued an Exposure Draft, Share-Based Payment An Amendment of FASB Statements No. 123 and 95 (proposed FAS 123R). The proposed FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The proposed FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25 and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. The Company would be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. The Company is currently evaluating option valuation methodologies and assumptions in light of the proposed FAS

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123R related to employee stock options. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

Note 6. Sale of Equity Securities

In February 2004, the Company sold 4,637,000 shares of common stock at a price of $33.75 per share in an underwritten public offering pursuant to an effective registration statement previously filed with the Securities and Exchange Commission. Also in February 2004, the underwriters for the offering purchased an additional 48,693 shares of the Company s common stock to cover over-allotments at a price of $33.75 per shares. The Company received aggregate net cash proceeds of approximately $148.3 million from this public offering.

Note 7. Restructuring

In June 2003, the Company announced the discontinuation of its therapeutic virus program and the termination of all internal research and development activities. The decision was part of a business realignment that placed an increased priority on the development of BAY 43-9006, Onyx s lead product candidate that is being developed jointly with Bayer Pharmaceuticals Corporation. In 2003, the Company recorded an aggregate charge of $5.5 million associated with the restructuring, including a reduction in force of approximately 75 positions. The Company recorded an additional restructuring charge of $258,000 in the second quarter of 2004 due to a change in estimate related to the discontinued use and inability to sublet a portion of the Company s leased facility. At December 31, 2003, the accrual for restructuring was $325,000. As of September 30, 2004, the accrual for restructuring was $306,000, consisting of charges related to the discontinued use of a portion of the Company s leased facilities. The remaining accrued restructuring costs are expected to be fully paid by the second quarter of 2005.

Note 8. Facility Lease

In August 2004, the Company entered into a new operating lease for 23,000 square feet of office space, which will serve as the Company s new corporate headquarters. The lease expires on February 28, 2010 with a renewal option at the end of the lease for a period of three years. The lease for the Company s current primary facility expires in April 2005, which the Company does not plan to renew.

Minimum rental commitments under this operating lease are as follows (in thousands):

Months 1-12	$ 353
Months 13-24	544
Months 25-36	557
Months 37-48	571
Months 49-60	585
Months 61-64	200
	$2,810

Note 9. Related Party Transaction

The Company had a loan receivable from a former employee for $275,000 that was repaid in August 2004 per the terms of the loan agreement.

Note 10. Subsequent Event

In September 2004, the Company announced that Pfizer initiated Phase I clinical trials advancing a lead candidate from the cell cycle kinase collaboration that the Company has with Warner-Lambert, now a subsidiary of Pfizer. The initiation of human clinical trials triggered a $500,000 milestone payment to the Company, which Onyx received from Pfizer in October 2004. The Company will recognize the receipt of this milestone payment as revenue in the fourth quarter 2004.

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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 drugs with the goal of *changing the way cancer is treated*. A common feature of cancer cells is the excessive activation of signaling pathways that cause abnormal cell proliferation. In addition, tumors require oxygen and nutrients from newly formed blood vessels to support their growth. The formation of these new blood vessels is a process called angiogenesis. We are applying our expertise to develop oral anticancer therapies designed to prevent cancer cell proliferation and angiogenesis by inhibiting proteins that signal or support tumor growth. By exploiting the genetic differences between cancer cells and normal cells, we aim to create novel anticancer agents that minimize damage to healthy tissue. Our lead drug candidate, BAY 43-9006, is currently in Phase III clinical development with our collaborator, Bayer Pharmaceuticals Corporation.

BAY 43-9006 is a novel, orally available signal transduction inhibitor and is one of a new class of anticancer treatments that target growth signaling in cancer. BAY 43-9006 operates through dual mechanisms of action by inhibiting proliferation of cancer cells and inhibiting angiogenesis. Several drugs developed and owned by others, and approved by the U.S. Food and Drug Administration, or FDA, validate this treatment approach. However, BAY 43-9006 is the first small molecule agent to enter clinical trials directed against the enzyme RAF kinase to inhibit tumor cell proliferation. In addition, BAY 43-9006 displays activity that inhibits VEGFR-2 and PDGFR-ß, two key proteins involved in angiogenesis.

