NANOGEN INC
Form 10-Q
May 10, 2005
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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 March 31, 2005

OR

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

For the transition period from _____ to _____

Commission File Number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0489621**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10398 Pacific Center Court, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip code)**

(858) 410-4600

(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 preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

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

YES x NO ¨

As of April 15, 2005, 47,771,773 shares of the Registrant s Common Stock were outstanding.

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FORM 10-Q

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NANOGEN, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	As of March 31, 2005 (unaudited)	As of December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,715	$ 15,372
Short-term investments	27,134	36,562
Receivables, net of allowance for doubtful accounts of $117 and $176 at March 31, 2005 and December 31, 2004, respectively	2,246	2,023
Inventories, net	2,117	1,744
Other current assets	1,571	1,741
Total current assets	45,783	57,442
Property and equipment, net	8,114	8,500
Acquired technology rights, net	11,152	11,819
Restricted cash	1,411	1,411
Other assets, net	786	780
Goodwill	96,178	96,072
Total assets	$ 163,424	$ 176,024
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 6,100	$ 9,923
Deferred revenue	322	420
Common stock warrants	231	1,112
Current portion of debt obligations	909	988
Total current liabilities	7,562	12,443
Debt obligations, less current portion	624	610
Other long-term liabilities	5,484	5,455
Total long-term liabilities	6,108	6,065
Stockholders equity:		

Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2005 and December 31, 2004		
Common stock, $0.001 par value, 135,000,000 shares authorized at March 31, 2005 and December 31, 2004; 47,771,773 and 47,765,581 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively	48	48
Additional paid-in capital	375,152	374,910
Accumulated other comprehensive loss	(134)	(174)
Deferred compensation	(971)	(1,184)
Accumulated deficit	(223,419)	(215,162)
Treasury stock, at cost, 500,189 shares at March 31, 2005 and December 31, 2004, respectively	(922)	(922)
Total stockholders equity	149,754	157,516
Total liabilities and stockholders equity	$ 163,424	$ 176,024

See accompanying notes.

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NANOGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended March 31,	
	2005	**2004**
Revenues:		
Product sales	$ 1,210	$ 1,132
License fees and royalty income	1,700	152
Sponsored research		375
Contracts and grants	266	500
Total revenues	3,176	2,159
Costs and expenses:		
Cost of product sales	1,146	914
Research and development	4,912	4,348
Selling, general and administrative	5,967	3,575
Amortization of purchased intangible assets	393	
Total costs and expenses	12,418	8,837
Loss from operations	(9,242)	(6,678)
Other income (expense):		
Interest income, net	179	102
Other expense	(88)	(20)
Warrant valuation adjustment	881	
Gain on foreign currency translation	13	1,221
Total other income	985	1,303
Net loss	$ (8,257)	$ (5,375)
Net loss per share basic and diluted	$ (0.17)	$ (0.20)
Number of shares used in computing net loss per share basic and diluted	47,773	26,936

See accompanying notes.

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NANOGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three months ended March 31,	
	2005	**2004**
Operating activities:		
Net loss	$ (8,257)	$ (5,375)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,488	854
Foreign currency translation gain	(13)	(1,221)
Other non-cash charges	209	15
Loss on disposal of fixed assets	31	
Accretion related to short-term investments	133	39
Stock-based compensation expense	299	
Realized loss on sale of short-term investments		6
Warrant valuation adjustment	(881)	
Increase (decreases) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions:		
Receivables	(223)	(918)
Inventories	(590)	401
Other current and long-term assets	168	317
Accounts payable and accrued liabilities	(2,248)	(315)
Deferred revenue and other long-term liabilities	(98)	(179)
Net cash used in operating activities	(9,982)	(6,376)
Investing activities:		
Purchase of short-term investments	(7,381)	(14,654)
Proceeds from sale and maturities of short-term investments	16,705	4,223
Acquisition of businesses, net of cash acquired	(1,681)	
Purchase of equipment	(432)	(120)
Funding of bridge notes receivable related to acquisition		(805)
Net cash provided (used in) by investing activities	7,211	(11,356)
Financing activities:		
Principal payments on long-term obligations	(284)	(219)
Issuance of common stock, net	156	41,288
Proceeds from long-term obligations	219	
Net cash provided by financing activities	91	41,069
Effect of exchange rate changes	23	143

Net (decrease) increase in cash and cash equivalents	(2,657)	23,480
Cash and cash equivalents at beginning of period	15,372	8,550
Cash and cash equivalents at end of period	$ 12,715	$ 32,030

See accompanying notes.

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NANOGEN, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

March 31, 2005

1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. The consolidated balance sheet as of March 31, 2005, consolidated statements of operations for the three months ended March 31, 2005 and 2004, and the consolidated statements of cash flows for the three months ended March 31, 2005 and 2004 are unaudited, but include all adjustments (consisting of normal recurring adjustments) which in the opinion of management are considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three months ended March 31, 2005 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2005.

For more complete financial information, these financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2004 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2004 filed with the Securities and Exchange Commission on March 15, 2005.

Basis of Consolidation

The Company s consolidated financial statements include the assets, liabilities and operating results of majority-owned subsidiaries and other subsidiaries controlled by the Company. All significant intercompany accounts and transactions have been eliminated. The Company does not have any investments in entities it believes are variable interest entities for which the Company is the primary beneficiary.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosures at the date of the financial statements, and the amounts of revenues and expenses reported during the period. Actual results could differ from those estimates.

Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for Impairment or Disposal of Long-Lived Assets, the Company periodically assesses certain of its long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset are less than its then carrying amount. Any required impairment loss would be measured as the amount by which the asset s carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. During the three months ended March 31, 2005 and 2004, the Company had no impairment losses.

Net Loss per Share

The Company computes net loss per share in accordance with SFAS No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net income (loss) per share is computed by dividing the net income (loss) available to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the

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net income (loss) for the period by the weighted average number of common shares outstanding during the period, and in the periods they are dilutive, common equivalent shares for outstanding stock options and warrants computed using the treasury stock method. The weighted average common shares outstanding during the period does not include those shares issued pursuant to the exercise of stock options prior to vesting. In loss periods, common stock equivalents are excluded from the computation of diluted net loss per share as their effect would be anti-dilutive.

Short-Term Investments

The Company invests excess cash in highly liquid debt instruments of financial institutions and corporations with strong credit ratings and in United States government obligations. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

The Company has evaluated its investments in accordance with the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Based on such evaluation, the Company s management has determined that all of its investment securities are properly classified as available-for-sale. Based on the Company s intent, investment policies and its ability to liquidate debt securities, the Company classifies such short-term investment securities within current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses included in accumulated other comprehensive loss within stockholders equity. The amortized cost basis of debt securities is periodically adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included as a component of interest income (expense). The amortized cost basis of securities sold is based on the specific identification method and all such realized gains and losses are recorded as a component within other income (expense), net.

Management reviews the carrying values of the Company s investments and writes down such investments to estimated fair value by a charge to operations when in management s determination, the decline in value of an investment is considered to be other than temporary. The cost of securities sold is based on the average cost method and is recorded on the settlement date.

At March 31, 2005, the excess of carrying cost over the fair value of the Company s short-term investments that are below carrying cost is immaterial and considered to be temporary.

Segment Information

SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information , establishes standards for reporting information on operating segments in interim and annual financial statements. The Company operates in one segment, which is the business of development, manufacturing and commercialization of advanced diagnostic products. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, Inventory Costs An Amendment of ARB No. 43, Chapter 4 (FAS 151). FAS 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, FAS 151 requires that allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in FAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe that the adoption of FAS 151 will have a significant effect on its financial statements.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment (FAS 123R), that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for either equity instruments of the enterprise or 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 statement eliminates the ability to account for share-based compensation transactions, as the Company does currently, using the intrinsic value method as prescribed by Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and generally requires that such transactions be accounted for using a fair-value-based

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method and recognized as expenses in our consolidated statement of operations. The statement requires companies to assess the most appropriate model to calculate the value of the options. The Company currently uses the Black-Scholes option pricing model to value options and is currently assessing which model the Company may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under the Company s employee stock purchase plan, and the presentation of tax benefits within the consolidated statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, the Company will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include prospective and retroactive adoption options. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of a new rule that amends the effective date of FAS 123R. The effective date of the new standard under these new rules for the Company s consolidated financial statements is January 1, 2006. Adoption of this statement will have a significant impact on the Company s consolidated financial statements as the Company will be required to expense the fair value of the stock option grants and stock purchases under the Company s employee stock purchase plan rather than disclose the impact on the consolidated results of operations within the footnotes, as is the Company s current practice.

2. Stock-Based Compensation

The Company applies the intrinsic value-based method of accounting as prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations including Financial Accounting Standards Board (FASB) Interpretation No. 44, Accounting for Certain Transactions involving Stock Compensation an interpretation of APB Opinion No. 25 to account for its stock option plans. Under the intrinsic value method, compensation expense is measured on the date of grant only if the then current market price of the underlying stock exceeded the exercise price and is recorded on a straight-line basis over the applicable vesting period. Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure.

The pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated at the date of grant using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. Black-Scholes does not consider the employment, transfer or vesting restrictions that are inherent in the Company s employee options. Use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each option grant. Because the Company s employee stock options have characteristics significantly different from those of freely traded options, and because the assumptions underlying the Black-Scholes model involve substantial judgment, the Company s estimate of the fair value of its awarded stock options may differ materially from the ultimate value realized by the recipient employee.

