

NANOGEN INC  
Form 10-Q  
November 14, 2002

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2002

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 000-23541

**NANOGEN, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**33-0489621**

(I.R.S. Employer  
Identification No.)

**10398 Pacific Center Court, San Diego, CA**

(Address of principal executive offices)

**92121**

(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 ý NO o

**As of November 12, 2002, 21,941,398 shares of the Registrant's Common Stock were outstanding.**

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NANOGEN, INC.

**FORM 10-Q  
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**PART I. FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**NANOGEN, INC.  
CONSOLIDATED BALANCE SHEETS  
(in thousands, except share data)**

	<u>September 30, 2002</u>	<u>December 31, 2001</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 13,340	\$ 10,455
Short-term investments	33,041	57,069
Receivables, net	1,396	4,380
Inventories, net	4,607	4,688

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	September 30, 2002	December 31, 2001
Other current assets	3,108	2,473
Total current assets	55,492	79,065
Property and equipment, net	5,220	5,386
Acquired technology rights, net	4,747	4,183
Other assets, net	908	1,158
Restricted cash	64	299
	<u>\$ 66,431</u>	<u>\$ 90,091</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 707	\$ 1,051
Accrued liabilities	5,435	4,916
Deferred revenue	863	522
Current portion of capital lease obligations	842	1,060
Total current liabilities	7,847	7,549
Capital lease obligations, less current portion	1,322	1,755
Other long-term liabilities	3,037	1,675
Total long-term liabilities	4,359	3,430
Minority interest in consolidated subsidiary	2,339	4,183
Stockholders' equity:		
Convertible preferred stock, \$.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2002 and December 31, 2001		
Common stock, \$.001 par value, 50,000,000 shares authorized; 21,941,398 and 21,616,172 shares issued and outstanding at September 30, 2002 and December 31, 2001, respectively	22	22
Additional paid-in capital	199,534	198,387
Accumulated other comprehensive income	1,051	1,253
Deferred compensation	(164)	(336)
Notes receivable from officers	(1,027)	(984)
Accumulated deficit	(147,530)	(123,413)
Total stockholders' equity	51,886	74,929
	<u>\$ 66,431</u>	<u>\$ 90,091</u>

See accompanying notes.

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	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
<b>Revenues:</b>				
Product	\$ 957	\$ 1,023	\$ 2,873	\$ 1,554
Sponsored research	354	1,828	980	6,229
Contract and grant	240	368	1,182	1,091
<b>Total revenues</b>	<b>1,551</b>	<b>3,219</b>	<b>5,035</b>	<b>8,874</b>
<b>Operating expenses:</b>				
Cost of product sales	687	727	2,080	1,127
Research and development	5,780	4,824	15,672	14,023
Selling, general and administrative	5,428	6,054	15,346	15,982
Litigation and settlement of patent matter, net	(963)	263	(165)	6,836
<b>Total operating expenses</b>	<b>10,932</b>	<b>11,868</b>	<b>32,933</b>	<b>37,968</b>
Loss from operations	(9,381)	(8,649)	(27,898)	(29,094)
Interest income, net	488	1,019	1,834	3,437
Minority interest in loss of consolidated subsidiary	651	485	1,634	485
Other income	18	125	153	123
<b>Net loss</b>	<b>\$ (8,224)</b>	<b>\$ (7,020)</b>	<b>\$ (24,277)</b>	<b>\$ (25,049)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.38)</b>	<b>\$ (0.33)</b>	<b>\$ (1.12)</b>	<b>\$ (1.20)</b>
Number of shares used in computing net loss per share basic and diluted	21,923	21,206	21,732	20,898

See accompanying notes.

