NANOGEN INC
Form 10-Q
November 15, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2004

OR

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

For the transition period from _____ to _____

Commission File Number 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 ¨ NO x

As of November 11, 2004, 33,892,892 shares of the Registrant s Common Stock were outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	September 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,063	$ 8,550
Short-term investments	47,074	20,564
Receivables, net	1,127	1,415
Inventories, net	2,428	4,774
Other current assets	1,943	1,590
Total current assets	58,635	36,893
Property and equipment, net	6,955	4,276
Acquired technology rights, net	1,732	2,508
Restricted cash	739	14
Other assets, net	982	158
Goodwill	10,566	
	$ 79,609	$ 43,849
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,599	$ 290
Accrued liabilities	4,303	4,519
Deferred revenue	416	469
Current portion of capital lease obligations	502	743
Total current liabilities	6,820	6,021
Capital lease obligations, less current portion	410	586
Other long-term liabilities	5,453	4,419
Total long-term liabilities	5,863	5,005
Commitments and contingencies (Note 2 and Note 7)		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2004 (unaudited) and December 31, 2003		
Common stock, $0.001 par value, 50,000,000 shares authorized; 33,880,727 and 24,867,325 shares issued and outstanding at September 30, 2004 (unaudited) and December 31, 2003, respectively	34	25
Additional paid-in capital	272,161	209,014
Accumulated other comprehensive income (loss)	(123)	1,136
Deferred compensation	(260)	(175)
Accumulated deficit	(203,964)	(176,255)

Treasury stock, at cost, 500,189 shares at September 30, 2004 (unaudited) and December 31, 2003	(922)	(922)
Total stockholders equity	66,926	32,823
	$ 79,609	$ 43,849

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Revenues:				
Product sales	$ 671	$ 752	$ 2,280	$ 1,642
License fees	25	46	214	46
Sponsored research		375	500	1,125
Contracts and grant	386	568	1,365	1,822
Total revenues	1,082	1,741	4,359	4,635
Costs and expenses:				
Cost of product sales	1,298	1,370	4,150	2,168
Research and development	4,514	4,280	12,901	13,473
Selling, general and administrative	4,811	3,485	12,626	11,681
Charge for acquired in-process research and development			3,758	
Impairment of acquired technology rights		1,024		1,024
Total costs and expenses	10,623	10,159	33,435	28,346
Loss from operations	(9,541)	(8,418)	(29,076)	(23,711)
Interest income, net	187	97	433	405
Other income (loss)	(36)	(24)	(209)	(150)
Gain (loss) on sale of investments	(37)	778	(47)	(2,790)
Gain (loss) on foreign currency translation	(15)		1,190	
Minority interest in loss of consolidated subsidiary		488		1,594
Net loss	$ (9,442)	$ (7,079)	$ (27,709)	$ (24,652)
Net loss per share basic and diluted	$ (0.28)	$ (0.33)	$ (0.89)	$ (1.14)
Number of shares used in computing net loss per share basic and diluted	33,336	21,781	31,034	21,652

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine months ended September 30	
	2004	**2003**
Operating activities:		
Net loss	$ (27,709)	$ (24,652)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,678	3,256
Inventory impairment charges	2,429	829
Other asset impairment and non-cash charges	3,758	1,029
Loss on disposal of fixed assets	43	131
Accretion related to short-term investments	175	169
Foreign currency translation gain	(1,190)	
Stock-based compensation expense	505	152
Minority interest in loss of consolidated subsidiary		(1,594)
Loss (gain) on sale of short-term investments	47	2,790
Changes in operating assets and liabilities:		
Receivables	706	58
Inventories	(118)	(1,625)
Other assets	(753)	471
Accounts payable	(294)	(363)
Accrued liabilities	(1,796)	(1,263)
Deferred revenue and other long-term liabilities	(53)	442
Net cash used in operating activities	(21,572)	(20,170)
Investing activities:		
Purchase of short-term investments	(61,809)	(12,856)
Acquisition of business, net of cash acquired	(2,669)	
Proceeds from sale and maturities of short-term investments	34,956	30,270
Purchase of equipment, net	(397)	(1,097)
Purchase of patents and technology rights		(3)
Net cash provided by (used in) investing activities	(29,919)	16,314
Financing activities:		
Principal payments on capital lease obligations	(420)	(594)
Proceeds from development partner	441	749
Proceeds from restricted cash balances	14	50
Issuance of common stock, net	48,956	6,869
Net cash provided by financing activities	48,991	7,074
Effect of exchange rate changes	13	196

Net increase/decrease in cash and cash equivalents	(2,487)	3,414
Cash and cash equivalents at beginning of period	8,550	9,353
Cash and cash equivalents at end of period	$ 6,063	$ 12,767
Supplemental disclosure of cash flow information:		
Interest paid	$ 82	$ 136
Supplemental schedule of noncash investing and financing activities:		
Equipment acquired under capital leases	$ 230	$ 164
Inventory transferred to fixed assets	$ 120	$ 541
Unrealized loss on short-term investments	$ (125)	$ 3,216
Acquisition of business in exchange for common stock, including related assumption of stock options and warrants	$ 13,720	
Warrant accrued for research and development collaboration		$ 700

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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 September 30, 2004, consolidated statements of operations for the three and nine months ended September 30, 2004 and 2003, and the consolidated statements of cash flows for the nine months ended September 30, 2004 and 2003 are unaudited, but include all adjustments (consisting of normal recurring adjustments, except for inventory and acquired technology rights valuation charges discussed elsewhere herein, and entries related to the acquisition of SynX Pharma Inc., including a $3.8 million charge to in-process research and development also discussed elsewhere herein) which the Company considers 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 and nine months ended September 30, 2004 and 2003 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2004.

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, 2003 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2003, and in conjunction with the registration statement on Form S-4, as amended on October 26, 2004, which includes a prospectus of Nanogen and a joint proxy statement for each of Nanogen s and Epoch s special stockholder meetings related to their proposed merger, filed with the Securities and Exchange Commission.

Basis of Consolidation

The accompanying unaudited consolidated financial statements include the accounts of: Nanogen, Inc.; its wholly-owned subsidiaries: SynX Pharma Inc. (SynX), Nanogen Europe B.V. and Nanotronics, Inc.; as well as its majority owned subsidiary, Nanogen Recognomics (collectively, the Company). SynX s accounts and operating results are included beginning on April 21, 2004, the date of acquisition. All significant intercompany transactions have been eliminated.

The accompanying unaudited consolidated financial statements do not include the accounts or operating results of Epoch Biosciences, Inc. (Epoch). In September 2004, the Company announced the signing of a definitive agreement to merge Epoch into Nanogen in an all-stock transaction. Special stockholder meetings of Nanogen and Epoch will be held on December 8, 2004 to vote, among other items, on the proposed merger. If stockholder approval is obtained, the accounts and operating results of Epoch will be included in the consolidated financial statements of Nanogen upon closing, which is expected to occur on or about December 9, 2004.

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. A particularly significant estimate included in the financial statements is the level of inventory reserves required to ensure net inventory is properly valued in accordance with accounting principals generally accepted in the United States. Actual results could differ from those estimates.

Net Loss per Share

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards (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 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 and shares issued under the Company s 401K benefit plan 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.

Stock-Based Compensation

The Company measures compensation cost related to stock option plans using the intrinsic value method and provides pro forma disclosures of net loss and loss per share as if a fair value based method had been applied. Accordingly, compensation cost for stock options is measured as the excess, if any, of the fair value of the Company s common stock at the date of grant over the amount an employee must pay to acquire the stock and is amortized over the vesting period.