The weighted average estimated fair values of stock options granted during the three months ended March 31, 2005 and 2004 was $3.87 and $7.04 per share, respectively. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	Stock Options Three months ended March 31,	
	2005	2004
Expected term	5 years	5 years
Interest rate	3.7%	3.2%
Volatility	82%	110%
Dividends		

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Had compensation expense been recorded based on SFAS 123, the Company s pro forma net loss, and pro forma loss per share would have been as follows:

	Three months ended March 31,	
	2005	2004
	(In thousands, except per share data)	
Net loss:		
As reported	$ (8,257)	$ (5,375)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects		
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(1,441)	(922)
Pro forma	$ (9,698)	$ (6,297)
Basic loss per share:		
Basic loss per common share:		
As reported	$ (0.17)	$ (0.20)
Pro forma	$ (0.20)	$ (0.23)

The amounts disclosed above are not necessarily indicative of the amounts that will be expensed upon adoption of FAS 123R Share-Based Payment . Compensation expense calculated under FAS 123R may differ from amounts currently disclosed within these footnotes based on changes in the fair value of the Company s common stock, changes in the number of options granted or the terms of such options, the treatment of tax benefits and changes in interest rates or other factors. In addition, upon adoption of FAS 123R, the Company may choose to use a different valuation model to value the compensation expense associated with employee stock options and stock purchases under the Company s employee stock purchase plan, as discussed under Recent Accounting Pronouncements.

Periodically, the Company issues options to non-employees. The options are recorded at their fair values (using the Black-Scholes model) as determined in accordance with SFAS 123 and periodically re-measured in accordance with EITF 96-18 Accounting for Equity Instruments That Are Issued To Other Than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services and are recognized over the related service period.

3. Warranty

The Company provides product warranty coverage under direct sale and fee per test transactions related to NanoChip® Molecular Biology Workstations. Warranty periods are generally for one year under direct sales, and over the period of the contract for a cost per test agreement transactions. Instruments sold to distributors typically are sold without warranty coverage.

Historically, warranty service was performed by Hitachi, the instrument manufacturer, under a service agreement. In March 2004, Hitachi exercised its right to terminate the service agreement. The responsibility for servicing units transferred to the Company. The Company has developed an in-house service function to handle this responsibility. Expenses under the in-house service functions are expensed as warranty costs in the period incurred.

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Changes in the Company s warranty liability were as follows (in thousands):

	Balance at January 1,	Warranty Additions (charges to expense)	Payment for warranty service	Balance at March 31,
2005:				
Warranty reserve	$ 17	$ 5	$ (2)	$ 20
2004:				
Warranty reserve	$ 159	$ 41	$ (83)	$ 117

4. Comprehensive Loss

SFAS No. 130, Reporting Comprehensive Income, requires the Company to report, in addition to net loss, comprehensive loss and its components. A summary is as follows (in thousands):

	Three months ended	
	March 31, 2005	March 31, 2004
	(Unaudited)	(Unaudited)
Comprehensive loss:		
Net unrealized gain / (loss) on short-term investments	$ 14	$ (4)
Foreign currency translation adjustment	26	(1,125)
Net loss	(8,257)	(5,375)
Comprehensive loss	$ (8,217)	$ (6,504)

5. Common Stock Warrant Liability

As a result of the Company s acquisition of Epoch, the Company assumed warrants representing 381,317 shares of the Company s common stock with an exercise price of $8.32 per share and an expiration in early 2009. These warrants contain a provision whereby, under certain circumstances pertaining to a change of control of the Company, the warrant holders have the right to redeem their warrant for cash equal to the estimated fair value of the warrant at such time using the Black Scholes method to calculate the fair value. The volatility factor to be used in this calculation, is limited to the lesser of 50% or the Company s actual historical volatility. As a result, and in accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock, the fair value of the cash redemption portion of the warrants, measured in accordance with the terms of the warrant agreements, is recorded as a current liability on the Company s balance sheet. The decrease in the market price of the Company s common stock and other changes in the valuation assumptions from December 31, 2004 to March 31, 2005 resulted in a decrease in the value of the warrants between these dates of $881,000. Therefore, the Company reported an other income of $881,000 as a warrant valuation adjustment in the Company s statement of operations for the year ended March 31, 2005.

The assumptions used in the Black-Scholes pricing model were:

	March 31, 2005	December 31, 2004
Expected term	3.9 years	4.2 years
Interest rate	3.3%	3.5%
Volatility	50%	50%
Dividends		

Until the warrants are exercised or expire, the valuation of the warrants and the corresponding liability will be re-measured quarterly and the financial statements will reflect a non-cash valuation adjustment based on the change in the fair value of the warrants during each reporting period.

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6. Commitments and Contingencies

Long-term debt obligations

In March 2005, the Company extended its December 2003 equipment funding agreement to provide financing of up to $1.2 million for equipment purchases.

In March 2005, the Company issued a promissory note under this agreement in an aggregate principal amount of approximately $219,000. This note is secured by equipment with a cost of $219,000. This note bears interest at 10.86% per annum with principal and interest due in monthly payments of approximately $7,000 for 36 months.

As of March 31, 2005, the future contractual principal payments on all of the Company s promissory notes are as follows (in thousands):

For the years ended December 31,	
2005	$ 733
2006	513
2007	266
2008	21
Total	$ 1,533

The interest expense for the three months ended March 31, 2005 and 2004 was $34,000 and $33,000, respectively.

Restricted Cash

The Company has pledged under a security agreement long-term certificates of deposit, in lieu of cash deposits, to secure operating lease obligations which are reflected as restricted cash in the accompanying consolidated balance sheet. The Company had approximately $1.4 million in long-term certificates of deposit at March 31, 2005 and December 31, 2004.

Litigation

The Company maybe subject to other potential liabilities under various claims and legal actions that may be asserted. These matters have arisen in the ordinary course and conduct of the Company s business, as well as through acquisitions, and some maybe be covered, at least partly, by insurance. Claim estimates that are probable and can be reasonably estimated are reflected as liabilities of the Company. The ultimate resolution of these matters is subject to many uncertainties. It is reasonably possible that some of the matters, which are pending or may be asserted, could

be decided unfavorably to the Company. Although the amount of liability at March 31, 2005, with respect to these matters cannot be ascertained, the Company believes that any resulting liability should not materially affect the Company s consolidated financial statements.

7. Financial Statement Details

Receivables

Receivables are comprised of the following (in thousands) as of:

	March 31, 2005	December 31, 2004
	(Unaudited)	
Product	$ 736	$ 721
License fees	1,475	1,375
Contract and grant	152	103
	2,363	2,199
Allowance for doubtful accounts	(117)	(176)
	$ 2,246	$ 2,023

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Inventories

Inventories include the cost of material, labor and overhead, and are stated at the lower of average cost, determined on the first-in, first-out method, or market. The Company periodically evaluates its on-hand stock and makes appropriate provision for any stock deemed excess or obsolete.

Inventories consist of the following (in thousands) as of:

	March 31, 2005	December 31, 2004
	(Unaudited)	
Raw materials	$ 2,678	$ 1,924
Work in process (materials, labor and overhead)	1,816	2,398
Finished goods (materials, labor and overhead)	3,963	3,282
	8,457	7,604
Reserve for excess and obsolescence	(6,340)	(5,860)
	$ 2,117	$ 1,744

In June 2003, the Company committed to a manufacturing agreement with Hitachi, Ltd. (Hitachi) that requires the Company provide annual purchase commitments to Hitachi for the second-generation workstation, the NanoChip® 400. As of March 31, 2005, the Company had commitments to purchase $588,000 of the NanoChip® 400 instruments from Hitachi through July 2005.

Property and Equipment

Property and equipment consist of the following (in thousands) as of:

	Estimated Useful Life (in-year)	March 31, 2005	December 31, 2004
		(Unaudited)	
Scientific equipment	5	$ 9,131	$ 9,338
Office furniture and equipment	3 - 5	4,228	4,061
Manufacturing equipment	5	1,985	1,858
Leasehold improvements	(lesser of lease term or life of improvements)	7,247	7,247

	22,591	22,504
Less accumulated depreciation and amortization	(14,477)	(14,004)
	$ 8,114	$ 8,500

For the three months ended March 31, 2005 and 2004, depreciation and amortization expense related to property and equipment totaled $796,000 and $602,000, respectively.

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Acquired Technology Rights

Acquired technology rights consist of the following (in thousands) as of:

		March 31, 2005		December 31, 2004	
	Life	Gross Carrying Amount	Accumulated amortization	Gross Carrying Amount	Accumulated amortization
		(Unaudited)			
In-licensed technology rights	3 10 years	$ 6,137	$ (5,197)	$ 6,111	$ (4,897)
Customer contracts acquired	7 years	1,210	(350)	1,210	
Completed technology acquired	3 10 years	9,395	(43)	9,395	
Total acquired technology rights		$ 16,742	$ (5,590)	$ 16,716	$ (4,897)
Intangible assets not subject to amortization:					
Trademarks & trade names		$ 294		$ 294	

The amortization expense of intangibles for the three months ended March 31, 2005 and 2004 was $692,000 and $252,000, respectively.