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**NANOGEN, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	Nine months ended September 30,	
	2002	2001
<b>Operating activities:</b>		
Net loss	\$ (24,277)	\$ (25,049)
Adjustments to reconcile net loss to net cash used in operating activities:		
Issuance of common stock pursuant to settlement of patent matter		2,500
Depreciation and amortization	3,067	2,516

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	<u>Nine months ended September 30,</u>	
Asset impairment and other non-cash charges	452	
Amortization (accretion) related to short-term investments	44	(51)
Stock-based compensation expense	64	353
Interest capitalized on notes receivables from officers	(43)	(48)
Minority interest in loss of consolidated subsidiary	(1,634)	(485)
Gain on sale of short-term investments	(182)	(116)
Changes in operating assets and liabilities:		
Receivables	2,984	(2,259)
Inventories	(926)	(1,923)
Other assets	(744)	(988)
Accounts payable	(344)	(280)
Accrued liabilities	528	(415)
Deferred revenue	340	321
Net cash used in operating activities	<u>(20,671)</u>	<u>(25,924)</u>
<b>Investing activities:</b>		
Purchase of short-term investments	(12,303)	(23,851)
Proceeds from sale and maturities of short-term investments	35,686	4,102
Purchase of equipment	(131)	(55)
Purchase of technology rights	(835)	
Net cash provided by (used in) investing activities	<u>22,417</u>	<u>(19,804)</u>
<b>Financing activities:</b>		
Principal payments on capital lease obligations	(1,108)	(1,946)
Proceeds from development partner	1,373	1,125
Proceeds from minority interest shareholder		4,794
Issuance of common stock, net of repurchases	313	382
Note receivable payments from officers		38
Proceeds from restricted cash balances	235	50
Net cash provided by financing activities	<u>813</u>	<u>4,443</u>
Effect of exchange rate changes	<u>326</u>	<u>204</u>
Net increase (decrease) in cash and cash equivalents	2,885	(41,081)
Cash and cash equivalents at beginning of period	10,455	55,330
Cash and cash equivalents at end of period	<u>\$ 13,340</u>	<u>\$ 14,249</u>
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid	<u>\$ 140</u>	<u>\$ 258</u>
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Equipment acquired under capital leases	<u>\$ 435</u>	<u>\$ 1,283</u>
Unrealized gain (loss) on short-term investments	<u>\$ (783)</u>	<u>\$ 1,141</u>

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	Nine months ended September 30,	
	\$	\$
Warrant issued for research and development collaboration	1,200	
Accrued fee for purchase of technology rights	225	
Common stock issued for settlement of patent matter	2,500	
Common stock issued in connection with purchase of license rights	872	
Common stock issued in connection with employee benefit plan, net of forfeitures	112	134
Cancellation of notes receivable related to unvested restricted stock, net of payments on notes receivable		139
Options issued to non-employees	4	105
Inventory acquired as fixed assets	1,007	483

See accompanying notes.

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**NANOGEN, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(unaudited)  
**September 30, 2002**

**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, 2002, consolidated statements of operations for the three and nine months ended September 30, 2002 and 2001, and the consolidated statements of cash flows for the nine months ended September 30, 2002 and 2001 are unaudited, but include all adjustments (consisting of normal recurring adjustments) 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, 2002 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2002.

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, 2001 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2001, filed with the Securities and Exchange Commission.

***Net Loss per Share***

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

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vesting. Due to the losses incurred by the Company during the three and nine months ended September 30, 2002 and 2001, common stock equivalents resulting from the assumed exercise of outstanding stock options and warrants have been excluded from the computation of diluted net loss per share as their effect would be anti-dilutive.

### *Recent Accounting Pronouncements*

In July 2001, the Financial Accounting Standards Board ("FASB") issued FASB Statements Nos. 141 and 142 (FAS 141 and FAS 142), "Business Combinations" and "Goodwill and Other Intangible Assets." FAS 141 replaces APB 16 and eliminates pooling-of-interests accounting prospectively. It also provides guidance on purchase accounting related to the recognition of intangible assets and accounting for negative goodwill. FAS 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Under FAS 142, goodwill will be tested annually and whenever events or circumstances occur indicating that goodwill might be impaired. FAS 141 and FAS 142 are effective for all business combinations completed after June 30, 2001. Upon adoption of FAS 142, amortization of goodwill recorded for business combinations consummated prior to July 1, 2001 will cease, and intangible assets acquired prior to July 1, 2001 that do not meet the criteria for recognition under FAS 141 will be reclassified to goodwill. Companies are required to adopt FAS 141 and 142 beginning

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in fiscal 2002. The adoption of these standards did not result in a material impact on the Company's results of operations and financial position.