We and Bayer are developing and, if approved, will market BAY 43-9006 under our collaboration agreement. Together with Bayer, we are conducting multiple clinical trials of BAY 43-9006. To date, we have treated over 1,000 patients. In October 2003, we announced the initiation of a pivotal Phase III clinical trial after a Special Protocol Assessment, or SPA, with the FDA, in patients with advanced renal cell carcinoma, also known as kidney cancer. In October 2004, we and Bayer further announced that we will pursue registration of BAY 43-9006 based on results from this Phase III trial and the data from our recently completed Phase II randomized discontinuation trial will be used to support the Phase III trial results. In addition, we also announced that, subject to FDA approval, we anticipate a United States launch for the product in 2006.

We and Bayer have also announced that we will initiate pivotal trials next year in both malignant melanoma and hepatocellular, or liver, cancer. We and Bayer have completed Phase II clinical trials of Bay 43-9006 in kidney and liver cancer. The agent is also being studied in multiple Phase II clinical trials for the treatment of melanoma, breast, non-small cell lung and other cancers, as well as in multiple Phase Ib trials evaluating its use in combination with standard chemotherapy drugs.

In 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. In September 2004, we announced that Pfizer initiated Phase I clinical trials advancing a lead candidate from that collaboration, a small molecule cell cycle inhibitor targeting a cyclin-dependent kinase, CDK4. The initiation of human clinical trials triggered a $500,000 milestone payment to us, which we received from Pfizer in October 2004.

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In February 2004, we sold 4,637,000 shares of our common stock at $33.75 per share in an underwritten public offering pursuant to an effective registration statement previously filed with the Securities and Exchange Commission. Also in February 2004, the underwriters for the offering exercised their over-allotment option and purchased an additional 48,693 shares of our common stock to cover over-allotments at a price of $33.75 per share. We received aggregate net cash proceeds of approximately $148.3 million from this public offering.

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 continuing development and commercialization of BAY 43-9006. We expect that losses will fluctuate from quarter to quarter and that such fluctuations may be substantial. As of September 30, 2004, our accumulated deficit was approximately $236.4 million.

Our business is subject to significant risks, including the risks inherent in our development efforts, the results of the BAY 43-9006 clinical trials, our dependence on collaborative parties, uncertainties associated with obtaining and enforcing patents, the lengthy and expensive regulatory approval process, and competition from other products. For a discussion of these and some of the other risks and uncertainties affecting our business, see 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 all of our revenues, if any, before 2006 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 2004 included estimated charges related to our restructuring and 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 other changes to our critical accounting policies since we filed our 2003 Annual Report on Form 10-K with the Securities and Exchange Commission on March 15, 2004. For a description of our critical accounting policies, please refer to our 2003 Annual Report on Form 10-K.

Recent Accounting Developments

On March 31, 2004, the FASB issued an Exposure Draft, Share-Based Payment An Amendment of FASB Statements No.123 and 95 (proposed FAS 123R). The proposed FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The proposed FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25 and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. We would be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. We are currently evaluating option valuation methodologies and assumptions in light of the proposed

FAS 123R related to employee stock options. Current estimates of option values using the Black-Scholes method may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

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Results of Operations

Three and nine months ended September 30, 2004 and 2003

Research and Development Expenses

Research and development expenses were $9.3 million for the three months ended September 30, 2004, a net increase of $429,000, or five percent, from the same period in 2003. In the three months ended September 30, 2004, expenses for Onyx s share of the codevelopment costs with Bayer for the BAY 43-9006 program increased by $2.9 million as compared to the same period in 2003. BAY 43-9006 development costs during the third quarter of 2004 reflect increased expenditures from the Phase III clinical trial initiated in the fourth quarter of 2003 and the expansion of Phase Ib and Phase II clinical trials evaluating BAY 43-9006 in a number of different tumor types. The increase in BAY 43-9006 program expenses was offset by a $2.5 million decrease in the therapeutic virus program expenses as a result of the termination of the program in 2003. Research and development expenses were $25.8 million for the nine months ended September 30, 2004, a net increase of $1.3 million, or five percent, from the same period in 2003. In the nine months ended September 30, 2004, expenses for Onyx s share of the codevelopment costs with Bayer for the BAY 43-9006 program increased by $10.8 million as compared to the same period in 2003 primarily due to the expansion into the Phase III clinical trial for BAY 43-9006. The increase in BAY 43-9006 program expenses was offset by a $9.5 million decrease in the therapeutic virus program expenses as a result of the 2003 termination of the program. Future cost savings from the discontinuation of our therapeutic virus program are expected to be offset by increased costs associated with advancing the clinical development of BAY 43-9006.