Estimated amortization of intangibles (in thousands) for the years ended:

2005	$ 1,438
2006	1,695
2007	1,688
2008	1,538
2009	1,488
Thereafter	3,305
	$ 11,152

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following (in thousands) as of:

	March 31, 2005	December 31, 2004
	(Unaudited)	
Accounts payable	$ 950	$ 998
Accrued compensation and benefits	1,958	2,443
Accrued legal fees	529	944
Accrued acquisition costs		2,249
Accrued warrant rescission		598
Other	2,663	2,691
	$ 6,100	$ 9,923

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

Forward Looking Statement

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. These risks and uncertainties include those included herein under the caption Factors That May Affect Results below. We assume no obligation to update any forward-looking statements. Results of Operations should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, Consolidated Financial Statements and Notes thereto for the year ended December 31, 2004 in our Annual Report on Form 10-K.

Quarterly summary:

During the first quarter of 2005, the following significant business developments occurred:

Our strategy in 2004 to deliver a broader range of revenue generating products in 2005 for the advance diagnostics market continues to come to fruition. As we continued to generate revenue from our first generation Nanochip® System and associated consumables, we also increased our revenue with expanded product offerings and license fees that were related to our December 2004 acquisition of Epoch.

Several new products, currently under development are progressing to market as planned. Our internal testing indicates we continue to be on track to receive the required regulatory approvals necessary to begin distribution of our point-of-care tests for congestive heart failure (CHF) in the latter half of this year. We also remain confident that our second generation molecular biology workstation system, the NanoChip® 400, will begin shipping in the latter half of this year as well and will begin generating revenue initially from research customers, and subsequently from clinical customers following release of our Analyte Specific Reagents (ASRs) that clinical laboratory customers could use to develop tests for respiratory viral conditions and for detection of mutations potentially related to Cystic Fibrosis.

The research, development, and administration associated with developing new products and the broadening of our markets requires a significant investment and use of cash. Our cash usage during the first quarter of 2005 was higher than our projected rate primarily due to payment of transaction costs related to our acquisition of Epoch in December 2004. We believe we will continue to consume cash and have quarterly net losses for at least the remainder of this year until our product offerings gain traction in the market place and generate a return on investment.

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We signed five European distributors for our congestive heart failure (CHF) and myocardial infarction point-of-care tests. When we completed development and receive regulatory approval for our point-of-care tests, our distribution network will provide access to 28 European nations and an exposure to a potential customer base of over 7,500 hospitals, 4,000 clinical laboratories and almost 11,000 cardiac specialists. Our European distributors will be responsible for the distribution and marketing of our CHF tests. We did not receive any payments or require purchase commitments from these distributors.

Epoch, whose acquisition was completed on December 16, 2004, was integrated into our operations during this quarter. Our work to fully integrate Epoch s systems, operations and staff are expected to continue into the next couple of quarters.

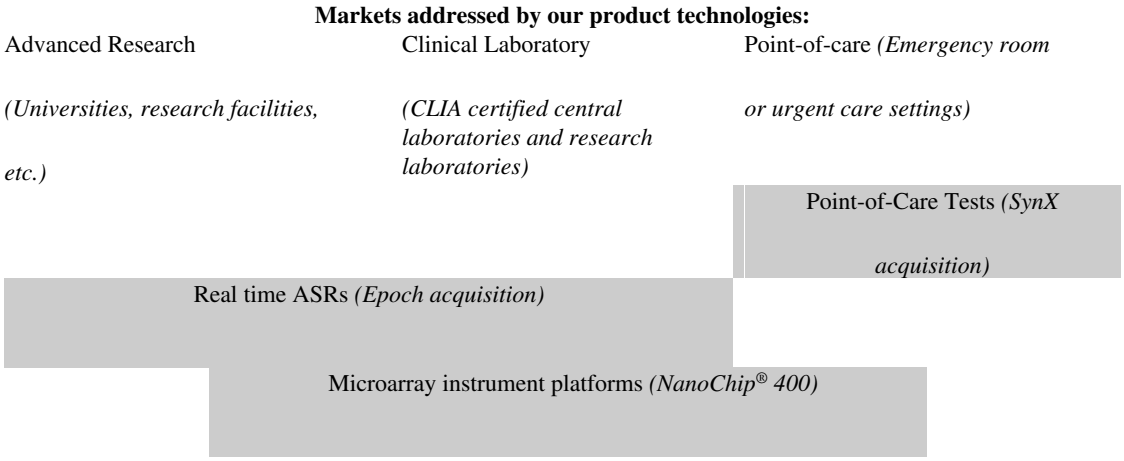
Our business:

We are headquartered in San Diego, California and were founded on the vision of providing a higher quality of healthcare through advanced medical diagnostic products. As disease is increasingly understood at a patient-specific level, we provide the tests that will allow doctors or researchers to make informed decisions based on specific proteins or genes specific to the individual patient or person. We believe we will be a leader in providing the products necessary to shift the focus of medicine from reactive to proactive through our advanced diagnostic platforms. With this vision, we have developed a product portfolio and pipeline that renders molecular biology information accessible to researchers and clinicians.

Products:

In 2004, we raised $43.8 million in capital and with that funding we focused on broadening our product portfolio to expand our sources of revenues. In 2005, with that expanded product portfolio, that includes the microarray platform (e.g. NanoChip®), real-time Analyte Specific Reagents (ASRs) and anticipated point-of-care platforms, we believe we will have the platform technologies to meet the needs of a broader range of customers within the advanced diagnostic market. Each of these technology platforms provides us greater revenue potential and the opportunity to increase our critical mass.

Below illustrates how our platform technologies address the market for advanced molecular diagnostic tools:



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As illustrated above we have three categories of advanced diagnostic products: 1) real-time ASRs, 2) microarray instrument platforms and related ASRs consumables, and 3) point-of-care tests.

1) Real-time ASRs

Our real-time ASRs are advanced molecular probes that amplify disease specific genetic sequences for analysis or identification. This platform technology provides real-time diagnosis of infectious and genetic diseases in a simple test with rapid turn around. The customers for this product line are primarily advanced research and clinical laboratories that test for single markers or mutations in genes. An advantage of our real-time ASRs is its platform independence providing us a broader market and customer base. In addition, we believe these products provide us name recognition and compliment our current sales and marketing efforts with a wider array of solutions for our customers.

2) Microarray instrument platforms and related ASRs

For our customers that require more complex testing than is available with real-time ASRs, we have developed the Molecular Biology Workstation and its second generation, the NanoChip®400 system, which is expected to be released later this year. These systems are based on our proprietary microarray-based or lab on a chip testing technology that allows testing for multiple gene markers or mutations on one test site. Our second generation system will offer customers a smaller footprint, faster throughput and simpler operating procedures than the current system. We are also developing a series of ASRs for the system which will provide our customers the capability to develop a series of tests including ones for respiratory viruses and for the genetic mutation associated with cystic fibrosis.

3) Point-of-care

Our point-of-care pipeline consists of highly specific tests for identifying protein markers that play a role in diseases. By identifying these proteins, doctors can more accurately diagnose and monitor the progress of specific diseases. Our researchers are developing products that focus on congestive heart failure, diagnosis of stroke and traumatic brain injury. We believe our technology will help to move many of these tests from the clinical reference lab to the point-of-care settings such as the emergency room. We are currently in the final stages of developing a congestive heart failure product, which is expected to be released in the later half of the year, which will test for levels of the protein NT-proBNP in the point-of-care setting.

Other sources of revenue:

License fee and royalty income

We own 128 issued U.S. patents as of March 31, 2005. We receive significant royalty payments from Applied Biosystems in an agreement that it assumed with its acquisition of Epoch Biosciences in December, 2004. This agreement provides for minimum quarterly royalties through the third quarter of 2005. Thereafter, we will receive royalty payments based on actual sales which may result in a significant reduction of royalties received. In addition, the contract can be terminated with a 180 day notice, although we expect our relationship with Applied Biosystems to

continue into the foreseeable future.

We do not currently receive significant royalty payments from its patent portfolio with the exception of the Applied Biosystems agreement. We are now evaluating our intellectual property position and may choose to license portions of our patent portfolio in the future, if we believe the terms and conditions are acceptable in relationship to our future product pipeline.

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Contracts and grants

We fund some of our research and development efforts through contracts and grants awarded by various federal and state agencies. Revenue is recognized under these contracts and grants as expenses are incurred. We do not believe these grants will be our primary source of on-going revenue but provide us additional revenue while offsetting our research and development costs. We will continue to seek new contracts and grants that are aligned with our internal research and development goals.

Other:

Acquisitions:

We actively and selectively seek to acquire companies with complementary products and strong intellectual property positions to allow us to expand our product offerings and penetrate emerging markets. In 2004, we acquired in all stock transactions, SynX and Epoch to obtain new product lines for the proteomics technology pipeline (e.g. point-of-care) and real-time ASR diagnostic markets, respectively. We believe that these acquisitions are important to our long-term strategy and are an example of our ongoing efforts to build a stronger company with products to serve the advanced diagnostic marketplace. We anticipate using our common stock as the primary currency to purchase future companies or product lines.

FDA regulations:

Many of our products are used for research purposes, and their use by our customers generally is not regulated by the United States Food and Drug Administration, or FDA, or by any comparable international organization, with several limited exceptions including ASR products which are subject to certain manufacturing standards. When we begin to distribute and manufacture products for non-CLIA laboratory customers and point-of-care customers, we are subject to additional FDA regulation and oversight and are required to comply with the Quality System Regulations, which was formerly known as current good manufacturing practice, or GMP, and is described in 21 CFR part 820. Additionally, some of these same sites and products are intended to comply with certain voluntary quality programs such as ISO 9001.