In August 2001, the FASB issued FAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." FAS 144 replaces FAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The FASB issued FAS 144 to establish a single accounting model, based on the framework established in FAS 121, as FAS 121 did not address the accounting for a segment of a business accounted for as a discontinued operation under APB 30, "Reporting The Results of Operations Reporting The Effects of Disposal of a Segment of a Business, and Extraordinary Unusual and Infrequently Occurring Events and Transactions." FAS 144 also resolves significant implementation issues related to FAS 121. The Company was required to adopt FAS 144 for 2002. The adoption of this standard did not have a material impact on the Company's results of operations and financial position.

In June 2002, the FASB issued Statement No. 146, or SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal." SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The principal difference between Statement 146 and Issue 94-3 relates to Statement 146's requirements for recognition of a liability for a cost associated with an exit or disposal activity. Statement 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as generally defined in Issue 94-3 was recognized at the date of an entity's commitment to an exit plan. The provisions of this Statement 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We do not expect the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

### *Reclassification*

Certain prior period amounts have been reclassified to conform to current period presentation.

## 2. Inventories

Inventories consist of the following (in thousands):

	September 30, 2002	December 31, 2001
	(unaudited)	
Raw materials	\$ 1,178	\$ 796
Work in process	805	1,436
Finished goods	4,656	3,956
	6,639	6,188
Reserve for excess and obsolete	(2,032)	(1,500)
	4,607	4,688

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	September 30, 2002	December 31, 2001
\$	4,607	\$ 4,688

Finished goods includes \$2.7 million and \$2.0 million of NanoChip® Molecular Biology Workstations ("NanoChip® Workstations") at September 30, 2002 and December 31, 2001, 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 nine 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

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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 us during the development site period. As of September 30, 2002, we had a total of thirty-two NanoChip® Workstations under agreements whereby we retain 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. This reserve totaled \$426,000 and \$303,000 at September 30, 2002 and December 31, 2001, respectively. In addition, the Company has recorded a reserve related to the older production units which may be deemed obsolete or sold to the customer at a discount due to the depreciation of the unit during the development site period. This reserve totaled \$1.4 million and \$982,000 at September 30, 2002 and December 31, 2001, respectively.

The Company's manufacturing agreement with Hitachi, Ltd. ("Hitachi") requires that the Company provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of September 30, 2002, the Company had commitments to purchase approximately \$2.7 million in NanoChip® Workstations through March 31, 2003. At September 30, 2002, the inventory under our purchase commitment with Hitachi is within our expected usage levels based upon current and estimated future demands.

### 3. 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 June 2002, the Company issued 254,151 shares of the Company's common stock valued at \$750,000, based on the closing price of the Company's stock at the effective date, to a licensor in exchange for license rights. In April 2002, the Company issued a warrant exercisable through April 12, 2007 to purchase 50,000 shares of the Company's common stock at a per share price of \$4.10, the fair market value on the effective date of the agreement. The value of the warrant was determined to be \$122,000 using the Black-Scholes valuation model. Assumptions used in determining the value of the warrant were as follows: dividend yield of 0%, expected volatility of 65%, risk-free interest rate of 5.5%, expected life of 5 years, stock price of \$4.10 per share, and an exercise price of \$4.10 per share. The warrant has a term of five years, and was issued in return for license rights.

In July 2002, the Company and Graviton, Inc. entered into an agreement to terminate and release Nanogen and Graviton of their obligations under the Collaboration and License Agreement dated December 15, 1999 (see footnote 9 for further discussion of this transaction) which originally resulted in acquired technology rights of \$1 million by the Company in fiscal 1999. In September 2002, the Company and Graviton, Inc. entered into a subsequent agreement to terminate and release Nanogen and Graviton of their obligations under the Collaboration and License Agreement dated December 15, 1999 and the termination and release agreement entered into in July 2002. As a result of the termination of this collaboration arrangement, the Company recorded a loss of approximately \$452,000 included in research and development expenses (the remaining value of the acquired technology rights obtained in 1999) for the three month period ended September 30, 2002.