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Had the compensation cost for the Company s stock-based compensation plans been determined based on the fair value at the grant dates for awards under those plans, the Company s net loss and loss per common share would have been as follows (in thousands, except for loss per share):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Net loss:				
As reported	$ (9,442)	$ (7,079)	$ (27,709)	$ (24,652)
Stock-based compensation expense under fair value based method	(1,222)	(1,345)	(3,122)	(3,329)
Pro forma net loss	$ (10,664)	$ (8,424)	$ (30,831)	$ (27,981)
Loss per share:				
As reported	$ (0.28)	$ (0.33)	$ (0.89)	$ (1.14)
Pro forma	$ (0.32)	$ (0.39)	$ (0.99)	$ (1.29)

The pro forma effect on net loss for the three and nine months ended September 30, 2004 and 2003 is not necessarily indicative of potential pro forma effects on results for future years.

Warranty

The Company provides product warranty coverage under direct sale and reagent rental 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 reagent rental transaction. Additionally, the Company provides warranty coverage on products that are placed at customer sites under programs such as development site arrangements. A liability is recorded at the time products are shipped. Instruments sold to distributors typically are sold without warranty coverage. Changes in the Company s warranty liability were as follows (in thousands):

	Three months ended September 30,)		Nine months ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Warranty additions	86	153	139	334
Payments to warranty service provider	(14)	(187)	(121)	(321)
Balance at end of period	$ 177	$ 203	$ 177	$ 203

2. Business Combination

On April 21, 2004, the Company acquired all the outstanding shares of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests. As a result of this acquisition, the Company expects to enter the point-of-care diagnostic market, initially using the research and development and products of SynX. Nanogen believes that the future markets for advanced diagnostics will include research and clinical reference labs as well as the point-of-care market. Historically, Nanogen has addressed the research and clinical reference lab market. In addition, sales and marketing synergies are anticipated as SynX s line of point-of-care products may be sold into the clinical reference labs market. In the future, Nanogen anticipates developing microarray products to address all of these markets.

The results of operations of SynX have been included in the accompanying consolidated financial statements from the date of acquisition. The valuation of the common stock exchanged was based on the market value as of April 21, 2004, the date of acquisition. The total cost of the acquisition has been recorded as follows (in thousands, unaudited):

Nanogen common stock exchanged	$ 12,493
Assumption of warrants	865
Assumption of stock options	362
Bridge credit facility	998
Direct transaction costs	1,037
Total purchase price	$ 15,755

The allocation of the above purchase price is as follows (in thousands, unaudited):

Fair value of net tangible assets acquired	$ 1,125
Fair value of intangible assets acquired	4,064
Goodwill	10,566
Total purchase price	$ 15,755

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Purchased intangibles include in-process research and development of $3.8 million, and an indefinite lived asset related to acquired trade names of approximately $294,000. The amount assigned to acquired in-process research and development was recorded as an expense in the statement of operations for the nine months ended September 30, 2004. Operations in a market niche that is complimentary and operational and technological synergies were among the factors that contributed to a purchase price resulting in the recognition of goodwill. In addition, as part of the acquisition, the Company acquired certain real estate commitments of SynX totaling approximately $1.2 million per year for the next five years, and a total of $2.8 million thereafter.

Pro Forma Information

The following unaudited pro forma information assumes that the April 21, 2004 acquisition of SynX occurred on January 1, 2003. The unaudited pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations that would have actually resulted had the acquisition been in effect as of the periods indicated, or of future results of operations. The unaudited pro forma results for the three and nine months ended September 30, 2004 and 2003, are as follows (in thousands, except per share data):

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Net loss [1]	$ (9,442)	$ (8,978)	$ (32,686)	$ (32,138)
Loss per share (basic and diluted)	$ (0.28)	$ (0.38)	$ (1.03)	$ (1.38)

[1] Includes $3.8 million for the write-off of in-process research and development costs in both of the nine months ended September 30, 2004 and 2003.

3. Inventories

Inventories consist of the following (in thousands):

	September 30, 2004	December 31, 2003
	(unaudited)	
Raw materials	$ 1,776	$ 1,469
Work in process	2,076	1,745
Finished goods	3,554	4,043
	7,406	7,257
Reserve for excess and obsolete	(4,978)	(2,483)
	$ 2,428	$ 4,774

During the three and nine months ended September 30, 2004, the Company increased its reserve related to its inventory of NanoChip® Molecular Biology Workstations and accessory items by approximately $900,000 and $2.4 million, respectively. These non-cash charges are reflected as additional cost of sales and were taken, in part, due to the announcement of the Company s second-generation workstation, the NanoChip® 400, in October 2004. This new product will begin shipping in 2005.

Finished goods includes approximately $300,000 and $600,000, net, of NanoChip® Molecular Biology Workstations (NanoChip® Workstations) at September 30, 2004 and December 31, 2003, respectively, that are installed at customer sites where title has not transferred to the customer. The majority of these instruments are placed at customer sites under development site agreements. Under these arrangements, a NanoChip® Workstation is placed at a customer site for a period normally between six and twelve months for the purpose of developing content and optimizing assays which may result in the creation or enhancement of intellectual property that the Company may license in the future. The customer has the option to purchase the NanoChip® Workstation during the period of the arrangement or at its expiration. The Company provides warranty for these NanoChip® Workstations as well as insures them during the development site period. Development site customers are normally required to purchase any cartridges to be used on the instrument from the Company during the development site period. As of September 30, 2004, the Company had a total of 17 NanoChip® Workstations under agreements whereby the Company retains title to the Workstation. The Company classifies this inventory as consignment inventory and includes this within finished goods. The Company accrues refurbishment costs for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. These accruals totaled $116,000 and $197,000 at September 30, 2004 and December 31, 2003, respectively.

The Company s manufacturing agreement with Hitachi, Ltd. (Hitachi) requires that the Company provide annual purchase commitments to Hitachi for the second-generation workstation, the NanoChip® 400, which was announced in October 2004. As of September 30, 2004, the Company had commitments to purchase approximately $590,000 of the NanoChip® 400 instruments from Hitachi through January 31, 2005.

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4. Licensed Technology

The Company has acquired various licenses to technologies which are incorporated into certain of the Company s current products or products under development. The Company capitalizes the cost (which includes cash and equity consideration) in conjunction with the acquisition of these licenses and amortizes the cost over the expected life of the product. In September 2003, the Company recognized $1.0 million in impairment related to two previously acquired licenses as a result of a decision to restructure or terminate the agreements. It was determined that minimum future royalty payments on such licenses significantly limit the financial viability of bringing the licensed technology to market. As a result, an impairment loss was recorded for the carrying amount of the technology acquired under the two licenses. There have been no similar acquired technology impairment determinations in the nine month period ended September 30, 2004.

As a result of the SynX acquisition, the Company gained access to a cross-licensing agreement between Roche Diagnostics and SynX entered into in July 2003. The Company has a non-exclusive world-wide license in the field of point-of-care diagnostics relating to the development, manufacture and marketing of immunoassays for point-of-care diagnostics that detect the congestive heart failure marker NT-proBNP. Also, as part of the cross-license agreement, SynX granted Roche Diagnostics a non-exclusive world-wide license on the Company s improvement of the technology relating to the development, manufacture and marketing of immunoassays that detect the congestive heart failure marker NT-proBNP. The estimated value of the license was included as a component of the $3.8 million acquired in-process research and development line item that was expensed upon consummation of the acquisition.