Manufacturing:

Hitachi manufactures our NanoChip® systems and we manufacture the majority of our consumable products in our manufacturing facilities in San Diego, California and Bothell, Washington.

Except for our oligonucleotide, genomics services and specialized manufacturing production businesses, which are make-to-order businesses, we principally manufacture products for inventory and ship products shortly after the receipt of orders, and anticipate that we will continue to do so in the future. We do not currently have a significant backlog and do not anticipate we will develop a material backlog in the near future. In addition, we rely on third-party manufacturers to supply many of our raw materials, product components, and in some cases, entire products.

Fluctuations:

We anticipate that our results of operations will fluctuate on a quarterly and annual basis and will be difficult to predict. The timing and degree of fluctuation will depend upon several factors, including those

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discussed under Risk Factors That May Affect Future Results. In addition, our results of operations could be affected by the timing of orders from distributors and the mix of sales between distributors and our direct sales force. Although we have experienced growth in the last quarter, we cannot assure you that we will be able to sustain revenue growth or achieve profitability on a quarterly or annual basis.

Results of operations three months ended March 31, 2005 compared to the three months ended March 31, 2004

Revenues

The following table summarizes our revenues for the three months ended March 31, 2005 and 2004 (in thousands):

	For the quarter ended March 31,		
	2005	2004	Difference
Product sales	$ 1,210	$ 1,132	$ 78
License fee and royalty income	1,700	152	1,548
Sponsored research		375	(375)
Contracts and grants	266	500	(234)
Total	$ 3,176	$ 2,159	$ 1,017

Product sales

Product sales include revenue from our three product lines of advanced diagnostic products, real-time ASRs, microarray instrument platforms and related ASRs consumables (NanoChip® system) and point-of-care tests. Product revenues rose during the first quarter of 2005 due to additional revenue from real-time ASRs and point of care tests acquired through the acquisitions of Epoch and SynX in December and April, 2004, respectively. Revenue from the NanoChip® system fell by approximately 55% in the first quarter of 2005 when compared to the same quarter of 2004, due to the limited size of the advanced research market and pending new products.

The future: During the second half of 2005, we are expecting to release several new products that will accelerate revenue growth including the NanoChip®400 and a point-of -care product to help diagnose congestive heart failure. We expect additional revenue when we release the NanoChip® 400, which has several features not available in the first generation system to address both the research and the larger clinical diagnostic market. In addition, we anticipate the release of ASRs for laboratory customers to use in developing tests on the NanoChip®400 which should further expand the market for this product.

License fees include nonrefundable fees generated from the licensing of our technology with third parties. License fees increased in the first quarter of 2005 as compared to the same quarter in 2004 due to the royalty bearing licensing agreement with Applied Biosystems for the TaqMan® 5 -nuclease real-time PCR assays.

The future: We continually evaluate additional licensing opportunities for our intellectual property. Through our recent acquisition we obtained a royalty bearing licensing agreement with Applied Biosystems, for the TaqMan® 5 -nuclease real-time PCR assays with contractual minimums through the third quarter of 2005 and thereafter we will receive royalty payments based on actual sales. We expect license fee revenue to

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remain consistent through the third quarter of 2005 due to contractual minimums. After the third quarter of 2005 we expect the licenses revenue to decrease based on our current analysis of the historic sales of the product.

Sponsored research revenue is nonrefundable money generated through the development agreement with Hitachi. We did not recognize any sponsored research revenue in the first quarter of 2005 due to the termination of the Hitachi collaborative research agreement in August 2003. Funding through this agreement was completed in the second quarter of 2004.

The future: With the conclusion of our sponsored research agreement with Hitachi in the second quarter of 2004, we do not expect any revenue from Hitachi in 2005 or thereafter. We may enter into additional sponsored research projects in the future.

Contracts and grants revenue is nonrefundable payments by various federal and state agencies for our research and development efforts awarded through contracts and grants. Contracts and grants revenue is recorded as the costs and expenses to perform the research are incurred, if the amount is reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Under certain arrangements where funding is provided for contractually on a scheduled basis, revenue is recorded ratably over the term of the arrangement. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. The decrease in contract and grant revenue in the first quarter of 2005 as compared to the same quarter in 2004 is a result of the completion of certain contracts and grants. No new contracts or grants were entered into during the first quarter of 2005 to replace those that were completed.

The future: The recognition of revenue under contracts and grants may vary from quarter to quarter and may result in significant fluctuations in operating results from year to year depending on the timing and quantity of agreements and contracts. In the future, we expect contract and grant revenue to become a decreasing portion of our overall revenues. We expect the majority of our revenue growth to be generated through an increase in product revenue.

Cost and expenses

Cost of product sales (in thousands):

	The three months ended March 31,		
	2005	2004	Difference
Cost of product sales	$ 1,146	$ 914	$ 232

Cost of product sales includes the material, manufacturing labor, overhead costs and inventory impairment charges related to our products. In the first quarter of 2005, the cost of product sales included costs related to the sale of the first generation microarray system (NanoChip® system), the cost of delivering real-time ASRs and other various diagnostic products from our SynX operations. The increase in cost of product sales in the first quarter of 2005 as compared to the same quarter in 2004, was primarily due to additional costs associated with the production of real-time ASRs.

In the first quarter of 2005, we had an inventory reserve of $6.3 million primarily related to our first generation NanoChip® system as compared to $2.3 million in the first quarter of 2004. This inventory reserve was accumulated throughout 2004 during our quarterly evaluations of anticipated sales for the next twelve months. After our announcement of a second generation system in October 2004 and evaluating actual sales during the year, we reserved (expensed) the net remaining carrying value of all first generation NanoChip® systems without purchase orders as of December 31, 2004. During the first quarter of 2005, the reserve did not have a significant impact on our NanoChip® gross margins. Going forward, future sales of our first generation system are highly uncertain in light of previous sales history and our anticipated release of a second generation system. Future sales of first generation NanoChip systems, if any, will have a minimal cost of product sales.

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The future. We are still in the early stages of commercialization of our real-time ASRs product line and are working to build in efficiencies into our manufacturing processes and expect to see improved gross margins in the future. We anticipate the second generation NanoChip® System will have a lower selling price per unit; therefore, our gross margins will depend on the number of units sold or rented to absorb our fixed capacity costs. We are still developing our models for accurately predicting the gross margins on our point-of-care testing products for the diagnosis of congestive heart failure as much depends on pricing and volume of sales.

Research and development expenses (in thousands):

	The three months ended March 31,		
	2005	2004	Difference
Research and development	$ 4,912	$ 4,348	$ 564

Research and development expenses include the associated costs of salaries and benefits for scientific, engineering and operations personnel, costs associated with improving and refining our current products as well as development of potential new products and protocols, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities. The increase in research and development expenditures in the first quarter of 2005 as compared to the first quarter of 2004, primarily related to continuing product development at the companies we acquired in 2004 which are intended to broaden our product lines and markets. In the first quarter of 2005, our research and development expenditures included the development of the second generation NanoChip®400 system and related consumables (general reagents and specific reagents for respiratory viruses and Cystic Fibrosis ASRs), development of new real time ASR products, advanced research related to real time ASRs and the development of diagnostic point-of-care products. In the first quarter of 2004, our research and development expenditure primarily focused on the NanoChip® 400 System and the associated consumables.

The future. We expect our research and development expenditures to remain level for the remainder of the year as we continue to control our development costs. However, we may incur additional costs if we acquire additional businesses or enter into significant development agreements later in the year. We will continue to focus our research and development expenditures in our current technology platforms (microarray, real time ASRs and point-of-care applications) in the advanced diagnostic and point-of-care market.

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Selling, general and administrative expenses (in thousands):

	For the three months ended March 31,		
	2005	2004	Difference
Selling, general and administrative	$ 5,967	$ 3,575	$ 2,392

Selling, general and administrative expenses include sales and marketing personnel, tradeshows, promotional activities and materials, administrative personnel, legal, other professional expenses and general corporate expenses. The increase in selling, general and administrative expenses in the first quarter of 2005 as compared to the first quarter of 2004, primarily relates to an additional $1.7 million in expenses related to operating costs in the companies we acquired and an additional $674,000 in expenses associated with the integration of our operations with Epoch, Sarbanes-Oxley Act compliance and managing a more complex and diverse business.

The future. In future quarters we expect selling, general and administrative expenses to remain consistent as we incur synergies and savings by consolidating many of the general and administrative functions as we fully integrate Epoch s operations. However, the savings from consolidation of general and administrative activities are expected to be offset by increased sales and marketing expenses required to support the various new product launches expected later in 2005. Expenses may also be further impacted by potential future business combinations or corporate development transactions.

Amortization of purchased intangible assets (in thousands):

	For the three months ended March 31,		
	2005	2004	Difference
Amortization of purchased intangibles assets	$ 393	$	$ 393

Amortization of purchased intangible assets relates to our acquisition of Epoch in 2004 where we acquired the rights to certain completed technology and customer contracts valued at approximately $10.6 million. We are amortizing (expensing) these intangible assets over periods ranging form 3 to 10 years.

The future. In future quarters in 2005, we expect this amortization expense to remain consistent at its current level. The amortization expense may also be impacted by potential future business combinations or our periodic impairment evaluations.