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### 4. Comprehensive Loss



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

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
<b>Comprehensive loss:</b>				
Net unrealized gain/(loss)	\$ (156)	\$ 549	\$ (783)	\$ 1,141
Foreign currency translation adjustment	(45)	21	581	21
Net loss	(8,224)	(7,020)	(24,277)	(25,049)
<b>Comprehensive loss</b>	<b>\$ (8,425)</b>	<b>\$ (6,450)</b>	<b>\$ (24,479)</b>	<b>\$ (23,887)</b>

### 5. Collaborative Alliances

#### *Hitachi, Ltd.*

##### *Manufacturing Agreement*

In January 2000, the Company executed an agreement with Hitachi, Ltd., effective as of December 15, 1999, for the full-scale commercial manufacturing and distribution of the NanoChip® Molecular Biology Workstation in specified research markets. Hitachi, Ltd.'s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip® Molecular Biology Workstation's components.

Hitachi, Ltd. has the right to be the sole distributor of NanoChip® Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip® Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip® Molecular Biology Workstations sold by Hitachi, Ltd. in Japan. The Company retains the right to distribute, directly or through others, NanoChip® Molecular Biology Workstations outside of Japan. In addition, the Company manufactures NanoChip® Cartridges at its San Diego, California facility for distribution worldwide. The Company also retains the right to form other manufacturing and distribution agreements.

Pursuant to our manufacturing agreement with Hitachi, the Company is required to provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of September 30, 2002, the Company had a commitment to purchase approximately \$2.7 million in NanoChip® Workstations from Hitachi through March 31, 2003.

##### *Research Collaboration Agreement*

In July 2000, the Company executed a ten-year 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. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute, toward the research and development efforts of the Company, up to \$28.5 million in cash over the ten-year period. At a minimum the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. In addition, the

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Company is liable to 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. Furthermore, Hitachi made an equity investment in the Company by purchasing 74,590 shares of the Company's common stock worth approximately \$2.0 million pursuant to a private sale by the Company based on a per share price of \$26.813 (the fair market value as of the signing date of the Hitachi agreement). Hitachi has the right to be the exclusive distributor of collaboration products in Japan and, based upon the attainment of minimum sales targets to be mutually agreed upon, in other Asian countries. The Company retains the exclusive right to distribute collaboration products outside of these countries.

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Sponsored research revenue recognized under this agreement totaled \$354,000 and \$980,000 for the three and nine months ended September 30, 2002, respectively, and \$292,000 and \$792,000 for the three and nine months ended September 30, 2001, respectively. In accordance with SFAS No. 68, the Company records sponsored research revenue under this arrangement as expenses are incurred 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 this agreement was \$3.0 million and \$1.6 million at September 30, 2002 and December 31, 2001, 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, we have classified the entire balance of this liability as long-term.

### *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 (as specified in the agreement) 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 December 2001, this agreement was amended to include, among other things, a commitment by the Company to provide Hitachi with a minimum of \$200,000 in payments for warranty service in fiscal 2002 and the expense is being recorded during fiscal 2002.

### *Aventis Research and Technologies*

In September 1999, the Company entered into two technology development programs with Aventis Research and Technologies, an affiliate of Hoechst AG ("Aventis"), which focused on the development of gene expression tools utilizing electronic bioarrays and the development of high throughput screening tools for kinase analyses. In total, the two programs provided \$11.9 million in funding to the Company through December 31, 2001. Under these programs, the Company demonstrated quantitative, multiplexed and reliable gene expression monitoring on a Nanogen electronic microarray system. Additionally, the Company delivered an electronic hybridization-based gene expression prototype detection system as well as a prototype system for analyzing protein kinases. This prototype system was sold during the fourth quarter of 2001 to an affiliate of Aventis. All project milestones established

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under these arrangements were completed as of December 31, 2001 at which time the agreements expired. The Company does not expect to receive additional funding for these projects.