5. 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 September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
	(unaudited)		(unaudited)	
Comprehensive loss:				
Net unrealized gain / (loss) on short-term investments	$ 25	$ 1,032	$ (120)	$ (3,216)
Foreign currency translation adjustment	78	4	(1,139)	194
Net loss	(9,442)	(7,079)	(27,709)	(24,652)
Comprehensive loss	$ (9,339)	$ (6,043)	$ (28,968)	$ (27,674)

6. Collaborative Alliances

Hitachi, Ltd.

Manufacturing Agreement

In June 2003, the Company entered into a manufacturing agreement with Hitachi for the manufacture of a second-generation instrument being developed under the collaborative research agreement (described below). Hitachi will manufacture the new NanoChip® 400 instrument, which was introduced in October 2004, exclusively for the Company for worldwide distribution. The Company is required to meet certain annual purchase commitments for the new NanoChip® 400 instrument. As of September 30, 2004, the Company had a commitment to purchase approximately $590,000 in NanoChip® 400 instruments from Hitachi through January 31, 2005.

Research Collaboration Agreement

In July 2000, the Company executed an agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute additional potential products based on the parties proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. Pursuant to the terms of the agreement, the Company must repay to Hitachi fifty percent of all funding provided by Hitachi over an indefinite period of time. Repayment amounts are determined as a percentage of the Company s gross NanoChip® Cartridge sales until the liability is paid in full.

Sponsored research revenue recognized under this agreement totaled $0 and $500,000 for the three and nine months ended September 30, 2004, respectively, and $375,000 and $1.1 million for the three and nine months ended September 30, 2003, respectively. In accordance with SFAS No. 68, the Company records sponsored research revenue under this arrangement as expenses are incurred, in amounts not exceeding scheduled payments under the agreement. The Company records a long-term liability for fifty percent of the funds received from Hitachi upon the receipt of such funds. The amount owed to Hitachi for proceeds received under

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this agreement was approximately $4.8 million and $4.3 million at September 30, 2004 and December 31, 2003, respectively. The current portion of the long-term liability remains immaterial as payment amounts due under this obligation are determined as a percentage of the Company s gross NanoChip® Cartridge sales which have not been significant to date. As such, the Company has classified the entire balance of this liability as long-term.

In August 2003, Hitachi exercised its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi s termination of this agreement did not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Based on joint discussions, Nanogen and Hitachi had determined to focus their joint efforts on the development and manufacture of a new instrument, which resulted in the October 2004 announcement of the NanoChip® 400. Nanogen and Hitachi will continue to be jointly responsible for development of the new instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

Service Agreement

In October 2000, the Company entered into an agreement with Hitachi for the service by Hitachi of the NanoChip® Molecular Biology Workstations in the United States after their sale or placement by the Company with the Company s customers. The Company pays an agreed-upon amount to Hitachi for annual service for each Workstation covered under the agreement. Nanogen amortizes the cost of the warranty agreement over the service period. As the Company provides the first year of warranty at no charge to the customer, the Company defers the portion of the Workstation sale revenue that relates to the warranty agreement. This deferred revenue is then amortized into revenue ratably over the annual service period. In subsequent years, the customer can pay an annual service fee to the Company and the Company will in turn pay Hitachi the annual service amount as specified in the agreement. The amount charged to the customer by the Company is based upon the cost of the service (i.e. the payment to Hitachi) plus an industry accepted profit margin for comparable service on similar types of products. Both the service revenue and the service expense are amortized ratably over the service period, generally one year.

In March 2004, Hitachi exercised its right to terminate the service agreement in accordance with the terms of the agreement. Hitachi will continue to service existing field units for a period of nine months from the date of notice, at which time the responsibility for servicing units will transfer back to the Company. The Company plans to service field units by developing an internal service capability.

Aventis Research and Technologies

In June 2001, the Company entered into agreements with Hoechst AG (Aventis) to create a new company, Nanogen Recognomics GmbH (Nanogen Recognomics). Nanogen Recognomics was established to develop new products and applications for the NanoChip® System. Nanogen Recognomics is sixty percent owned by the Company and forty percent owned by Aventis and is based in Frankfurt, Germany. As a result of the agreements, Nanogen Recognomics owns several patent applications filed jointly by the Company and Aventis and the Company has licensed certain aspects of its NanoChip® technology to Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics.

During the first quarter of 2004, the initial capital infusion of $5 million provided by Aventis to Nanogen Recognomics in June 2001 was depleted. As a result, in February 2004, the shareholders of Nanogen Recognomics decided to reorganize into a non-operating holding company and therefore, discontinue all the business activities. The Company is required pursuant to the original joint venture agreement to assume reorganization costs and the Company may restructure Nanogen Recognomics to hold the original patents contributed by Aventis and any jointly owned patents. The restructured company will collect royalties, if any, and pay the equity owners accordingly. Our exclusive commercialization

license will continue for 10 years after restructuring.

The results of operations for Nanogen Recognomics are fully consolidated in the Company s financial statements. During the three and nine months ended September 30, 2004, Nanogen Recognomics incurred approximately $0 and $1.3 million in operating expenses, respectively. Approximately $946,000 of the total expenses during the nine month period ended September 30, 2004, respectively, related to reorganization costs. These reorganization costs and expenses are reflected as research and development costs in the statement of operations. The Company will expense future reorganization costs as incurred. Such costs are not expected to be significant. For the three and nine month periods ended September 30, 2003, the total operating loss of Nanogen Recognomics is reflected as a reduction of the minority interest in consolidated subsidiary liability account and totaled approximately $488,000 and $1.6 million, respectively.

The functional currency of Nanogen Recognomics is the Euro. As a result of the increasing value of the Euro versus the U.S. Dollar during the period from inception of Nanogen Recognomics through February 2004, the time the shareholders decided to reorganize, we had recorded cumulative unrealized gains on foreign currency translation of approximately $1.2 million. In accordance with Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation* and its related interpretations, the Company, upon discontinuance of its business activity in the first quarter of 2004, realized the approximately $1.2 million in previously unrealized foreign currency translation gains during the first quarter of 2004. As a result of the discontinuance of business activity, there was no material gain or loss in the three month period ended September 30, 2004.

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Princeton BioMeditech Corporation

In October 2001, the Company s wholly-owned subsidiary, SynX, entered into a development and manufacturing agreement with Princeton BioMeditech Corporation (PBM). PBM has the right to perform development, production and distribution functions for SynX s point-of-care product line, including the right to be SynX s exclusive producer of certain rapid assay diagnostic point-of-care products. Payment for PBM s services will be based on a defined percentage of the net sales price to customers of such products. In November 2002, SynX and PBM signed an exclusive agreement for Canadian distribution rights for PBM s LifeSign® brand point-of-care diagnostic products. SynX also distributes certain LifeSign® brand products in Europe.

7. Litigation

In September 2002, the Company entered into a settlement agreement with CombiMatrix Corp. (CombiMatrix) and Dr. Donald Montgomery concluding pending litigation in the U.S. District Court for the Southern District of California. Pursuant to the settlement agreement, Nanogen agreed to drop its claims against CombiMatrix and Dr. Montgomery that include certain causes of action relating to U.S. patent Nos. 6,093,302 and 6,280,595 (the patented technology) that were assigned by Dr. Montgomery, an ex-Nanogen employee, to CombiMatrix in 1995 and assertions relating to other matters. In exchange, CombiMatrix agreed to pay $1.0 million as a reimbursement of legal costs; issue 4,016,346 shares of CombiMatrix tracking common stock that as of December 18, 2002 became publicly tradable on the Nasdaq National Market and were initially valued upon receipt at $10.8 million, which represents seventeen and one-half percent (17.5%) of its outstanding common stock; and make royalty payments of twelve and one-half percent (12.5%) on sales of products by either CombiMatrix or its affiliates that incorporate the patented technology. Also, as part of the settlement agreement, CombiMatrix and Dr. Montgomery agreed to drop their counterclaims against Nanogen and CombiMatrix retained sole ownership of the patented technology. During the nine months ending September 30, 2003, the Company sold 3,583,600 shares of CombiMatrix common stock for net proceeds totaling $6.9 million and recognized a loss of approximately $2.8 million. The remaining 432,746 shares were sold in the fourth quarter of 2003 for net proceeds totaling $2.0 million and a recognized gain of approximately $850,000.