Other income

The following table summarizes our other income for the three months ended March 31, 2005 and 2004 (in thousands):

	Three months ended March 31,		
	2005	2004	Difference
	(unaudited)		
Interest income, net	$ 179	$ 102	$ 77
Other expense	(88)	(20)	(68)
Warrant valuation adjustment	881		881
Gain (loss) on foreign currency translation	13	1,221	(1,208)
Total other income	$ 985	$ 1,303	$ (318)

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Interest income, net

Interest income primarily relates to the interest we receive on our cash, cash equivalents, and short-term investments netted against the interest expense we incur from debt obligations. Our interest income increased in the first quarter of 2005 due to higher interest rates and larger balances of cash and investment balances during the whole quarter as compared to the first quarter of 2004 where our direct placement of stock occurred in the month of March.

Warrant valuation adjustment

Warrant valuation adjustment relates to our acquisition of Epoch in 2004 where we assumed warrants convertible into 381,317 shares of our common stock that contain a cash redemption feature which may be triggered under certain conditions. We accounted for the fair value of these warrants in our purchase accounting, with a portion of the value assigned to the cash redemption liability, and the remaining portion recorded as additional paid-in capital. We are required to revalue the cash redemption liability related to these warrants quarterly using the Black-Scholes valuation model with the changes in value accrued in the balance sheet and the associated non-cash income or expense recorded in the statement of operations. This revaluation adjustment occurred due to a decline in our stock price during the quarter thereby reducing the implied value of the warrant. Should our stock price rise in future quarters, this non-cash warrant valuation adjustment will become an expense rather than income as it was in the current quarter.

Gain on Foreign Currency Translation

The decrease in foreign currency translation income in the first quarter of 2005 primarily relates to the first quarter of 2004 decision to reorganize and discontinue all business activities of our majority owned subsidiary, Nanogen Recognomics GmbH. In accordance with Statement of Financial Accounting Standards No. 52, Foreign Currency Translation, and its related interpretations, when the business activity at this entity was discontinued we were required to recognize a one time gain of $1.2 million related to previously unrealized gains from foreign currency translation.

Liquidity and capital resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures as of March 31, 2005 and December 31, 2004:

	March 31, 2005	December 31, 2004	Difference
Cash and cash equivalents	$ 12,715	$ 15,372	$ (2,657)
Short-term investments, available for sale	27,134	36,562	(9,428)
Total cash and cash equivalents and short-term investment, available for sale	$ 39,849	$ 51,934	$ (12,085)

Current assets	$ 45,783	$ 57,442	$ (11,659)
Current liabilities	(7,562)	(12,443)	4,881
Working capital	$ 38,221	$ 44,999	$ (6,778)

Our cash and cash equivalents and short-term investments, available for sale and working capital decreased $12.0 million and $6.8 million, respectively, in the current quarter. Our cash use was higher this quarter than we are projecting for the remaining quarters this year due to the payment of costs accrued in the fourth quarter of 2004 associated with our acquisition of Epoch in December of 2004. In addition, we are in the early stages of our products life cycle, requiring us to expend cash as we develop and expand our product pipeline, bring products to market and manage this activity. We

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believe we will continue to consume cash and have quarterly net losses during the rest of 2005. Our cash burn and quarterly net loss will continue until our product offerings gain traction in the market place and begin to generate a return on investment.

We believe that existing funds and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditures and debt service requirements at least through March 31, 2006. However, to provide greater flexibility, additional liquidity, ability to complete strategic mergers and acquisitions and commercialize our products in development, we anticipate raising additional funds through the sale of our common stock and/or the issuance of debt.

From inception to March 31, 2005, we have financed our operations primarily by:

- Issuing our stock
- Generating revenues
- Cash obtained through our acquisition of Epoch
- Using proceeds from our litigation settlement with CombiMatrix
- Obtaining a modest amount of capital equipment long-term financing

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash.

We invest excess funds in short-term investments that are classified as available-for-sale. We believe that it is important to maintain a significant amount of cash and short-term investments on hand to ensure that we have adequate resources to fund future research and development, provide working capital and assuage legal risks and challenges to our business model.

We expect that our existing capital resources, combined with anticipated product revenues, license fees and contract and grant funding, will be sufficient to support our planned operations, through at least the next twelve months. However, this estimate is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. Our future liquidity and capital funding requirements for reminder of 2005 will depend on numerous factors including, but not limited to: potential business combinations, potential corporate development transactions, commercial success of our products, or lack thereof, the extent to which our products under development are successfully developed and gain market acceptance, the timing of regulatory actions regarding our potential products, the costs and timing of expansion of sales, marketing and manufacturing activities, prosecution and enforcement of patents important to our business and any litigation related thereto, the results of clinical trials, competitive developments, and our ability to maintain existing collaborations and to enter into additional collaborative arrangements. We have incurred negative cash flow from operations since inception and do not expect to generate positive cash flow to fund our operations for at least the next several years. We will need to raise additional capital to fund our research and development programs, to scale-up manufacturing activities and expand our sales and marketing efforts to support the commercialization of our products under development. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, we may be required to curtail or cease our operations or to obtain funds through entering into collaborative agreements or other arrangements on unfavorable terms. Our failure to raise capital on acceptable terms when needed could have a material adverse effect on our business, financial

condition or results of operations.

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Cash provided by (used in) operating, investing and financing activities of the three months ended March 31, 2005 and 2004 is as follows (in thousands):

	March 31, 2005	March 31, 2004
Net cash used in operating activities	$ (9,982)	$ (6,376)
Net cash provided by (used in) investing activities	7,211	(11,356)
Net cash provided by financing activities	$ 91	$ 41,069

Operating activities

Net cash used in operating activities for the three months ended March 31, 2005 and 2004 primarily related to our net losses, changes in working capital due to the product shipments and payments in liabilities. The net loss in both periods was primarily related to the costs associated with commercializing our products that includes broadening our product lines, the development and support of our sales and marketing organization, continuing research and development efforts on existing products and the administration of this activity. In the three months ended March 31, 2005, we used $598,000 to refund proceeds received to exercise certain warrants which were subsequently rescinded and an additional $1.7 million for the payment of other short term liabilities.

Investing activities

Net cash provided by investing activities in the three months ended March 31, 2005 primarily related to net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we utilized short-term investments to fund our operating activities). In addition, we had approximately $1.7 million in payments related to our December 2004 acquisition of Epoch. Net cash used in investing activities in the three months ended March 31, 2004 primarily related to reinvesting the cash we realized from our common stock sale into purchasing available-for-sale short-term investments in order to enhance our yield on our cash balances. In addition, we provided $805,000 to fund the operations of SynX before we acquired the company in April of 2004.

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. In the three months ended March 31, 2005 and 2004, we used cash to purchase $432,000 and $120,000, respectively, in equipment to support the development of our product lines.

Financing activities

Net cash provided by financing activities in the three months ended March 31, 2005 related to proceeds of $156,000 from the exercise of employee stock options and to offset the cost of purchasing equipment, we issued a $219,000 promissory note secured by the equipment. We currently have $1.2 million of funding available under our financing line as of March 31, 2005.

Net cash provided by financing activities in the three months ended March 31, 2004 related to the $33.7 million in gross proceeds from sale of common stock, $4.6 million in gross proceeds from the exercise of warrants related to financing in September 2003, and approximately $4.9 million from the exercise of employee stock options.

In the three months ended March 31, 2005 and 2004, net cash provided by financing activities was offset by payments related to our debt obligations of $284,000 and $219,000, respectively.

We have no significant contractual obligations not fully recorded on our Consolidated Balance Sheets or fully disclosed in the Notes to our Condensed Consolidated Financial Statements. We have no off-balance sheet arrangements.

Critical Accounting Policies

There were no material changes in the critical accounting policies or estimates from those at December 31, 2004.

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Future Accounting Requirements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), Share-Based Payment (FAS 123R), that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for either equity instruments of the enterprise or 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 statement eliminates the ability to account for share-based compensation transactions, as we do currently, using the intrinsic value method as prescribed by Accounting Principles Board, or APB, Opinion No. 25, Accounting for Stock Issued to Employees, and generally requires that such transactions be accounted for using a fair-value-based method and recognized as expenses in our consolidated statement of income. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options and are currently assessing which model we may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the consolidated statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, we will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include prospective and retroactive adoption options. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of a new rule that amends the effective date of FAS 123R. The effective date of the new standard under these new rules for our consolidated financial statements is January 1, 2006. Adoption of this statement will have a significant impact on our consolidated financial statements as we will be required to expense the fair value of our stock option grants and stock purchases under our employee stock purchase plan rather than disclose the impact on our consolidated net income within our footnotes, as is our current practice.

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RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

You should carefully consider the following risks, together with other matters described in this Form 10-Q or incorporated herein by reference in evaluating our business and prospects. If any of the following risks occurs, our business, financial condition or operating results could be harmed. In such case, the trading price of our securities could decline. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Certain statements in this Form 10-Q (including certain of the following factors) constitute forward-looking statements.

If our products are not successfully developed or commercialized, we could be forced to curtail or cease operations.