Revenue was primarily recognized under these agreements as expenses were incurred, and totaled \$1.5 million and \$5.4 million for the three and nine months ended September 30, 2001, respectively. No revenue was recognized during 2002 as these projects were completed as of December 31, 2001.

In June 2001, the Company entered into agreements with 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. Aventis provided the first \$5 million of funding for the operations of Nanogen Recognomics and also contributed intellectual property in the form of eighteen patents. The Company is also required to spend an aggregate of \$5.5 million, at the rate of \$1.1 million per year beginning April 1, 2001, for its own general technology development which benefits the commercialization and development of potential Nanogen Recognomics products. This funding is recorded as research and development expense in the Company's statement of operations as incurred. The amounts contributed by Aventis are spent by the joint venture and reported in the operating results of the joint venture. Aventis has no further commitments to provide funding beyond the first five years of operation. In addition, Nanogen Recognomics will own several patent applications filed jointly by the Company and Aventis. The Company has licensed certain aspects of its NanoChip® technology to Nanogen Recognomics and will seek to commercialize new products and applications developed by Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics. In conjunction with the agreement to form Nanogen Recognomics, the Company issued a warrant to Aventis to purchase 315,863 shares of common stock exercisable through July 17, 2006 at an agreed upon price of \$9.828 per share. The value of this warrant, as determined by the Black-Scholes valuation model, was \$1.2 million, is included in other assets in the accompanying consolidated financial statements and is being amortized over a two and a half year period, the estimated period for which the \$5 million in funding will provide for operating expenses. Assumptions used in determining the value of the warrant were as follows: dividend

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yield of 0%, expected volatility of 70%, risk-free interest rate of 6.5%, expected life of 5 years, stock price of \$6.79 per share, and an exercise price of \$9.828 per share. In the event Nanogen Recognomics should run out of funds, we will take over wind-down costs and Nanogen Recognomics will be restructured 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 our financial statements. There is no off-balance sheet component to this joint venture. The total operating loss of Nanogen Recognomics is reflected as a reduction of the "minority interest" in the accompanying balance sheet and totaled \$651,000 and \$1.6 million for the three and nine months ended September 30, 2002, respectively, and 485,000 for the three and nine months ended September 30, 2001, respectively.

### 6. Litigation

In July 2001, the Company entered into a settlement agreement with Motorola, Genometrix, and MIT concluding the declaratory judgment action by the Company against Motorola, Genometrix and MIT and Motorola's counterclaim against the Company. In connection with the settlement, the Company has secured a license from Motorola to certain claims of the disputed patent. In exchange, the Company made a one-time payment of \$2.5 million in cash and issued 416,666 shares of the Company's common stock (valued at approximately \$2.5 million based upon a per share price of \$6.00, the fair market value on the date of settlement) to the parties involved. The settlement does not

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include any cross-licensing provisions of the Company's technology to Motorola, Genometrix or MIT. The lawsuit and the counterclaim have now been dismissed. For the three and nine months ended September 30, 2001 costs associated with the litigation of the Motorola patent matter totaled approximately \$123,000 and \$6.4 million, respectively. There were no costs incurred in 2002 related to this litigation matter.

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 common stock, 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. Additionally, because CombiMatrix is a wholly owned subsidiary of Acacia Research Corporation and a market value for the CombiMatrix stock could not be determined, the Company has deferred recognizing the value of its 4,016,346 shares of CombiMatrix common stock until the value of the stock can be more readily determined. Acacia Research Corporation has announced a Special Meeting of Stockholders to be held on December 11, 2002 at which shareholders will vote on a measure to recapitalize Acacia's stock into two new classes "New CombiMatrix" stock, that would reflect the performance of its subsidiary CombiMatrix Corporation, and new "Acacia Technologies" stock. If the plan is approved, Nanogen, as a holder of old CombiMatrix stock, would receive shares of the New CombiMatrix tracking stock, and CombiMatrix has agreed to attempt to register such shares on the Nasdaq National Market or another market. It is Nanogen's intention to value the shares received under this settlement agreement based upon the value they are traded at when the new shares are traded separately on the Nasdaq National Market or another market.