In December, 2002, Oxford Gene Technologies (OGT) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that Nanogen infringes U.S. Patent No. 6,054,270 (the 270 Patent) entitled Analyzing Polynucleotide Sequences. In April 2003, Nanogen filed an answer to the complaint that denies that it infringes the 270 Patent. In October, 2003, the Company and OGT entered into a settlement agreement pursuant to which the lawsuit was dismissed by OGT without prejudice.

8. Stock Transactions

In April 2004, the Company sold 900,000 shares of its common stock to institutional investors at a price of $8.60 per share, for gross proceeds of approximately $7.7 million. After deducting fees and expenses, the Company received approximately $7.4 million from the sale.

In March 2004, the Company sold 4.25 million shares of its common stock to institutional investors at a price of $7.94 per share, for gross proceeds of approximately $33.7 million. After deducting fees and expenses, the Company received approximately $31.5 million from the sale.

9. Related Party Transactions

Mr. Birndorf, Chief Executive Officer, owns an aircraft that is leased by a local charter aircraft company. For the nine months ended September 30, 2004 and 2003, the Company paid approximately $13,000 and $80,000, to the local charter aircraft company for the Company s use of Mr. Birndorf s aircraft for business related travel. Mr. Birndorf receives approximately $1,250 per hour of usage when his aircraft is leased to outside parties. Mr. Birndorf received approximately $5,000 and $44,000 as a result of the Company s use of Mr. Birndorf s aircraft during the nine months ended September 30, 2004 and 2003, respectively. The Company believes that the terms of the charter arrangements are comparable to those that could be obtained from unrelated third parties.

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

This report includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties that could cause our actual results to vary materially from those reflected in the forward-looking statements. These risks and uncertainties include possible delays in the introduction of new products, customer acceptance of existing products, price competition, the actions of competitors, infringement of intellectual property rights and licenses of the Company or others, the effects of government regulation, both foreign and domestic, availability of funded research and government contracts and grants,

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preservation of productive relationships with our manufacturer and collaborator Hitachi and our distributors, ability to manage our capital resources and other factors. Words such as believes, anticipates, plans, estimates, future, could, may, should, expect, envision, variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements contained in this Form 10-Q may include, but are not limited to, statements about matters including the following: (i) the development of the markets and demand for our products and services; (ii) our product development plans and anticipated activities designed to pursue these plans, including acquisitions of businesses and technologies, collaborations and other corporate partnering arrangements; (iii) our ability to derive substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements; (iv) the ability of our product platform to affect the market and become an industry standard; (v) our ability to generate license and other fee revenue in the future; (vi) the amounts we invest in research and development activities in the future; (vii) future levels of selling, general and administrative expenses and other expenses associated with our business; (viii) future levels of interest income; (ix) any amounts we may be able to realize from the liquidation of our investments, including our investments in short-term securities; (x) operating results of acquired companies, businesses, collaborations, joint ventures and other corporate partnering arrangements; (xi) the amounts and timing of our contractual obligations and capital commitments; (xii) our future capital needs and our ability to fund those needs; and (xiii) our product launch plans. Factors that could cause or contribute to these differences include those discussed below under the caption Factors that May Affect Results elsewhere herein, and under the caption Risk Factors in the registration statement on Form S-4, as amended on October 26, 2004, which includes a prospectus of Nanogen and a joint proxy statement for each of Nanogen s and Epoch s special stockholder meetings related to the proposed merger. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We disclaim any intent or obligation to update these forward-looking statements.

Overview

Nanogen was founded on the vision of integrating multiple scientific disciplines to develop diagnostic products. Through advances in genomic and pharmaceutical research, we believed that diagnostics and therapeutics would become closely linked. Further, we believed that by using electronics, we could develop a highly accurate and flexible set of products that would facilitate the analysis of complex genetic relationships and the correlation to disease and therapies. This vision in turn led to the definition of the Company s mission: to become a leading provider of high quality innovative advanced diagnostic products and services to patients, providers and pharmaceutical companies.

Nanogen currently develops and commercializes molecular diagnostics products and tests for the gene-based testing market for sale primarily in the United States, Europe and the Pacific Rim. By integrating microelectronics and molecular biology into a core proprietary technology platform, the Company seeks to establish the unique, open-architecture design of its primary products, the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge (collectively, the NanoChip® System), as a standard platform for molecular identification and analysis. In furtherance of its mission to become a leading supplier of advanced diagnostics testing products, Nanogen is developing a broad menu of Analyte Specific Reagents (ASRs) and other commercial applications for the NanoChip® System. The Company continually conducts research and development by itself and with third parties, to improve the NanoChip® System and to extend its technology to other applications such as biodefense, forensics, drug discovery and pharmacogenomics.

Nanogen believes that its technology platform provides a key advantage over conventional manual and mechanical platforms in that it provides an accurate, simple, versatile and cost-effective integrated microelectronic system that is capable of improving the quality of molecular diagnostic testing while reducing the overall cost of such testing. At the heart of Nanogen s technology is a silicon chip called the NanoChip® Electronic Microarray. Each Electronic Microarray has 100 microlocations or test sites upon which genetic tests can be conducted. DNA or RNA is moved and concentrated by controlling the electric current at each test site, improving accuracy, speed and flexibility. This electronic concentration of molecules greatly accelerates molecular binding at each test site. In addition, our technology allows the simultaneous analysis of multiple test results, or multiplexing, from a single sample. Current applications of the NanoChip® Electronic Microarray include single nucleotide polymorphisms (SNPs), short tandem repeats (STRs), insertions, deletions and other mutation analyses.

In October 2004, Nanogen announced its second-generation instrument, the NanoChip® 400. The NanoChip® 400 is an advanced molecular diagnostic testing and diagnostic development platform for clinical research and clinical reference laboratories. The automated multi-purpose

system facilitates detection of known genetic sequences, such as single nucleotide polymorphisms (SNPs), utilizing a 400-site electronic microarray upon which molecular tests can be developed and conducted. Building on the features of the first-generation NanoChip® Molecular Biology Workstation, the NanoChip® 400 offers increased throughput for running multiplex molecular assays on an instrument that is half the size and more automated than the first-generation instrument. As of September 30, 2004, the NanoChip® 400 was not commercially available. This new product will begin shipping in 2005.

The Company s current commercially available products include (1) the NanoChip® Molecular Biology Workstation, an automated, multi-purpose instrument primarily used for DNA-based analyses, (2) the NanoChip® Cartridge, which incorporates the NanoChip® Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules, (3) various ASRs for detection of gene mutations associated with diseases such as cystic

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fibrosis, (4) Nanogen s general purpose reagents and accessories used to facilitate assay and protocol development and validation on the NanoChip® Platform, (5) point-of-care diagnostic tests for myocardial infarction (obtained through the acquisition of SynX), and (6) point-of-care diagnostic tests for drugs of abuse (obtained through the acquisition of SynX). The Company also has several other ASRs and applications of its proprietary technology under development and (through the acquisition of SynX), is developing a pipeline of point-of-care tests, including tests for congestive heart failure, stroke and traumatic brain injury.