We are at an early stage of development. As of March 31, 2005, we had only a limited product offering that includes our NanoChip® System (which consists of our NanoChip® Molecular Biology Workstation and NanoChip® Cartridge), NanoChip® Cartridge, various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis, general purpose reagents and accessories to facilitate assay and protocol development and validation on the NanoChip® Platform and through our acquisition of SynX, point-of-care diagnostic tests for myocardial infarction and drugs of abuse. We announced our second-generation instrument, the NanoChip® 400, in October 2004. This new instrument is expected to begin shipping this year. All of our other platforms and ASRs and other potential products are under development. Our NanoChip® System, ASRs or our other products may not be successfully developed or commercialized on a timely basis, or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of our new products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a NanoChip® System at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. These reagent rentals and cost-per-test agreements might have an adverse impact on our short-term instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer. Our success will depend upon our ability to continue to overcome significant technological challenges and successfully introduce our products into the marketplace. A number of applications envisioned by us may require significant enhancements to our basic technology platform. There can be no assurance that we can successfully develop such enhancements.

Lack of market acceptance of our products and technology would harm us.

Although we have developed a number of products as discussed above, we may not be able to further develop these products or to develop other commercially viable products. Even if we develop a product, it may not be accepted in the marketplace. If we are unable to achieve market acceptance, we will not be able to generate sufficient product revenue to become profitable. We may also be forced to carry greater inventories of our products for longer periods than we may have anticipated. If we are unable to sell the inventory of our products in a timely fashion and at anticipated price levels, we may not become profitable. In addition, we may have to take accounting charges and reduce the value of our product inventory to its net realizable value. In the three months ended March 31, 2005 we did not incur any charge to reduce our inventory to its net realizable value, however, in the years ended December 31 2004, 2003 and 2002 we took accounting charges of approximately $3.7 million, $908,000 and $1.1 million, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or

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market conditions are less favorable than those currently projected by us, additional inventory write-downs may be required. Market acceptance will depend on many factors, including our ability to:

- convince prospective strategic partners and customers that our technology is an attractive alternative to other technologies,
- manufacture products in sufficient quantities with acceptable quality and at an acceptable cost and
- sell, place and service sufficient quantities of our products.

In addition, our technology platform could be harmed by limited funding available for product and technology acquisitions by our customers, internal obstacles to customer approvals of purchases of our products and market conditions in general.

Performance issues with our products may also harm market acceptance of our products and reduce our revenues. During the year ended December 31, 2004 and the quarter ended March 31, 2005, we experienced performance issues with our CFTR ASR which negatively impacted our revenue. Certain of the clinical research laboratories using our CFTR ASR experienced validation rates and repeat rates which were not satisfactory, increasing their costs and labor associated with the tests. We are in the process of making improvements to our CFTR ASR to address these issues. Nonetheless, we may not be able to address these issues to the satisfaction of our clinical laboratory customers and they may decide to adopt alternative products or may not resume purchases of our CFTR ASR.

Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to find collaborators in the future, we may not be able to develop these products.

Our strategy for the research, development and commercialization of some of our products requires us to enter into contractual arrangements with corporate collaborators, joint venture partners, licensors, licensees and others. Our success depends in part upon the performance by these collaboration partners and potential collaboration partners of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect, and we may not derive any revenue or other benefits from these arrangements. We do not know whether our collaborations will successfully develop and market any products under our respective agreements. Moreover, some of our collaborators are also researching competing technologies targeted by our collaborative programs.

Our NanoChip® System instruments, including Molecular Biology Workstation and the second-generation NanoChip® 400, are manufactured by Hitachi. As such our success in the micro-array based diagnostics market is largely dependent upon Hitachi s ability to perform under our manufacturing agreement. In October 2001, SynX entered into a development and manufacturing agreement with Princeton BioMeditech Corporation (PBM) which granted PBM exclusive rights to develop and manufacture certain point-of-care products of SynX, as well as rights to share in the profits of such products. As a result, our success in the point-of-care market is dependent upon PBM s ability to perform under the agreement.

We may be unsuccessful in entering into other collaborative arrangements to develop and commercialize our products. In addition, disputes may arise over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

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We recently announced our second-generation instrument system. The transition to new products subjects us to risks and uncertainties, including increased risks of excess or obsolete inventory and inventory related write-downs.

In October 2004, we announced our second-generation instrument system, the NanoChip® 400. This new instrument is expected to begin shipping in 2005. Risks inherent in the transition to our second-generation system and other new products we may release in the future include:

- potential delays in initial shipments of new products,
- the possibility that new products may erode demand for our current products, including those under reagent rental agreements, causing a decline in sales of current products and an excessive, obsolete supply of inventory,
- potential delays in customer purchases in anticipation of new product releases or a decision by customers to evaluate new products for longer periods of time before making a purchase,
- uncertainties in product pricing and market acceptance,
- additional costs related to providing customer support and service for both first generation and second generation systems, and
- unexpected technical or operational problems with the new products.

If any of these risks occur, our revenues could decline and our financial condition could be harmed.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to complement our internally developed products. We expect that acquisitions will remain a part of our growth strategy going forward. Acquisitions involve numerous risks, including the following:

- The possibility that we will pay more than the value we derive from the acquisition;
- Difficulties in integration of the operations, technologies, and products of the acquired companies;
- The assumption of certain known and unknown liabilities of the acquired companies;
- Difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired company;

Any of these factors could have a negative impact on our business, results of operations or financing position.

Future acquisitions could also result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to certain intangible assets and increased operating expenses, which could adversely affect our results of operations and financial condition. In addition, to the extent that the economic benefits associated with any of our acquisitions diminish in the future, we may be required to record additional write downs of goodwill, intangible assets or other assets associated with such acquisitions, which would adversely affect our operating results.

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We may not realize the benefits that we anticipate from our recent acquisitions of Epoch Biosciences, Inc. and SynX Pharma Inc. due to integration and other challenges.

We completed two significant acquisitions in 2004: the acquisition of SynX Pharma Inc. in April 2004 and Epoch Biosciences, Inc. in December 2004. We expect that the SynX product line will accelerate our entry into the point-of-care market and we expect that the acquisition of Epoch will result in a material increase in revenues during 2005. However, we cannot be certain that we will achieve these and other benefits which we currently expect from these acquisitions. The process of integrating these acquired companies requires significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Combining our product offerings is a complex and lengthy process involving a number of steps in which we will seek to achieve increasing degrees of integration of our products. Additionally, SynX is located in Canada and Epoch is located in Washington, and because our facilities are physically separated, it may be difficult for us to communicate effectively with, manage and integrate these employees and operations with the rest of the Company. If we are not able to integrate the operations of these acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations.

Factors that will affect the success of these acquisitions and any future acquisitions include:

- our ability to manage a more complex corporate structure that requires additional resources for such responsibilities as tax planning, foreign currency management, financial reporting and risk management;
- our ability to retain key employees of acquired companies; and
- our ability to increase revenues due to the integration of the products and technologies of the acquired companies; and
- our ability to operate efficiently following the completion of acquisitions and to achieve cost savings.

Even if we are able to successfully integrate our acquired operations, we may never realize the anticipated benefits of the SynX and Epoch acquisitions, or any other acquisition. Our failure to achieve these benefits and synergies could have a material adverse effect on our business, results of operations and financial condition.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

Since our inception, we have incurred cumulative net losses which, as of March 31, 2005, total approximately $223.4 million. Moreover, our negative cash flow and losses from operations will continue for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, which fluctuations could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the NanoChip® System choose to enter into sales, reagent rentals, cost-per-test or development site transactions. We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, market acceptance of the second generation NanoChip® 400 System, acquisitions, and potential other products under development, including the CHF product and diagnostics related to infectious disease, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements with Hitachi and various government agencies. The recognition of revenue under contracts, grants and sponsored research agreements will be subject to significant fluctuations in both timing and

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amount and therefore our results of operations for any period may not be comparable to the results of operations for any other period.

To develop and sell our products successfully, we may need to increase our spending levels in research and development, as well as in selling, marketing and administration. We may have to incur these increased spending levels before knowing whether our products can be sold successfully.

Changes in financial accounting standards related to stock option expenses are expected to have a significant effect on our reported results.

The FASB recently issued a revised standard that requires that we record compensation expense in the statement of operations for employee stock options using the fair value method. The adoption of the new standard is expected to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to establish the value of stock options. As a result, the adoption of the new standard in the first quarter of fiscal 2006 could negatively affect our stock price and our stock price volatility.

We will need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We will need to raise more money to continue the research and development necessary to further develop our current products to bring our products to market and to further our manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. If we can not raise more money, we will have to reduce our capital expenditures, scale back our development of new products, reduce our workforce and seek to license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we will need will depend on many factors, including among others:

- the progress of our research and development programs;
- the commercial arrangements we may establish;
- the time and costs involved in:
- scaling up our manufacturing capabilities;
- meeting regulatory requirements, including meeting necessary Quality System Regulations (QSRs) and obtaining necessary domestic and international regulatory clearances or approvals;
- filing, prosecuting, defending and enforcing patent claims and litigation; and

the scope and results of our future clinical trials, if any.

Additional capital may not be available on terms acceptable to us, or at all. Any additional equity financing would likely be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

Competing technologies may adversely affect us.

We expect to encounter intense competition from a number of companies that offer products in our targeted application areas. We anticipate that our competitors in these areas will include:

health care and other companies that manufacture laboratory-based tests and analyzers;

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diagnostic and pharmaceutical companies;

companies developing drug discovery technologies;

companies developing molecular diagnostic tests; and

companies developing point-of-care diagnostic tests.