Research and development expenses related to the orderly wind-down of the therapeutic virus program and the preservation of assets associated with this program for potential future divestiture or commercialization were $546,000 for the three months ended September 30, 2004, and $2.3 million for the nine months ended September 30, 2004. These expenses were comprised primarily of stock-based compensation and consulting fees for consultants retained in connection with the orderly wind-down of the virus program and preservation of related assets, sponsored research at the University of California, San Francisco related to the preservation of the program s assets and outside services related to stability testing and storage of virus product related to the program.

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. Success in development results in increasing expenditures, and the timing for completion of these steps is uncertain.

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. The actual timing of completion of those phases could differ materially from the estimates provided in the table. 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.

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Product	Description	Collaborator	Phase of Development-Estimated Completion	Research and Development Expenses			
				Three Months Ended September 30,		Nine Months Ended September 30,	
				2004	2003	2004	2003
				(In thousands)			
BAY 43-9006	Small Molecule Inhibitor of tumor cell proliferation and angiogenesis, targeting RAF Kinase, VEGFR-2 and PDGFR-ß	Bayer	Phase I 2002 Phase II Unknown Phase III-Unknown	$8,724	$5,818	$23,541	$12,745
Therapeutic Virus Program				546	3,023	2,303	11,848
	p53-Selective Replicating Virus		Phase II/III - (1)				
	RB-Selective Replicating Virus		Preclinical - (1)				
	RB-Selective Replicating Virus Armed with Anticancer Genes		Preclinical - (1)				
Cell Cycle Kinases (2)	Small Molecule Inhibitor of Cyclin-Dependent Kinase	Warner-Lambert	Phase I - Unknown				
			Total Research and Development Costs	$9,270	$8,841	$25,844	$24,593

(1) Program discontinued during the second quarter of 2003. See Note 7 to our condensed financial statements. Costs in 2004 relate to the orderly wind-down of the program and preservation of the related assets.

(2) Warner-Lambert is responsible for research and development costs.

The overall completion dates of our major research and development programs are estimates based on current

information. 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. These risks and uncertainties make the reliable estimate of overall completion dates and total costs to complete development highly speculative. For additional discussion of factors affecting overall completion dates and total costs, see the Business Risks section below.

Marketing Expenses

Marketing expenses consist primarily of salaries and employee benefits, consulting and other third-party costs, and allocations for overhead and occupancy costs. We reclassified $195,000 from research and development expenses to marketing expenses for the three months ended September 30, 2003, and $504,000 for the nine months ended September 30, 2003, to conform to the current period presentation. Marketing expenses were $859,000 for the three months ended September 30, 2004, a net increase of $664,000, from the same period in 2003. Marketing expenses were $2.6 million for the nine months ended September 30, 2004, a net increase of $2.1 million, from the same period in 2003. The increases for both the three-month and nine-month periods ended September 30, 2004 as compared to the same periods in the prior year were due to third-party costs and employee-related expenses as Onyx and Bayer establish a commercial infrastructure and engage in precommercial marketing activities. It is anticipated that marketing expenses will increase in future periods as we develop our marketing capabilities in order for us to copromote BAY 43-9006 with Bayer in the U.S. should BAY 43-9006 receive marketing approval.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee benefits and corporate functional expenses. General and administrative expenses were $2.0 million for the three months ended September 30, 2004, a net increase of $692,000, or 51 percent, from the same period in 2003. General and administrative expenses were $6.0 million for the nine months ended September 30, 2004, a net increase of $1.7 million, or 41 percent, from the same period in 2003. The increases for both the three months and nine months ended September 30, 2004 as compared to the same periods in the

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prior year were related to consulting expenses, primarily for information systems, and costs related to satisfying the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We anticipate that general and administrative expenses may continue to increase modestly to support our growing infrastructure needs.

Restructuring

In June 2003, we announced that we were discontinuing our therapeutic virus program and terminating all internal research and development activities. The decision was part of a business realignment that placed an increased priority on the development of BAY 43-9006. We recorded $5.5 million of restructuring expenses in 2003, including a reduction in force of approximately 75 positions. See Note 7 to our condensed financial statements included in this quarterly report for more description of our restructuring activities. We recorded additional restructuring charges of $258,000 in the second quarter of 2004 due to a change in estimate related to the discontinued use and inability to sublet a portion of our leased facility. We expect that the remaining accrued restructuring costs of $306,000 at September 30, 2004 will be fully paid by the second quarter of 2005 coincident with the termination of our lease obligation on our existing facility.