On April 21, 2004, the Company acquired all the outstanding shares of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests. The primary reason for the acquisition was to provide an initial entry into the point-of-care diagnostic market for Nanogen. Nanogen believes that the future markets for advanced diagnostics will include research and clinical reference labs as well as the point-of-care market. Nanogen addresses the research and clinical reference lab market and SynX provides the basis for addressing the point-of-care market. In addition sales and marketing synergies are anticipated as SynX s line of point-of-care products may be sold into the clinical reference labs market. In the future, Nanogen anticipates developing microarray products to address all of these markets. Through the acquisition of SynX, the Company gained access to a worldwide license to the Congestive Heart Failure (CHF) marker NT-proBNP (N-terminal pro-hormone brain natriuretic peptide) from Roche Diagnostics to develop a test for the point-of-care market. We believe the new Nexus Dx(TM) product will offer improvements over other CHF diagnostics and will enable health professionals to provide an enhanced level of care. Analysts predict the CHF market will have above-average growth and will reach approximately US $300 million by 2005 as use increases internationally.

On September 7, 2004, the Company announced the signing of a definitive agreement to merge Epoch Biosciences, Inc. (Epoch) into Nanogen in an all-stock transaction. Under terms of the merger, Nanogen has agreed to an offer price of $2.00 per Epoch share, representing a 30% premium over the average closing price of Epoch s shares for the 20 trading days ending on September 1, 2004. Epoch shareholders will receive a number of Nanogen shares based on an exchange ratio determined by dividing the offer price of $2.00 per share by Nanogen s issue price as calculated at closing. Nanogen s issue price will be calculated based on the average closing price of Nanogen s shares for the 20 trading days ending on and including the third trading day prior to the closing. The companies have agreed that the exchange ratio will not be less than 0.4673 nor exceed 0.6329 of one Nanogen share. Accordingly, based on Epoch s capitalization as of the record date, as many as 18,182,347 shares of Nanogen common stock could be issued to Epoch stockholders in consummation of the merger, or as few as 13,424,886 shares of Nanogen common stock could be issued. The transaction is subject to approval by Nanogen and Epoch stockholders and other customary closing conditions. If stockholder approval is obtained, the merger is expected to close on or about December 9, 2004.

In July 2004, we executed a term sheet with Epoch for a collaborative research project regarding utilization of Epoch s proprietary chemistries on our Molecular Biology Workstation. Under the term sheet, Epoch is providing contract research over an eight month period and supplying small amounts of test material for our use.

Since commencing operations in 1993, we have applied substantially all of our resources to our research and development programs. We have incurred losses since inception and, as of September 30, 2004, had an accumulated deficit of $204 million. We expect to continue to incur significant losses over at least the next few years as we attempt to further commercialize our products as well as expand the menu of applications for our current products.

For the three and nine months ended September 30, 2004, as well as for the three months ended September 30, 2003, product related revenue was a primary driver of total revenue**.** While we recognized revenue from product sales during the nine months ended September 30, 2003, as well as in prior fiscal years, our main sources of revenues during those fiscal years were payments under our sponsored research agreements, contracts and grants and, in 2002, a license fee valued at $10.8 million received from a litigation settlement with CombiMatrix Corp. We believe that in future periods, our revenue will continue to be more product driven as certain research collaboration agreements expire and we introduce new products to the marketplace. 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 NanoChip® System and potential 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 amount and therefore our results of operations for any period may not be comparable to the results of operations for any other period.

Critical Accounting Policies and Estimates

This Management s Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates and judgments,

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including those related to bad debts, inventories, investments, goodwill and other intangible assets, service obligations and contingencies. We base our estimates and judgments on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue recognition

Product revenue is generated by the sale of commercial products and services under various sales programs to the end user or through distribution channels. Revenue is recognized in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements and is recorded as follows:

The Company s NanoChip® Molecular Biology Workstation revenues are earned under various commercial programs such as sales to end users, sales to distributors, and reagent rentals. Additionally, the Workstations are placed with potential customers under development site programs that may ultimately result in a direct sale or reagent rental agreement.

Revenue from the sale of NanoChip® Molecular Biology Workstations and point-of-care diagnostic tests are recognized following receipt of a purchase order, shipment (f.o.b. shipping point) of product, and transfer of title when sold directly to the end user or to a distributor. In transactions where a right-of-return exists, revenue is deferred until acceptance has occurred and the period for the right-of-return has lapsed. The NanoChip® Molecular Biology Workstation is sold with a one year warranty contract. The fair value of the warranty is recorded as deferred revenue and recognized ratably over the warranty period included in the customer contract. The fair value of the warranty is based on the renewal price paid by the same customer. This renewal price for the maintenance contract is consistent for all customers. The Company includes the estimated cost of product warranty in deferred revenue and recognizes as revenue over the warranty period. Revenue from the sale of consumables is recognized upon shipment (f.o.b. shipping point) as the Company does not sell consumables with a right of return.

The Company also recognizes revenue from the sale of the NanoChip® System under reagent rental transactions whereby customers pay a premium for consumable products (NanoChip® Cartridges or ASRs) over a number of years that is intended to cover the sales price of the NanoChip® Workstation, consumables and warranty. Under a reagent rental transaction, the customer commits to purchasing a fixed number of consumable products on a periodic basis for a specified period of time (i.e. a certain number of cartridges for a certain number of years). Revenue for the Workstation, consumables and warranty under reagent rental transactions is recognized as consumable products are shipped, generally over a period of two to five years, depending on the specific customer arrangement as they may vary by customer. The Company reclassifies the recorded value of the Workstation from inventory to fixed assets, recognizing the depreciation expense as cost of sales ratably over the period of the arrangement. The Company provides product warranty coverage for the Workstation over the period of the contract and the fair value of the warranty is recognized ratably over the warranty period. The cost of sales related to the consumables is recorded in line with the revenue (i.e., as consumables are shipped).

The Company also places NanoChip® Molecular Biology Workstations at customer sites under programs, such as development site arrangements, where title of the NanoChip® Workstation does not transfer to the customer. No revenues are recognized at the time of placement under these agreements. These arrangements are for a period normally between six and twelve months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that the Company may license in the future. In addition, a primary intent of the program is for the customer to purchase the NanoChip® Workstation during the period of the arrangement or at its

expiration. The Company provides a warranty for these NanoChip® Workstations as well as insures them during the development site period. Warranty expense is recorded ratably over the period of the arrangement within selling, general, and administrative (SG&A) expenses. Development site customers are normally required to purchase any consumables to be used on the instrument from the Company during the development site period. The Company classifies this inventory of workstations as consignment inventory and includes this within finished goods.

Workstations sold to distributors are sold outright with title transferring at point of shipment (i.e. f.o.b. shipping point) without a right of return. Workstations are sold at a discount to the standard sales price and without warranty coverage.

Sponsored research and contract and grant revenue are generally recorded as the costs and expenses to perform the research are incurred. Under certain arrangements, revenue is recorded ratably over the term of the arrangement as funding is provided for contractually on a scheduled basis. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Continuation of certain sponsored research, contracts and grants are dependent upon the Company achieving specific contractual milestones.

License fees include nonrefundable fees generated from the licensing of the Company s technology. Revenue is recognized immediately when the Company has no further obligation to perform and collections are reasonably assured.