Costs for litigation and settlement of patent matters are shown net of the settlement payment due Nanogen. Costs associated with the litigation and settlement of the CombiMatrix and Dr. Montgomery litigation patent matter totaled approximately \$337,000 and \$1.1 million for the three and nine months ended September 30, 2002, respectively, excluding the settlement receivable of \$1.0 million from CombiMatrix and a credit of \$300,000 from outside counsel. As of September 30, 2002, a receivable totaling \$1.3 million has been recorded in the Company's financial statements.

### 7. Stock Transaction

In July 2002, the Compensation Committee of the Board of Directors ("the Compensation Committee") approved the issuance of employee retention options for 969,500 shares of the Company's common stock. The options were issued to the Company's employees and the employees of the Company's subsidiary, Nanogen Europe B.V. pursuant to the Company's 1997 Stock Incentive Plan, as amended. Each incentive stock option grant will be 50% vested on January 1, 2003 and 50% will vest ratably over the period January 1, 2003 through July 26, 2004.

### 8. Subsequent Events

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In October 2002, the Company reduced its workforce by approximately 10%. A one-time severance charge of approximately \$300,000 will be recognized in the fourth quarter of fiscal 2002 related to this event.

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In November 1997, Mr. Birndorf purchased 437,496 shares of Common Stock at \$.90 per share. In connection with this purchase, the Company loaned approximately \$394,000 to Mr. Birndorf at an interest rate of 6.01% per annum pursuant to a five-year full recourse promissory note. This note was secured by the shares purchased by Mr. Birndorf. In November 2002, Mr. Birndorf repaid this promissory note plus accrued interest by tendering to the Company 339,857 shares of common stock valued based on the closing price, as reported on the Nasdaq National Market, on the day the shares were tendered.

In November 2002, the Company announced that its Board of Directors had approved a stock repurchase program under which the Company may purchase up to an aggregate of ten percent (10%) of its outstanding common stock from time-to-time. Any purchases under the stock repurchase program may be made by the Company through its broker in the open market or in privately negotiated transactions and may be initiated and discontinued at any time.

### 9. Related Party Transactions

In November 1998, the Company entered into a Standstill Agreement and Right of First Negotiation (the "Agreement") with Graviton, Inc. ("Graviton"), granting the Company an exclusive period of time to negotiate a license to certain technologies licensed to and/or developed by Graviton. In exchange for the Agreement, the Company advanced to Graviton through a secured loan the sum of \$500,000. In May 1999, the Company advanced to Graviton through a secured loan an additional \$500,000, the proceeds of which were to be used by Graviton in part to secure additional intellectual property rights which the Company could license. In December 1999, the Company entered into a Collaboration and License Agreement with Graviton. Pursuant to this agreement, the total loans of \$1.0 million, plus accrued interest, were exchanged for a warrant for 23,076 shares of Graviton Series B Preferred Stock with a per share exercise price of \$1.00 and two technology licenses to certain intellectual property licenses provided to Graviton by third parties. The Company recognized the value of such licenses as "acquired technology rights" in the accompanying consolidated balance sheets that totaled approximately \$603,000 as of December 31, 2001.

In July 2002, the Company entered into an agreement with Graviton, Inc. to terminate and release ("the July 2002 Release") Nanogen and Graviton of their obligations under the Collaboration and License Agreement dated December 15, 1999. The Company received compensation from Graviton for termination of this arrangement in the form of 50,000 shares of Graviton Series D-Prime Preferred Stock and a waiver of the exercise price of \$1.00 per share for a warrant to purchase 23,076 shares of Graviton Series B Preferred Stock, which was exercised in July 2002.

In September 2002, Graviton commenced a recapitalization and a new round of financing. In exchange for Nanogen's consent for the recapitalization and new round of financing, Graviton also issued to Nanogen a ten year warrant to purchase 440,000 shares of Series 1 Preferred Stock at a price of \$2 per share, the price at which the September 2002 financing was completed. As Graviton is privately-held and currently does not maintain a market for its stock, the fair value of these securities could not be determined. As a result of the termination of the collaboration agreement, the Company recorded a loss of approximately \$452,000 (the remaining carrying value of the acquired technology rights obtained in 1999) for the three month period ended September 30, 2002.