Interest Income, net

Interest income increased $698,000 to $952,000 for the three months ended September 30, 2004, and increased $1.7 million to $2.2 million for the nine months ended September 30, 2004, from the same periods in 2003, primarily due to higher average cash and investment balances resulting from our February 2004 and July 2003 sale of equity securities from which we received approximately $222.0 million in net cash proceeds. Interest expense was immaterial for the periods presented.

Other Expense Related Party

In April 2003 based on a further round of financing completed by Syrrx, Inc., we recorded a write-down of $275,000 as Other expense-related party to reduce the carrying value of our investment in Syrrx to $375,000. We consider the reduction in carrying value of the investment to be other than temporary. We did not record any write-downs in the three months or nine months ended September 30, 2004.

Liquidity and Capital Resources

Since our inception, our cash expenditures have substantially exceeded our revenues, and we have relied primarily on the proceeds from the sale of equity securities to fund our operations.

At September 30, 2004, we had cash, cash equivalents, and marketable securities of $230.2 million, compared to $105.4 million at December 31, 2003. The increase of $124.8 million was attributable to our public offering completed in February 2004, which raised aggregate net cash proceeds of $148.3 million, as well as $3.9 million received from the exercise of stock options and warrants and $581,000 received from the sale of fixed assets. These sources of cash were partially offset by net cash used in operating activities of $27.9 million. The cash was used primarily for cofunding the clinical development program with Bayer for BAY 43-9006.

Total capital expenditures for equipment and leasehold improvements for the nine months ended September 30, 2004, were $130,000. We currently expect to make expenditures for capital equipment and leasehold improvements of up to $1.5 million for the remainder of 2004 primarily relating to the anticipated move to our new corporate headquarters in the fourth quarter of 2004.

We believe that our existing capital resources and interest thereon will be sufficient to fund our current and planned operations through the end of 2006. We anticipate that our codevelopment costs for the BAY 43-9006 program will increase over the next several years as the clinical trial program advances. In addition, marketing expenses are expected to increase as we and Bayer incur costs in anticipation of the commercial launch of BAY 43-9006. While these costs are unknown at the current time, we expect that we will need to raise additional capital to continue the cofunding of the program in future periods beyond 2006.

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Changes in our research and development and marketing plans or other changes affecting our operating expenses may result in the expenditure of our resources before the end of 2006, and in any event, we will need to raise additional capital to fund our operations beyond 2006. We intend to seek this additional funding through 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.

Our collaboration agreement with Bayer calls for Bayer to advance us creditable milestone-based payments. To date, Bayer has advanced us $20 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 products.

In August 2004, we entered into an operating lease for 23,000 square feet of office space, which will serve as our new corporate headquarters. The lease expires on February 28, 2010 with a renewal option at the end of the lease for a period of three years. The lease for our current primary facility expires in April 2005, which we do not plan to renew.

Our contractual obligations as of September 30, 2004, including the new facility lease, for the next five years and thereafter are as follows:

Contractual Obligations (1)	**Payments Due by Period**				
	Total	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**After 5 Years**
			(In thousands)		
Operating leases, net of sublease income	$3,203	$ 684	$1,104	$1,160	$ 255

(1) This table does not include any payments under research and development collaborations, as the amount and timing of such payments are not known. This table also does not include the obligation to repay the $20 million creditable milestone-based payments that we received from Bayer, because the repayment of these amounts is contingent upon Onyx generating profits or royalties on any products. Whether Onyx will ever generate any profits or royalties is not known at this time.

Business Risks

BAY 43-9006 is our only product candidate currently in Phase II and Phase III clinical development, and our ability to discover and promote additional candidates to clinical development is constrained. If BAY 43-9006 is not successfully commercialized, we may be unable to identify and promote alternative product candidates and our business would fail.

BAY 43-9006 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 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 remaining scientific and administrative employees are dedicated to managing our relationship with Bayer, and the development of BAY 43-9006, 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 BAY 43-9006. If BAY 43-9006 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 clinical development, which would cause our business to fail.

If our clinical trials fail to demonstrate the safety and effectiveness of BAY 43-9006, we will be unable to commercialize BAY 43-9006, and our business may fail.