If we are successful in developing products in these areas, we will face competition from established companies and numerous development-stage companies that continually enter these markets. In many instances, our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Moreover, these competitors may offer broader product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Our competitors may succeed in developing, obtaining approval from the U.S. Food and Drug Administration (FDA) or marketing technologies or products that are more effective or commercially attractive than our current or potential products or that render our technologies and current or potential products obsolete.

As these companies develop their technologies, they may develop proprietary positions that may prevent us from successfully commercializing products.

Also, we may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future.

The uncertainty of patent and proprietary technology protection may adversely affect us.

Our success will depend in part on obtaining and maintaining meaningful patent protection on our inventions, technologies and discoveries. Our ability to compete effectively will depend on our ability to develop and maintain proprietary aspects of our technology, and to operate without infringing the proprietary rights of others, or to obtain rights to third-party proprietary rights, if necessary. Our pending patent applications may not result in the issuance of patents. Our patent applications may not have priority over others applications, and even if issued, our patents may not offer protection against competitors with similar technologies. Any patents issued to us may be challenged, invalidated or circumvented, and the rights created thereunder may not afford us a competitive advantage.

We also rely upon trade secrets, technical know-how and continuing inventions to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology and we may not be able to meaningfully protect our trade secrets, or be capable of protecting our rights to our trade secrets. We seek to protect our technology and patents, in part, by confidentiality agreements with our employees and contractors. Our employees may breach their existing Proprietary Information, Inventions, and Dispute Resolution Agreements and these agreements may not protect our intellectual property. This could have a material adverse effect on us.

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Our products could infringe on the intellectual property rights of others, which may subject us to future litigation and cause us to be unable to license technology from third parties.

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in an action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

There are many U.S. and foreign patents and patent applications held by third parties in our areas of interest, and we believe that there may be significant other litigation in the industry regarding patent and other intellectual property rights. Additional litigation could result in substantial costs and the diversion of management s efforts regardless of the result of the litigation. Additionally, the defense and prosecution of interference proceedings before the U.S. Patent and Trademark Office, or (USPTO), and related administrative proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may in the future become subject to USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.

We are aware of U.S. and European patents and patent applications owned by Oxford Gene Technologies (Oxford Gene). We have opposed one allowed European patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. Oxford Gene s position with respect to the opposed patent is that the claims relate to what it terms the diagnostic mode. Those claims have now been narrowed before the Opposition Division of the European Patent Office to the point that, if these claims remain final before the European Patent Office, we believe they would not be infringed by our technology. In the oral proceedings before the Opposition Division on November 13, 14, and 15, 2001, the Division determined that the claims language must be limited to arrays with smooth, impermeable surfaces. The case is currently on appeal. If the decision of the Opposition Division is successfully appealed by Oxford Gene and the original claims are reinstated, or if an application relating to arrays is issued in another country with claims as broad as the original European patent, we could be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

We may continue to be involved in intellectual property litigation that may be costly, time-consuming and may impact our competitive position.

In December 2002, Oxford Gene filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with Oxford Gene pursuant to which the lawsuit was dismissed by Oxford Gene without prejudice. If the litigation were to be reinitiated, significant attorneys costs and fees could result. Although it is our position that Oxford Gene s assertions of infringement have no merit, neither the outcome of any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

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The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining or maintaining required approvals for the commercialization of our products.

The manufacturing, labeling, distribution and marketing of any diagnostic products we may develop will be subject to regulation in the U.S. and other countries. These regulations could subject us to several problems such as:

- failure to obtain necessary regulatory approvals or clearances for our products on a timely basis, or at all;
- delays in receipt of or failure to receive approvals or clearances;
- the loss of previously received approvals or clearances;
- limitations on intended uses imposed as a condition of approvals or clearances; or
- failure to comply with existing or future regulatory requirements.

In the U.S., the FDA, regulates as medical devices most test systems, kits and reagents that are marketed for human in vitro diagnostic use. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, safety, effectiveness, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of these products until we receive an exemption, clearance or approval from the FDA, which can be a lengthy, expensive and uncertain process. We have not applied for FDA or other regulatory approvals with respect to any of our current products or products under development. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of proposed products. Regulatory clearance or approval of any proposed products may not be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Noncompliance with applicable FDA requirements can result in:

- criminal prosecution, civil penalties, other administrative sanctions or judicially imposed sanctions, such as injunctions;
- recall or seizure of products;
- total or partial suspension of production; and
- failure of the government to grant premarket clearance or premarket approval for devices or withdrawal of marketing clearances or approvals once granted.

The FDA also has the authority to request the recall, repair, replacement or refund of the cost of any regulated device that may eventually be manufactured or distributed by us. Any devices manufactured or distributed by us pursuant to FDA clearance or approvals are subject to thorough and continuing regulation by the FDA and certain state agencies, including the California Department of Health Services.

Our dependence on suppliers for materials could impair our ability to manufacture our products.

Outside vendors provide key components and raw materials used by us, Hitachi and PBM in the manufacture of our products. Although we believe that alternative sources for these components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our and Hitachi s ability to manufacture our products until a new source of supply is identified and qualified, including qualification under applicable FDA regulations. In addition, an uncorrected defect or supplier s variation in a component or raw material, either unknown to us, Hitachi or PBM or incompatible with our, Hitachi or PBM s manufacturing processes, could harm our, Hitachi or

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PBM s ability to manufacture our products. We, Hitachi or PBM may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we, Hitachi or PBM fail to obtain a supplier for the manufacture of components of our products, we may be forced to curtail or cease operations.

If we are unable to manufacture products on a commercial scale, our business may suffer.

Hitachi manufactures our NanoChip® System, including the second-generation NanoChip® 400, we manufacture our NanoChip® Cartridges, our ASRs and most of our other products, and PBM manufactures our point-of-care products. We, Hitachi and PBM rely on subcontractors to manufacture the limited quantities of microchips and other components we require for use by and sale to our customers, as well as for internal and collaborative purposes. Manufacturing, supply and quality control problems may arise as we, Hitachi or PBM either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We, Hitachi or PBM may not be able to scale-up in a timely manner or at a commercially reasonable cost. Problems could lead to delays or pose a threat to the ultimate commercialization of our products and cause us to fail.

We, Hitachi or PBM or any of our contract manufacturers could encounter manufacturing difficulties, including those relating to:

- the ability to scale up manufacturing capacity;
- production yields;
- quality control and assurance; or
- shortages of components or qualified personnel.

Our manufacturing facilities and those of Hitachi and PBM and any other of our contract manufacturers are or will be subject to periodic regulatory inspections by the FDA and other federal, state and international regulatory agencies and these facilities are or may become subject to Quality System Regulation, or QSR, requirements of the FDA. If we, Hitachi, PBM or our third-party manufacturers, fail to maintain facilities in accordance with QSR regulations, other international quality standards or other regulatory requirements, then the manufacture process could be suspended or terminated which would harm us.

Lead times for obtaining materials and components for our products and the manufacturing and introduction of our products may vary significantly which could lead to excess inventory levels as well as shortages of critical components and products if our supply and demand forecasts are inaccurate.

We anticipate that our products, including our ASRs and most of our other products will be manufactured and introduced by us and third parties, if any, based on forecasted demand and that we will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and components to be included in our products vary significantly and may depend on factors such as the business practices of each specific supplier and the terms of the particular contracts, as well as the overall market demand for such materials and components at any given time. Also, we often rely on our own and third party forecasted demand for various products and the

accuracy of such forecasts may depend on a number of factors, including but not limited to, government reports and recommendations for certain genetic testing, regulatory burdens, competitive products, the nature and effectiveness of our products, the timing and extent of the introduction of our products into the marketplace and other factors. If the forecasts are inaccurate, we could experience fluctuations in excess inventory of our products, or shortages of critical components or products, either of which could cause our business to suffer.

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We currently rely on one manufacturer of our Workstation and for certain future generations of the Workstation and other hardware products, one manufacturer for our point-of-care products, and only we manufacture our NanoChip® Cartridges, and our ASRs and most of our other products, which may delay the manufacture and shipment of our products to customers.

We have signed an exclusive manufacturing agreement with Hitachi to manufacture our second generation NanoChip® 400 workstations and other hardware products to be developed. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreements and the collaboration agreement, each party is obligated to provide the other with certain notice periods if such party determines to curtail or terminate the manufacturing relationship. Nevertheless, while alternative manufacturers of our Workstation and other products currently exist, a lengthy process would be required to negotiate and begin work under a manufacturing agreement with a new manufacturer which could disrupt our manufacturing process and harm our business.

The number of our sales and marketing employees may not result in corresponding numbers of sales or placements of the NanoChip® System, the sale of ASRs, point-of-care diagnostic products or other products

As of March 31, 2005, we had 26 total employees in our worldwide sales and marketing group.

Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by us and certain of our employees. The size of our sales and marketing force may not result in corresponding numbers of sales or placements of the NanoChip® System nor increased product revenues associated with such sales or placements or our ASRs, point-of-care diagnostic products or other products. We may be required to increase or decrease the size of the sales and marketing force as deemed necessary and such increases or decreases in staff will require additional capital and time expenditures by us and our employees.

Failure to expand our international sales as we intend would reduce our ability to become profitable.

We expect that a portion of our sales will be made outside the United States. A successful international effort will require us to develop relationships with international customers and partners. We may not be able to identify, attract or retain suitable international customers and distribution partners. As a result, we may be unsuccessful in our international expansion efforts. Furthermore, expansion into international markets will require us to continue to establish and expand foreign sales and marketing efforts, hire additional sales and marketing personnel and maintain good relations with our foreign customers and distribution partners.