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Bad debts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We record additions to our reserve based on specific analysis of each customer s balance due us. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

Inventory

We reduce the carrying value of our inventory, including NanoChip® Molecular Biology Workstations placed under development site arrangements, for estimated obsolescence or non-marketability, as well as provide reserves for estimated sales discounts below cost, after considering future purchase commitments, the potential impact of next generation instruments, and based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

Intangible Assets

We have intangible assets, including goodwill and acquired technology rights. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments. Impairment is measured by a comparison of the carrying amount of an asset to the future net cash flows that are expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances.

Results of Operations

Product Revenue. For the three and nine months ended September 30, 2004, product revenue totaled $671,000 and $2.3 million compared to $752,000 and $1.6 million for the three and nine months ended September 30, 2003. Product revenue during the periods presented includes sales and rental payments related to our NanoChip® Molecular Biology Workstation, as well as sales of NanoChip® Cartridges, reagents, point-of-care diagnostics, and product warranty agreements. We offer our Molecular Biology Workstation and related products to customers under several different types of acquisition programs, some of which pass title of the instrument to the customer and some of which do not pass title to the customer. Our product revenue may vary from year to year due to, among other things, the types of acquisition programs our potential customers may choose. Product revenue during the three and nine months ended September 30, 2004 was negatively impacted by performance issues with our CFTR ASR (related to cystic fibrosis), one of our largest molecular testing markets for clinical laboratories. We are working on an improved CFTR ASR to address these issues. In the meantime, we shifted our primary sales force emphasis to the research and clinical research laboratories where our molecular biology workstation is used for research and assay development purposes. Research labs were our first customers and we have continued to sell to them even as we added clinical laboratories to our sales efforts. We anticipate that the majority of our product revenue in the fourth quarter of 2004 will come from these research laboratory customers.

Beginning in 2005, we anticipate increased sales into the clinical market driven primarily by the introduction of our second-generation instrument, the NanoChip® 400. We believe that the NanoChip® 400 is well-suited to the needs of clinical research or reference laboratories due to its enhanced automated capabilities which allows walkaway operation of the system, increased density providing increased number of tests

that can be run, and its reduced size and cost. Further, for the clinical research customers, the NanoChip® 400 ability to develop and test a user defined panel of mutations on one chip should make it easier and more cost effective to use than research-grade thousand-gene chip arrays. We believe the system is ideal for mid- to high-volume laboratories where the need to streamline testing and workflow is a high priority.

The merger with Epoch, which is subject to stockholder approval, should significantly increase the level of revenue in 2005 if approved.

Sponsored Research. For the three and nine month periods ended September 30, 2004, revenues from sponsored research totaled $0, and $500,000, respectively, compared to $375,000 and $1.1 million for the three and nine months ended September 30, 2003, respectively. Revenues are primarily recorded under these arrangements as expenses are incurred. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Sponsored research revenue recognized during the three and nine months ended September 30, 2004 and 2003 represents revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. During August 2003, the Company received written notification from Hitachi that Hitachi was terminating the research collaboration agreement in accordance with the terms of that agreement. Funding by Hitachi under the collaboration agreement was completed during the three months ended June 30, 2004.

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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. Revenues are recognized under these contracts and grants as expenses are incurred, and totaled $386,000 and $1.4 million for the three and nine months ended September 30, 2004, respectively, and $568,000 and $1.8 million, respectively, for the three and nine months ended September 30, 2003. The decrease in revenues for the three and nine months ended September 30, 2004 compared to the same periods in 2003 is primarily related to the completion of two government contracts.

Cost of Product Revenue and Gross Margins. Cost of product sales and reagent rentals totaled $1.3 million and $4.2 million for the three and nine months ended September 30, 2004, respectively, compared to $1.4 million and $2.2 million for the three and nine months ended September 30, 2003, respectively. Gross margins on product revenue were negative 93% and negative 82% for the three and nine months ended September 30, 2004, respectively, compared to negative 82% and negative 32% for the three and nine months ended September 30, 2003. Cost of product revenue for the three and nine months ended September 30, 2004 were negatively impacted primarily by increased inventory reserves for excess instruments, underabsorbed overhead costs due to underutilized capacity and manufacturing scrap. The inventory reserves, recorded in the three and nine month periods ended September 30, 2004, were approximately $900,000 and $2.4 million, and related primarily to the write down of excess Molecular Biology Workstations and accessory items in our inventory that could potentially not be saleable or could become obsolete, primarily as a result of the performance issues with our CFTR ASR and corresponding shifting of sales force emphasis from the clinical laboratory market to the research market, as well as the October 2004 announcement of our second-generation instrument, the NanoChip® 400. This new product will begin shipping in 2005. We believe that the sales of the original Molecular Biology Workstation will continue and these reserves will permit us to competitively position the first-generation system against the recently announced second-generation system. In addition, as we are still in the early stages of commercialization, we expect to continue to incur significant costs associated with excess production capacity within our manufacturing facility in 2004. Gross margins in future periods may be further impaired by minimum product royalties or potential adjustments made to reflect the impairment of intangible assets related to products sold. The sale of NanoChip® Workstations is directly related to the successful validation of assays developed and implemented by clinical laboratories based on our ASRs. Should the successful validation or rate of adoption by clinical laboratories vary from our estimates, gross margins could be impacted by additional reserves for obsolete and slow moving inventory.

Research and Development Expenses. For the three and nine months ended September 30, 2004, research and development expenses totaled $4.5 million and $12.9 million, respectively, compared to $4.3 million and $13.5 million, respectively, for the three and nine months ended September 30, 2003. During these periods, research and development expenses included the cost 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. For the three and nine months ended September 30, 2004, research and development activities primarily related to the development of new ASRs and the second-generation instrument, the NanoChip® 400, and related products. The savings resulting from the restructuring of Nanogen Recognomics into a non-operating entity (i.e. substantial discontinuation of business activity) in the first quarter of 2004 has been offset by the addition of SynX research and development expenses which have been included since April 21, 2004. We anticipate research and product development costs to remain at similar levels in the fourth quarter as experienced in the current quarter. The merger with Epoch, which is subject to stockholder approval, will significantly increase the level of research and development expenses in 2005 if approved.

Selling, General and Administrative Expenses. For the three and nine months ended September 30, 2004, selling, general and administrative expenses totaled $4.8 million and $12.6 million, respectively, compared to $3.5 million and $11.7 million, respectively, for the three and nine months ended September 30, 2003. Selling, general and administrative expenses include salaries, benefits, consulting, travel and other expenditures related to executive, legal, finance, human resources, sales and marketing personnel. In addition, these expenses include costs related to enhancing and maintaining our intellectual property portfolio. The increase in selling, general, and administrative expense for the three and nine months ended September 30, 2004 as compared to the same period during the prior year is primarily the result of increased expenditures associated with the launch of products, increased costs related to maintaining and enhancing our intellectual property portfolio, and the inclusion of a full quarter of SynX expenditures. We anticipate selling, general and administrative expenses to remain at similar levels experienced during the three months ended September 30, 2004 during the remainder of 2004. The merger with Epoch, which is subject to stockholder approval, will significantly increase the level of selling, general and administrative expenses in 2005 if approved.

Charge for Acquired In-Process Research and Development. The three and nine month periods ended September 30, 2004 include a $3.8 million non-cash charge related to the write-off of acquired in-process research and development resulting from the SynX acquisition and represent current research and development projects in process. There were no acquisitions during the same periods in 2003.