In collaboration with Bayer, we are conducting multiple clinical trials of BAY 43-9006. We have completed Phase I single-agent clinical trials of BAY 43-9006. We are currently conducting a number of Phase Ib clinical trials of BAY 43-9006 in combination with standard chemotherapeutic agents. Phase I trials are not designed to test the efficacy of a drug

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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 BAY 43-9006 in kidney and liver cancer and are currently conducting Phase II clinical trials in breast, non-small cell lung and other cancers. Phase II trials are designed to explore the efficacy of a product candidate in several different types of cancers and are normally randomized and double-blinded to ensure that the results are due to the effects of the drug. We and Bayer have initiated a Phase III clinical trial to treat patients with advanced kidney cancer without conventional randomized Phase II clinical trial data. In October 2004, we and Bayer announced that we will pursue registration utilizing results from this trial, and pending FDA approval, we would anticipate a United States launch in 2006. We further announced that we completed the Phase II randomized discontinuation trial, and data from this trial will be used to support the Phase III trial results.

We believe that any clinical trial to test patients with advanced kidney cancer designed to test the efficacy of BAY 43-9006, whether Phase II or Phase III, will involve a large number of patients to achieve statistical significance and will be expensive. We may conduct a lengthy and expensive clinical trial of BAY 43-9006 only to learn that this drug candidate is not an effective treatment. 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, we may observe previously unforeseen adverse side effects.

If efficacy of BAY 43-9006 is not demonstrated, or if previously unforeseen and unacceptable side effects are observed, we may not proceed with further clinical trials of BAY 43-9006. If we do not proceed with additional clinical trials of BAY 43-9006, we cannot seek regulatory approval of BAY 43-9006 with the FDA, which may cause our business to fail.

In our clinical trials, we treat patients who have failed conventional treatments and who are in advanced stages of cancer. During the course of treatment, these patients may die or suffer adverse medical effects for reasons unrelated to BAY 43-9006. These adverse effects may impact the interpretation of clinical trial results, which could lead to an erroneous conclusion regarding the toxicity or efficacy of BAY 43-9006.

We are dependent upon our collaborative relationship with Bayer to develop, manufacture and commercialize BAY 43-9006 and to obtain regulatory approval. There may be circumstances which delay or prevent the development and commercialization of BAY 43-9006.

Our strategy for developing, manufacturing and commercializing BAY 43-9006 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 these 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 BAY 43-9006.

Under the terms of the collaboration agreement, we and Bayer are conducting multiple clinical trials of BAY 43-9006. We and Bayer must agree on the development plan for BAY 43-9006. 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 sales. We

are currently funding 50 percent of development costs for BAY 43-9006, 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 BAY 43-9006, 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 which 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 BAY 43-9006. If Bayer terminates its cofunding of BAY 43-9006 development, we may be unable to fund the development costs on our own and may be unable to find a new collaborator.

Bayer manages the development of BAY 43-9006, including the FDA regulatory process and scope, size and schedule of clinical development. We are 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 $20 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 products.

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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 BAY 43-9006. At present, it is anticipated that, if issued, the last to expire of the United States patents 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 expenditure of resources can vary because of decisions by Bayer;
- possible disagreements as to development plans, including clinical trials or regulatory approval strategy;
- the right of Bayer to terminate its collaboration agreement with us on limited notice and for reasons outside our control;
- loss of significant rights if we fail to meet our obligations under the collaboration agreement;
- withdrawal of support by Bayer following the development or acquisition by it of competing products; and
- possible disagreements with Bayer regarding the collaboration agreement or ownership of proprietary rights.

Due to these factors and other possible disagreements with Bayer, we may be delayed or prevented from developing or commercializing BAY 43-9006, 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 BAY 43-9006. If this happened, Onyx, or the successor to Onyx, would receive a royalty based on any sales of BAY 43-9006 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 clinical trials for BAY 43-9006, 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 BAY 43-9006 as projected or at all.

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We rely on Bayer, academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving BAY 43-9006. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. In addition, we may suffer a delay in the completion of any one of our clinical trials because of requests from the FDA to revise the size or scope of the clinical trial. Failure to commence or complete, or delays in, any of our planned clinical trials would prevent us from commercializing BAY 43-9006, and thus seriously harm our business.