Mr. Birndorf, Chairman of the Board and an officer of the Company, is also a director of and investor in Graviton. Mr. Birndorf held an approximate 10% ownership interest in Graviton as of September 30, 2002 and an approximate 3.5% ownership interest as of October 31, 2002 after Graviton's recapitalization and additional financing. Mr. Buonaiuto, a director of the Company, held less than 1% ownership interest in Graviton as of September 30, 2002 and as of October 31, 2002. Given the interrelationship among the parties, the Company's Board appointed a committee of disinterested Board members to evaluate these transactions with Graviton. After full disclosure of the above-referenced interrelationships, the Committee determined that it was in the best interest of the Company to enter into the license agreement which was executed on December 15, 1999, and the subsequent July 2002 Release and September 2002 Settlement Agreement.

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### 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, 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," "potentially," variations of such words and similar expressions are intended to identify such forward-looking statements. Factors that could cause or contribute to these differences include those discussed below under the caption "Factors that May Affect Results" and elsewhere in this Quarterly Report on Form 10-Q and which are described in our Annual Report on Form 10-K for the year ended December 31, 2001. 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

It is our goal to become a leading provider of molecular diagnostic tests. We integrate advanced microelectronics and molecular biology into a core technology platform with potentially broad and diverse commercial applications. Our primary areas of focus have been in genomics and biomedical research, medical diagnostics, forensics and drug discovery. The first application we have developed, the NanoChip® System, is an integrated bioassay system consisting of the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge. The NanoChip® Workstation is comprised of two automated instruments and the NanoChip® Cartridge, a consumable cartridge, which incorporates a proprietary microchip (the "NanoChip® Electronic Microarray"). The NanoChip® System provides a flexible tool for the rapid identification and precision analysis of biological test samples containing charged molecules.

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, 2002, had an accumulated deficit of \$147.5 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.

While we recognized revenue from product sales during the years ended December 31, 2001 and 2000, our main sources of revenues during these fiscal years were payments under our sponsored research agreements, contracts and grants. However, during the three and nine months ended September 30, 2002 our revenue base has begun to shift from primarily sponsored research revenues to product revenues. We anticipate that this shift in our revenue base will continue as we introduce new products to the marketplace and if our instrument and consumable revenues grow. We offer our Workstations to customers under various commercial programs as a method of expanding our installed base to further increase our consumable revenue. As we are still in the early stage of commercialization, we maintain limited data to provide qualitative sales trends under these programs. 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, 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. 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 judgements, including those related to bad debts, inventories, investments, intangible assets, service obligations and contingencies. We base our estimates and judgements 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 judgements and estimates used in the preparation of our consolidated financial statements:

#### *Revenue recognition*

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We generate product revenue by the sale of our commercial products and services under various sales programs to the end user or through distribution channels. We recognize revenue in accordance with SAB 101 "Revenue Recognition in Financial Statements" and record as follows:

We offer our NanoChip® Molecular Biology Workstations under various commercial programs such as; direct sale, reagent rental, and cost-per-reportable agreements. We also offer our Workstations to customers under development site programs that may result in one of the above commercial transactions. We sell our Workstations direct to the end user and to distributors. Revenue from the sale of consumables is recognized upon shipment (f.o.b. shipping point) as we do not sell consumables with a right of return. Warranty revenue is recognized ratably over the period of coverage.

Revenue from the direct sale of NanoChip® Molecular Biology Workstations is 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. We provide for the estimated cost of product warranty at the time revenue is recognized.

We also recognize revenue from the sale of our NanoChip® System under reagent rental and cost-per-reportable transactions whereby customers pay a premium for our consumable products (NanoChip® Cartridges or ASR's) 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. 50 cartridges a month for 3 years). Revenue for the Workstation, consumables and warranty under reagent rental transactions is recognized as consumable products are shipped, over a period of generally two to five years, depending on the specific customer arrangement as they may vary by customer. We reclass 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. Under a cost-per-reportable transaction, the customer agrees to purchase a certain number of

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consumable products on a periodic basis determined by the customer's volume of reported test results (to third parties) from the use of our consumable products. We recognize revenue under this type of transaction at the time we receive evidence of the customer's test results reported to third parties. Under these arrangements, we provide product warranty coverage for the Workstation over the period of the contract. Under both of these sale transactions, the fair value of the warranty is recognized ratably over the warranty period included in the customer contract. The cost of sales related to the consumables is recorded in line with the revenue (i.e. as consumables are shipped or consumed, depending on the terms of the contract).