Impairment of Acquired Technology Rights. For the three and nine months ended September 30, 2003, impairment of acquired technology rights totaled $1.0 million as a result of a decision to restructure or terminate two license agreements. The impairment losses recognized represents the difference between the assets carrying values and their estimated fair values. There were no similar impairment losses in the three or nine months ended September 30, 2004.

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Interest Income, Net. For the three and nine months ended September 30, 2004, net interest income totaled $187,000 and $433,000, respectively, compared to $97,000 and $405,000, respectively, for the three and nine months ended September 30, 2003. The increase in net interest income for the three and nine months ended September 30, 2004 is primarily a result of higher average cash and investment balances. As a result of a net cash use from operations, average cash and investment balances are expected to decrease and we expect a corresponding decrease in net interest income is subsequent quarters.

Gain/(Loss) on Sale of Investments. During 2003, material gains and losses were recorded on the sale of investments. These gains and losses primarily related to the sale of CombiMatrix common stock obtained as a result of a settlement agreement between the Company and CombiMatrix in 2002 whereby the Company received 4,016,346 shares. The Company sold 3,000,000 of CombiMatrix common stock in February 2003 for net proceeds totaling $4.5 million and 583,600 shares in September 2003 for net proceeds totaling $2.3 million. During the three and nine months ended September 30, 2003, the Company recognized a realized gain of approximately $778,000 and a realized loss of approximately $2.8 million, respectively, relating to the sale of these shares. There are no gains or losses in 2004 related to CombiMatrix shares as the Company sold all remaining shares in the fourth quarter of 2003.

Gain on Foreign Currency Translation.

During the nine months ended September 30, 2004, the Company recognized a gain of $1.2 million related to a previously unrealized gain for foreign currency translation of its Nanogen Recognomic s subsidiary financial statements. In February 2004, the Company and the minority shareholder of Nanogen Recognomics decided to reorganize Nanogen Recognomics and discontinue all its business activities. In accordance with Statement of Financial Accounting Standards No. 52, Foreign Currency Translation, and its related interpretation, the Company recognized the gain of $1.2 million as all the business activities of this subsidiary have been discontinued.

Minority Interest in Loss of Consolidated Subsidiary. The minority interest in losses relating to our majority-owned subsidiary, Nanogen Recognomics GmbH, totaled $0 for each of the three and nine months ended September 30, 2004, compared to $488,000 and $1.6 million for the three and nine months ended September 30, 2003, respectively. Through December 2003, the losses were funded by the investment from minority interest investor and are therefore offset against the minority interest balance in its balance sheet. Subsequently, any losses incurred are recognized solely by the Company and are reflected in the consolidated net loss.

Liquidity and Capital Resources

At September 30, 2004, we had $53.1 million in available cash, cash equivalents and short-term investments, compared to $29.1 million at December 31, 2003. The increase is primarily due to $41.4 million in gross proceeds from the sale of common stock during the nine months ended September 30, 2004. Also during 2004, the Company received $4.6 million in gross proceeds from the exercise of warrants related to a financing that originally closed in September 2003, and approximately $5.5 million related to the exercise of stock options. These sources of cash were partially offset by cash used in operations as well as transaction costs related to the acquisition of SynX, as well as transaction costs related to the pending merger with Epoch, which is subject to stockholder approval.

Net cash used in operating activities was $21.6 million and $20.2 million for the nine months ended September 30, 2004 and 2003, respectively. During both periods cash use was primarily related to costs associated with commercializing our products, including the expansion, development and support of our sales and marketing organization; the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd.; support of our continuing research and development efforts including development of the ASRs which may be used by customers to develop tests for the detection of mutations in the CFTR gene associated with cystic fibrosis, the ASRs for mutations in the HFE gene associated

with the hereditary hemochromotosis, and the and other products; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio. In addition, the period ended September 30, 2004 included the operating cost of SynX from the date of acquisition, April 21, 2004. The majority of SynX s costs were associated with the commercialization of new products, including a point-of-care test for CHF, and the reduction of outstanding past due liabilities incurred prior to the date of acquisition.

Net cash used in investing activities was $29.9 million for the nine months ended September 30, 2004, as compared to $16.3 million provided by investing activities for the nine months ended September 30, 2003. We purchase short-term investments in order to enhance the yield on our cash balances, and in the nine months ended September 30, 2004, a portion of the excess cash that resulted from the $41.4 million sale of common stock during the nine months ended September 30, 2004 was invested. These securities mature from time to time or are sold to fund operating expenses. During the nine months ended September 30, 2004, certain securities matured or were sold to help fund operating activities. In addition, $2.7 million of cash was used related to the acquisition of SynX, including the payment of transaction costs and a bridge funding made to SynX prior to the completion of the acquisition.

We have funded some of our equipment acquisitions and leasehold improvements through capital leasing facilities. As of September 30, 2004, we have approximately $1.7 million available on an equipment line of credit which expires in December 2004.

Net cash provided by financing activities for the nine months ended September 30, 2004 was $49.0 million as compared to cash use of $7.1 million for the nine months ended September 30, 2003. The funding for the nine months ended September 30, 2004

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primarily relates to $41.4 million in gross proceeds from the March and April 2004 sale of common stock. During the nine months ended September 30, 2004, the Company also received $4.6 million in gross proceeds from the exercise of warrants related to a financing that closed in September 2003, and approximately $5.5 million related to the exercise of stock options.

Our manufacturing agreement with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip® 400 instruments. As of September 30, 2004, we had commitments to purchase approximately $590,000 in NanoChip® 400 instruments from Hitachi for shipments of product through January 2005.

We are a party to development site agreements with various entities and to license agreements under which we acquired rights to pay license fees, annual minimum royalties or product royalties for any customer owned or licensed intellectual property used to develop any Nanogen commercial products. None of these agreements individually are considered material.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a workstation 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. Many of our reagent rentals and cost-per-test agreements entered into to date require customer acceptance of our CFTR ASRs as a pre-condition to this commitment. These reagent rentals and cost-per-test agreements might have a short-term adverse impact on our instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, which is typically two to five years, as reagents are shipped to the customer.

We expect that our existing capital resources, combined with anticipated revenues from potential product sales, reagent rentals, leases or other types of acquisition programs for both generations of our NanoChip® System, point-of-care product sales, sponsored research agreements, contracts and grants will be sufficient to support our planned operations for at least one year from the date of this filing. This estimate of the period for which we expect our available sources of liquidity to be sufficient to meet our capital requirements is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. Our future liquidity and capital funding requirements will depend on numerous factors including, but not limited to, commercial success of our products, or lack thereof, of our current products, 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, our ability to enter into additional collaborative arrangements, our ability to realize the anticipated benefits of acquisitions, and transaction, integration and operating costs and expenses of acquisitions. 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 may need to raise additional capital to fund our research and development programs, to scale-up manufacturing activities, to expand our sales and marketing efforts to support the commercialization of our products under development and otherwise to fund operations beyond the one-year period referenced above. 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 our operations significantly 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.

FACTORS THAT MAY AFFECT RESULTS

An investment in our common stock involves a high degree of risk. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business

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 September 30, 2004, 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 will begin shipping in 2005. 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.

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We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a Workstation 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. Many of our reagent rentals and cost-per-test agreements entered into as of September 30, 2004 require customer acceptance of our CFTR ASRs as a pre-condition to the customer s commitment to purchase reagents. Our CFTR ASRs may be utilized by customers to develop and validate tests for the detection of mutations in the CFTR gene associated with cystic fibrosis. 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 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 September 2004, June 2004 and September 2003 we took accounting charges of approximately $904,000, $1.5 million and $829,000, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those 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 nine months ended September 30, 2004, 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.