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

We will require substantial additional funds to conduct the costly and time-consuming clinical trials necessary to develop BAY 43-9006, 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 BAY 43-9006 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 or 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 through 2006. 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 BAY 43-9006 program will increase over the next several years as the Phase III clinical trial program advances, and new trials are initiated. 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 BAY 43-9006 program in future periods. We may have to curtail our funding of BAY 43-9006 if we cannot raise sufficient capital. If we do not cofund development of BAY 43-9006, we will receive a royalty on future sales of any product that is ultimately commercialized, instead of a share of profits.

The efficacy of RAF inhibition in the treatment of human cancer has not been established.

As a part of BAY 43-9006 s dual mechanism of action, it is designed to act as a RAF inhibitor, blocking inappropriate growth signals in tumor cells by inhibiting RAF kinase, an enzyme involved in cancer cell growth. BAY 43-9006 is the first small molecule RAF inhibitor to reach the stage of clinical testing, and there is currently no direct evidence that the inhibition of RAF is an effective treatment for cancer in humans. BAY 43-9006 also inhibits VEGF and PDGF receptors, two key receptors involved in angiogenesis. In addition, the inhibition of RAF kinase has also been shown to have anti-

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angiogenic effects. BAY 43-9006 has been shown to inhibit angiogenesis and tumor growth in preclinical models. However, preclinical models to study anticancer activity of compounds are not necessarily predictive of sufficient clinical efficacy of these compounds in the treatment of human cancer to warrant a full commercial development program. BAY 43-9006 has also been tested in Phase I and Phase II human clinical trials, but the number of patients in these trials, and the design of the trials, did not lead to data that could be used as a pivotal trial for regulatory purposes. RAF inhibition, a method of action of BAY 43-9006, may ultimately fail as an effective treatment of cancer in humans, or BAY 43-9006 may not inhibit RAF sufficiently to be effective. If RAF inhibition is not an effective treatment of cancer in humans, BAY 43-9006 may have no commercial value as a drug candidate, which could seriously harm our business.

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

Our net loss for the year ended December 31, 2001 was $27.6 million, for the year ended December 31, 2002 was $45.8 million, and for the year ended December 31, 2003 was $45.0 million. Our net loss for the nine months ended September 30, 2004 was $32.6 million. As of September 30, 2004, we had an accumulated deficit of approximately $236.4 million. We have incurred these losses principally from costs incurred in our research and development programs and from our general and administrative costs. We derived no revenues from product sales or royalties. We expect to incur significant and increasing operating losses over the next several years as we expand our clinical trial activities. We expect our operating losses to increase with our cofunding of ongoing BAY 43-9006 clinical trial costs under our collaboration agreement with Bayer.

We do not expect to generate revenues from the sale of products for the foreseeable future, and we must repay the milestone-based advances we receive from Bayer from our future profits and royalties, if any. Our ability to achieve profitability depends upon success by us and Bayer in completing development of BAY 43-9006, obtaining required regulatory approvals and manufacturing and marketing the approved product.

We do not have manufacturing expertise or capabilities and are dependent on third parties 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 BAY 43-9006 for clinical trials and to support any commercial requirements. We lack the resources, experience and capabilities to manufacture BAY 43-9006 or any future product candidates on our own. We would require substantial funds to establish these capabilities. Consequently, we are 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 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 BAY 43-9006 in the United States, but we do not have significant marketing or sales experience or capabilities.

We have the right under our collaboration agreement with Bayer to copromote BAY 43-9006 in the United States in conjunction with Bayer. In order to copromote BAY 43-9006, we will need to develop marketing and sales

capabilities. We may not successfully establish marketing and sales capabilities or have sufficient resources to do so. If we do not develop marketing and sales capabilities, we may not meet our copromotion obligations under our collaboration agreement, which could result in our losing these 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.

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

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services of one or more of our 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 BAY 43-9006 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 BAY 43-9006, but are not actively involved in new product candidate discovery. If we resume our research and development of other product candidates, we will either need to rehire these individuals or hire individuals with similar skills. If we cannot rehire these individuals or others with similar skills in a timely fashion, we will be unable to resume these activities.

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, BAY 43-9006 or any future product candidates that we may develop may not gain market acceptance among physicians, patients, healthcare payers and the medical community. 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;

availability of third-party reimbursement;

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 BAY 43-9006 or any future product candidates that we may develop do not achieve market acceptance, we may lose our investment in that product candidate, which may cause our stock price to decline.