International operations involve a number of risks not typically present in domestic operations, including:

- currency fluctuation risks;
- changes in regulatory requirements;

additional costs resulting from deploying the NanoChip® System, including the second-generation NanoChip® 400, ASRs, point-of-care diagnostics, and other products in foreign countries due to:

licenses, tariffs and other trade barriers;

political and economic instability, including the war on terrorism;

difficulties in staffing and managing foreign offices;

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costs and difficulties in establishing and maintaining foreign distribution partnerships;

potentially adverse tax consequences; and

the burden of complying with a wide variety of complex foreign laws and treaties.

Our international sales and marketing efforts will also be subject to the risks associated with the imposition of legislation and regulations relating to the import or export of high technology products. We cannot predict whether tariffs or restrictions upon the importation or exportation of our products will be implemented by the United States or other countries.

We may lose money when we exchange foreign currency received from international sales into U.S. dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which we do business will cause foreign currency transaction gains and losses. We cannot predict the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We currently do not engage in foreign exchange hedging transactions to manage our foreign currency exposure.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. Any product liability claim brought against us could be expensive to defend and could result in a diversion of management s attention from our core business. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.

We are highly dependent on the principal members of our scientific, manufacturing, marketing, administrative, management and executive personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. For the three months ended March 31, 2005 and the years ended December 31, 2004, 2003 and 2002 we experienced turnover rates of 5.6%, 27%, 25% and 29%, respectively. Turnover at these rates may, and if they continue, will adversely affect us.

The turnover rates above exclude the impact of reductions in workforce. In April 2003, we reduced our workforce by approximately 20% and incurred a severance charge of approximately $500,000 in the second quarter of 2003. Also, in October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately $290,000 during the fourth quarter of 2002. Continued layoffs could have an adverse effect on us.

Health care reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

government health administration authorities;

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private health coverage insurers;

managed care organizations; and

other organizations.

If appropriate reimbursement cannot be obtained, we could be prevented from successfully commercializing our potential products.

There are efforts by governmental and third party payors to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

Additionally, third party payors are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and whether adequate third party coverage will be available.

If ethical and other concerns surrounding the use of genetic information become widespread, we may have less demand for our products.

Genetic testing has raised ethical issues regarding confidentiality and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulation of the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Any of these scenarios could reduce the potential markets for our products, which could seriously harm our business, financial condition and results of operations.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials including, but not limited to, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

Our stock price could continue to be highly volatile and our stockholders may not be able to resell their shares at or above the price they paid for them.

The market price of our common stock, like that of many other life sciences companies, has been highly volatile and is likely to continue to be highly volatile. The following factors, among others, could have a significant impact on the market price of our common stock:

- the results of our premarket studies and clinical trials or those of our collaborators or competitors or for diagnostic testing in general;

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evidence of the safety or efficacy of our potential products or the products of our competitors;

the announcement by us or our competitors of technological innovations or new products;

the announcement by us of acquisitions by customers of our NanoChip® System, ASRs or our other products;

announcements by us of government grants or contracts or of failure to obtain such government grants or contracts;

announcements by us of involvement in litigation;

developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;

loss of key board, executive, management or other personnel or the increase or decrease in size of our sales and marketing staff;

governmental regulatory actions or the failure to gain necessary clearances or approvals;

the ability to obtain necessary licenses;

changes or announcements in reimbursement policies;

developments with our subsidiaries and collaborators;

changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;

period-to-period fluctuations in sales, inventories and our operating results;

market conditions for life science stocks, nanotechnology stocks and other stocks in general;

purchases by us pursuant to our stock repurchase program;

changes in estimates of our performance by securities analysts and the loss of coverage by one or more securities analysts;

the announcement by us of any stock repurchase plan, any purchases made thereunder by us and any cessation of the program by us;

changes in the United States war on terrorism and other geopolitical and military situations in which the country is involved; and

changes in the price of petroleum, heating oil and any other raw materials that we use at our facilities.

Investor confidence and share value may be adversely impacted if our independent auditors are unable to provide us with the attestation of the adequacy of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include a report of management on our internal

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controls over financial reporting in our annual reports on Form 10-K and quarterly Form 10-Qs that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must attest to and report on management s assessment of the effectiveness of our internal controls over financial reporting as of the end of the fiscal year. How companies are maintaining their compliance with these requirements including internal control reforms, if any, to comply with Section 404 s requirements, and how independent auditors are applying these requirements and testing companies internal controls, remain subject to uncertainty. We expect that our internal controls will continue to evolve as our business activities change. Although we will continue to diligently and vigorously review our internal controls over financial reporting in order to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. If, during any year, our independent auditors are not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management s assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares.

Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation.

Further, pursuant to the terms of our stock-holder rights plan adopted in November 1998, as amended, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved in advance by our board of directors and may have the effect of deterring unsolicited takeover attempts.

Our business is subject to changing regulation of corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and Nasdaq, have recently issued new requirements and regulations and continue to develop additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. Our efforts to comply with these new regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

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We will be dependent upon our agreement with Applied Biosystems for a significant portion of our revenues for 2005 and future periods, and a reduction of sales under or early termination of this agreement would seriously harm our revenues and operating results and would likely cause our stock price to decline

In January 1999, Epoch and Applied Biosystems entered into a License and Supply Agreement pursuant to which we licensed some of our technology to Applied Biosystems for use in its TaqMan® 5 - nuclease real-time PCR assays, (TaqMan® is a registered trademark of Roche Molecular Systems, Inc.). In July 1999, Epoch licensed its proprietary software, which speeds the design of oligonucleotide probes used in the study of genes, to Applied Biosystems. In August 2000, the agreement was amended to, among other things, provide for Epoch manufacturing product for Applied Biosystems. In July 2002 this agreement was further amended to remove the manufacturing rights from the contract effective October 2002, redefine product categories, increase the minimum royalties and royalty rates, and establish that minimum royalties are measured and paid quarterly. We will depend upon product sales and royalties from Applied Biosystems sales of its TaqMan® assays under this agreement for a significant portion of our revenues in 2005 and future periods.

The technology licenses and Applied Biosystem s obligation to pay us royalties on their sale of products that incorporate Epoch s technologies continue until the expiration of the underlying patents. Since the July 2002 amendment that increased the minimum royalty levels, quarterly royalties earned based on actual sales by Applied Biosystems have been less than the contractual minimum royalty levels. As a result, the royalty payments have been in the amount of the specified quarterly minimum level. The current agreement calls for quarterly royalty minimums through the third quarter of 2005. Thereafter, we will receive royalty payments based on actual sales which may result in a significant reduction of royalties received.

Either party may terminate the agreement upon 180 days written notice. In the event that this agreement is terminated, our revenues, financial condition and operating results would be adversely affected and our stock price would likely decline.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest rate exposure

Our exposure to market risk due to fluctuations in interest rates relates primarily to short-term investments. These short-term investments, reported at an aggregate fair market value of $27.1 million as of March 31, 2005, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at March 31, 2005, for example, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income we earn on our cash balances after re-investment.

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Foreign Currency Exchange Rate Exposure

The functional currency for our Canadian and Netherlands subsidiaries is the U.S. dollar. The functional currency of our majority owned subsidiary in Germany is the euro. The German subsidiary s accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. The net tangible assets of our foreign subsidiaries, excluding intercompany balances, was approximately $17.5 million at March 31, 2005.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business financial condition and results of operations. For example currency exchange rate fluctuations may affect international demand for our products. In addition, interest rates fluctuations may affect our customers buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

Foreign currency exchange rates can be obtained from the website at www.oanda.com.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures.

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the fiscal quarter covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(b) Change in Internal Control over Financial Reporting.

During the first quarter of 2005, we continued to implement new processes and controls over net product sales, cost of sales and other commercial transactions related to the commercial operations resulting from the December 2004 acquisition of Epoch. To enhance our operational efficiencies and effectiveness, we changed our internal controls over financial reporting through the outsourcing of our payroll

processing. We implemented various key controls to mitigate the risks associated with such a transition. However, as of March 31, 2005 we have not tested the operating effectiveness of the new internal controls related to payroll processing or integration of Epoch. Other than these changes, there were

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no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation

In the normal course of business, the Company has been and will likely continue to be subject to routine litigation incidental to our business, such as claims related to customer disputes, employment practices, product liability, warranty or patent infringement. Responding to litigation, regardless of whether it has merit, can be expensive and disruptive to normal business operations. However, as litigation is inherently uncertain, the Company cannot predict the outcome of such matters. The Company can provide no assurance that the ultimate outcome, either individually or in the aggregate, will not have a material adverse effect on its financial statements.

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

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

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

Not applicable

ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

Exhibit No.	Description
31.1	Certifications of Chief Executive Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certifications of Chief Financial Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer Pursuant to Section 906 of the Sarbanes - Oxley Act of 2002.
32.2	Certifications of Chief Financial Officer Pursuant to Section 906 of the Sarbanes - Oxley Act of 2002.

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SIGNATURES

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

NANOGEN, INC.

Date: May 10, 2005

/s/ HOWARD C. BIRNDORF
Howard C. Birndorf
Chairman of the Board and Chief Executive Officer

Date: May 10, 2005

/s/ ROBERT SALTMARSH
Robert Saltmarsh
Chief Financial Officer

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NANOGEN, INC.

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