In August 2003, Hitachi, Ltd. exercised its right to terminate the research collaboration agreement it has with us. The agreement terminated during the second quarter of 2004. Our manufacturing and distribution agreements with Hitachi remain in place. 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. In June 2001, we formed a new company, Nanogen Recognomics GmbH, with Aventis Research and Technologies & Co. KG, in which we own 60% of the stock of Nanogen Recognomics and Aventis R&T owns the remaining 40%. Nanogen Recognomics seeks to combine our NanoChip® technology and Aventis R&T s intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to develop new products and applications for the NanoChip® System. In February 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sales transactions.

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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.

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 will begin shipping next year. 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.

During the three and nine months ended September 30, 2004, we increased our reserve related to our inventory of NanoChip® Molecular Biology Workstations and accessory items by approximately $900,000 and $2.4 million respectively, due in part to our announcement of the NanoChip® 400. If actual future demand for our first-generation products is less favorable than management s projections, additional inventory write-downs may be required, and would be reflected in cost of sales in the period the revision is made.

Past and future mergers and acquisitions could be difficult to integrate, disrupt our business, dilute the ownership interests of our stockholders and harm our operating results

If appropriate opportunities become available, we may attempt to acquire businesses, technologies, services or products that we believe are a strategic fit with our business. In April 2004 we completed our acquisition of SynX Pharma Inc., a point-of-care diagnostic company. The process of integrating SynX or any other acquired business, technology, service or product requires significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Additionally, SynX is located in Canada 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 acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations. 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.

On September 7, 2004, the Company announced the signing of a definitive agreement to merge Epoch Biosciences, Inc. (Epoch) into Nanogen in an all-stock transaction. Under terms of the merger, Nanogen has agreed to an offer price of $2.00 per Epoch share, representing a 30% premium over the average closing price of Epoch s shares for the 20 trading days ending on September 1, 2004. Epoch shareholders will receive a number of Nanogen shares based on an exchange ratio determined by dividing the offer price of $2.00 per share by Nanogen s issue price as calculated at closing. Nanogen s issue price will be calculated based on the average closing price of Nanogen s shares for the 20 trading days ending on and including the third trading day prior to the closing. The companies have agreed that the exchange ratio will not be less than 0.4673 nor exceed 0.6329 of one Nanogen share. There are approximately 29 million Epoch shares and share equivalents outstanding. The transaction is subject to approval by Nanogen and Epoch stockholders and other customary closing conditions. The merger is expected to close on or about December 9, 2004.

Factors that will affect the success of our mergers and acquisitions include:

presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;

the ability to retain key employees

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- competitive factors, including technological advances attained by competitors and patents granted to, or contested by competitors, which would result in increased efficiency in their ability to compete against us;

- the ability of the combined company to increase sales of all such companies products; and

- the ability of the combined company to operate efficiently and achieve cost savings.

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

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 September 30, 2004, total approximately $204 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 NanoChip® System, including the NanoChip® 400, 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 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.

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 cannot 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 or QSRs and obtaining necessary 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 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.

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

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management personnel. One such interference has recently been declared between U. S, Patent 6,461,828 owned by our Canadian subsidiary, SYN-X Pharma, and a patent application owned by Biosite Incorporated (Biosite). The count of the interference is directed to a method for predicting cardiac mortality in a patient using pairs of biological markers. Among the markers within the scope of the count are pro-BNP and troponin I, markers which are the basis of a product being developed by SYN-X for the prognosis of congestive heart failure. Even though Biosite is the senior party in the interference because of its earlier filing date, the Company believes that it will be able to prove an earlier date of invention and thus prevail in the interference. However, if Biosite prevails it may obtain a patent having claims corresponding exactly or closely to the count of the interference. If that were to occur, the Company would be precluded from marketing in the United States a product for predicting cardiac mortality using the markers within the scope of any claim obtained by Biosite. We may in the future become subject to other 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. 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 Technologies 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 Technologies pursuant to which the lawsuit was dismissed by Oxford Gene Technology 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.

The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining 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 Food and Drug Administration, or 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;

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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 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,

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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.

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 Nanogen products

As of September 30, 2004, we had 38 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;

costs and risks of deploying the NanoChip® System, including the second-generation NanoChip® 400, ASRs, point-of-care diagnostics, and other products in foreign countries;

licenses, tariffs and other trade barriers;

political and economic instability, including the war on terrorism;

difficulties in staffing and managing foreign offices;

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

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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 year ended December 31, 2003, the turnover rate at all levels at Nanogen was 25%. For the years ended December 31, 2002 and 2001 the turnover rates at Nanogen were 29% and 31%, respectively. During the nine month period ended September 30, 2004, we experienced a turnover rate equivalent to approximately 31% annualized. 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;
- 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.

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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 DNA testing in general;
- 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 Nanogen 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.

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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 stockholder 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 (SOX). 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.

In particular, our efforts to comply with Section 404 of SOX and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors audit of that assessment has required, and continues to require, the commitment of significant financial and managerial resources. Although we believe that the ongoing review of our internal controls will enable us to provide an assessment of our internal controls and our external auditors to provide their audit opinion as of December 31, 2004 as required by Section 404 of SOX, we can give no assurance that these efforts will be completed on a timely and successful basis.

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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Short-term investments. We invest our excess cash in short-term, interest-bearing investment-grade securities that primarily are held for the duration of the term of the respective instrument. We have not utilized derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not generally subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

Foreign currency rate fluctuations. The functional currency for our Canadian and Netherlands subsidiaries is the U.S. dollar, and the euro for our German subsidiary. 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. In February 2004, the shareholders of Nanogen Recognomics, our German majority owned subsidiary, elected to reorganize as a non-operating entity. As a result of this reorganization, in accordance with Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation*, the Company realized approximately $1.2 million in foreign currency translation gains, previously unrealized. The net tangible assets of our subsidiaries, excluding intercompany balances, was approximately $7.8 million at September 30, 2004.

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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.

We are evaluating the effectiveness of our internal controls over financial reporting in order to comply with Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to evaluate annually the effectiveness of our internal controls over financial reporting as of the end of each fiscal year beginning in 2004, and to include a management report assessing the effectiveness of our internal controls over financial reporting in all annual reports beginning with our Annual Report on Form 10-K for the fiscal year ending on December 31, 2004. Section 404 also requires our independent accountants to attest to, and report on, management s assessment of our internal controls over financial reporting. In evaluating our internal controls over financial reporting, we have identified a number of changes that need to made to our internal controls, primarily related to more formally documenting the performance of controls, and related changes to general controls used in financial reporting. We began making these changes during the third quarter of 2004. The changes during the third quarter of 2004 did not, individually or in the aggregate, have a material effect on our internal controls over financial reporting.

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PART II - OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit No.	Description
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 7, 2004, by and among Nanogen, Inc., Epoch Biosciences, Inc. and Empire Acquisition Corp., including the form of Company Voting Agreement and Parent Voting Agreement attached as Annex A and Annex B thereto (incorporated by reference to exhibit 2.1 of Nanogen s current report on Form 8-K filed with the SEC on September 8, 2004).
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 Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.
32.2	Certifications of Chief Financial Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.

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NANOGEN, INC.

SIGNATURES

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

NANOGEN, INC.

Date: November 15, 2004

/s/ HOWARD C. BIRNDORF

Howard C. Birndorf

Chairman of the Board, Executive Chairman and

Chief Executive Officer

Date: November 15, 2004

/s/ NICHOLAS J. VENUTO

Nicholas J. Venuto

Senior Director, Finance

(Chief Accounting Officer)

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NANOGEN, INC.

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