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 competitive product candidates are in clinical trials, and others are approved. Competitors that target the same tumor types as our BAY 43-9006 program and that have commercial products or product candidates in clinical development include Pfizer, Novartis, AstraZeneca PLC, OSI Pharmaceuticals, Inc., Genentech, Inc., and Abgenix, Inc., among others. Novartis, Pfizer and others have in clinical development for advanced kidney cancer small molecules targeting VEGF receptor tyrosine kinases and other enzymes. In addition, potential competition may come from agents that target Epidermal Growth Factor, or EGF, receptors and Vascular Endothelial Growth Factor, or VEGF, receptors. These agents include antibodies and small molecules. In particular, OSI Pharmaceuticals with Tarceva ™ and AstraZeneca with IRESSA ™ are developing small

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molecule inhibitors of the EGF receptor tyrosine kinase. IRESSA has been approved in the United States. Companies working on developing antibody approaches include ImClone Systems, Inc. with Erbitux and Abgenix with antibodies targeting EGF receptors. Erbitux has been approved in the United States. Genentech has Avastin TM, an antibody targeting VEGF, which is now approved. We believe several companies have small molecule compounds in clinical development that target MEK, an enzyme that is also involved in the RAS signaling pathway. In addition, many other pharmaceutical companies are developing novel cancer therapies that, if successful, would also provide competition for or be used in combination with BAY 43-9006. We believe that other companies have inhibitors of kinases in preclinical or clinical development that could be potential competitors.

Certain of these product candidates have recently been approved by the FDA. These and product candidates of other competitors now in clinical trials will compete directly with BAY 43-9006. 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 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. If BAY 43-9006 receives regulatory approval but cannot compete effectively in the marketplace, our business will suffer.

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 BAY 43-9006 or any other product candidate.

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 BAY 43-9006. 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 BAY 43-9006. 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

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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 BAY 43-9006. Delays in obtaining regulatory approvals may:

adversely affect the successful commercialization of BAY 43-9006;

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, including our competitors, could have an adverse effect on our ability to obtain or maintain regulatory approval for BAY 43-9006.

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 BAY 43-9006, 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 last to expire of the United States patents related to BAY 43-9006 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 BAY 43-9006 are also pending throughout the world. As of September 30, 2004, we owned or had licensed rights to 53 United States patents and 36 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 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

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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 BAY 43-9006 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 BAY 43-9006.

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 BAY 43-9006 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.

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

We deal with hazardous materials and must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

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Our activities involve the controlled storage, use, and disposal of hazardous materials, including infectious agents, corrosive, explosive and flammable chemicals and various radioactive compounds. We are subject to federal, state, and local laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials.

In the event of an accident, state or federal authorities may curtail our use of these materials and we could be liable for any civil damages that result, which may exceed our financial resources and may seriously harm our business. While we believe that the amount of insurance we carry is sufficient for typical risks regarding our handling of these materials, it may not be sufficient to cover pollution conditions or other extraordinary or unanticipated events. Additionally, an accident could damage, or force us to shut down, our operations. In addition, if we develop a manufacturing capacity, we may incur substantial costs to comply with environmental regulations and would be subject to the risk of accidental contamination or injury from the use of hazardous materials in our manufacturing process.

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, 2001 and ending September 30, 2004, the closing sales price for one share of our common stock reached a high of $58.75 and a low of $3.50. Factors affecting our stock price include:

interim or final results of, or speculation about, clinical trials from BAY 43-9006;

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 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 and ownership and voting arrangements, our officers, directors and principal stockholders may be able to effectively control the election of all members of the board of directors and to determine all corporate actions.

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ONYX PHARMACEUTICALS, INC.

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 recent announcement in October 2004 of Phase II clinical trial data in patients with advanced kidney cancer, our stock price declined significantly. Our closing stock price on the last trading day before the announcement was $40.81, and our closing stock price on the day of the announcement was $27.34. We may in the future be the target of securities class action litigation. Securities litigation could result in substantial costs, could divert management s attention and resources, and could seriously harm our business, financial condition and results of operations.

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 10 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 10 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 of control, even at stock prices higher than the then current stock price.

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ONYX PHARMACEUTICALS, INC.

We have entered into change of 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. These change of control severance agreements may have the effect of preventing a change of control.

Failure to complete our assessment of the effectiveness of our internal control over financial reporting may subject us to regulatory sanctions and could result in a loss of public confidence, which could harm our operating results and our stock price.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, beginning with our year ending December 31, 2004, we will be required to include in our annual report our assessment of the effectiveness of our internal control over financial reporting and our audited financial statements as of the end of 2004. Furthermore, our independent registered public accounting firm will be required to attest to whether our assessment of the effectiveness of our internal control over financial reporting is fairly stated in all material respects and separately report on whether it believes we maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004. If we fail to timely complete our assessment, or if our independent registered public accounting firm cannot timely attest to our assessment, we could be subject to regulatory sanctions and a loss of public confidence in our internal control. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to timely meet our regulatory reporting obligations.

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 manager, 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, 2004 rates, the fair value of our portfolio would decline by approximately $781,000.

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

	September 30, 2004			December 31, 2003		
	Maturity	Fair Value ($ in millions)	Average Interest Rate	Maturity	Fair Value ($ in millions)	Average Interest Rate
Cash equivalents, fixed rate	0-1 month	$ 70.9	1.53%	0-3 months	$ 55.2	1.04%
Marketable securities, fixed rate	0-18 months	$ 159.2	1.90%	0-19 months	$ 50.1	1.49%

We did not hold any derivative instruments as of September 30, 2004, and we have not held derivative instruments in the past. However, our investment policy does allow us to use derivative financial instruments for the purposes of hedging foreign currency denominated obligations. Our cash flows are denominated in U.S. dollars.

Item 4. Controls and Procedures

Evaluation of disclosure controls and procedures: The Company s principal executive and 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 principal executive and financial officer concluded that the Company s disclosure controls and procedures were sufficiently effective as of September 30, 2004 to ensure that information required to be disclosed by the Company in this Quarterly Report on Form 10-Q was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission s rules and Form 10-Q.

Changes in internal controls over financial reporting: There were no significant changes in the Company s internal controls over financial reporting during the three months ended September 30, 2004 that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Limitation on the effectiveness of controls: A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

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ONYX PHARMACEUTICALS, INC.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

Not applicable.

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

On July 19, 2004, we issued an aggregate 28,129 shares of our common stock to Quogue Capital, LLC pursuant to the cashless exercise of a warrant dated May 7, 2002 . The warrant was exercisable for a total of 37,037 shares of common stock and had an exercise price of $9.59 per share. In connection with the cashless exercise, the number of shares issuable under the warrant was reduced by 8,908 shares based on the operation of the cashless exercise provisions in the warrant. The issuance of the shares under this warrant was exempt from registration under the Securities Act of 1933 in reliance on Section 4(2) as a transaction not involving 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

Consistent with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, we are responsible for listing the non-audit services approved by our Audit Committee to be performed by Ernst & Young LLP, our independent registered public accounting firm. Non-audit services are defined as services other than those provided in connection with an audit or a review of our financial statements. The Audit Committee has approved our recurring engagements of Ernst & Young LLP for the following non-audit services: (1) preparation of tax returns, and tax advice in preparing for and in connection with the filings; (2) all work required to be performed by Ernst & Young LLP in connection with preparing and giving consents required to be given in connection with our filings with the Securities and Exchange Commission; (3) all work required to be performed by Ernst & Young LLP in connection with preparing and giving consents required to be given in connection with our planned filing with the Securities and Exchange Commission of a Form S-8 to register 600,000 shares of the Company s common stock pursuant to the amendment to the Company s 1996 Equity Incentive Plan approved at the Company s annual meeting of stockholders; and (4) advice in preparing for the internal control documentation requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Item 6. Exhibits

a) Exhibits

3.1	Restated Certification of Incorporation of the Company. (1)
3.2	Bylaws of the Company. (1)
3.3	Certificate of Amendment to Amended and Restated Certification of Incorporation. (2)
4.1	Reference is made to Exhibits 3.1, 3.2 and 3.3.
4.2	Specimen Stock Certificate. (1)
10.43	Sublease between the Company and Siebel Systems, Inc. dated August 5, 2004.
31.1	Certification required by Rule 13a-14(a) or Rule 15d-14(a).

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ONYX PHARMACEUTICALS, INC.

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 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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ONYX PHARMACEUTICALS, INC.

SIGNATURES

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

ONYX PHARMACEUTICALS, INC.

Date: November 8, 2004 By: /s/ Hollings C. Renton

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

Date: November 8, 2004 By: /s/ Marilyn E. Wortzman

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

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