We also place our 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 nine and twelve months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that we 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. We provide a warranty for these NanoChip® Workstations as well as insure 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 us during the development site period. We classify this inventory as consignment inventory and include this within finished goods. We record a reserve for the refurbishment costs, recorded within SG&A, for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. This reserve totaled approximately \$426,000 and \$303,000 at September 30, 2002 and December 31, 2001, respectively and is included in accrued liabilities. In addition, we have recorded a reserve related to the older production units that may be deemed obsolete or sold to the customer at a discount due to the age of the unit during the development site period. Transactions under these types of programs do not result in the recognition of revenue, however, if the customer opts to purchase the NanoChip® Workstation at any time, sales revenue is recognized upon receipt of a purchase order. Cost of sales for the Workstation is provided for at the time revenue is recognized. For the three and nine months ended September 30, 2002, we converted two and six development site agreements, respectively. There were no development site agreement conversions during the three and nine months ended September 30, 2002.

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 (but not below the cost of manufacturing the instrument) and without warranty coverage. The shipments are made to distributors at the time the distributor has identified a third party customer.

Sales revenue is subject to fluctuation due to the type of acquisition program our customers may choose. 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 and contracts and grants are dependent upon our achieving specific contractual milestones.

*Bad debts*

We maintain reserves for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. 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.

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*Inventory*

We reduce the carrying value of our inventory, including NanoChip® Molecular Biology Workstations placed under Development Site arrangements (consigned inventory), for estimated obsolescence or non-marketability based upon assumptions about future demand, supply, market conditions and new product introductions. We often rely on our own and third party forecasted demand for various of our products and the accuracy of such forecasts may depend on a number of factors, including but not limited to, government reports and recommendations for certain genetic testing, regulatory burdens, competitive products, the nature and effectiveness of our products, the timing and extent of the introduction of our products into the marketplace and other factors. If actual demand, supply or market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

*Intangible Assets*

We have capitalized the costs related to acquired technology rights, such as rights to specific genetic markers, as intangible assets. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances.

**Results of Operations**

**Product Revenues.** For the three and nine months ended September 30, 2002 sales totaled \$1.0 million and \$2.9 million, respectively, compared to \$1.0 million and \$1.6 million for the three and nine months ended September 30, 2001, respectively. Sales revenue during the three months ended September 30, 2002 included the sale of six NanoChip® Molecular Biology Workstations as well as sales of NanoChip® Cartridges, reagents and warranty revenue. Sales revenue for the nine months ended September 30, 2002 included the sale of nineteen NanoChip® Molecular Biology Workstations, royalty revenue earned in connection with two NanoChip® Workstations which were sold in Japan by our distributor, Hitachi, Ltd., sales of NanoChip® Cartridges, reagents and warranty revenue. Sales revenue during the three months ended September 30, 2001 included the sale of seven NanoChip® Molecular Biology Workstations under outright sales transactions as well as sales of NanoChip® Cartridges and warranty revenue. For the nine months ended September 30, 2001, sales revenue included sales of ten NanoChip® Molecular Biology Workstations in addition to sales of NanoChip® Cartridges and warranty revenue. All revenue recorded related to sales of our NanoChip® Molecular Biology Workstation resulted from outright sales transactions where title of the instrument passed to the customer. We offer our 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 sales revenue may vary from year to year due to, among other things, the types of acquisition programs our potential customers may choose.

**Sponsored Research.** For the three and nine months ended September 30, 2002 revenues from sponsored research totaled \$354,000 and \$980,000, respectively, compared to \$1.9 million and \$6.2 million for the three and nine months ended September 30, 2001, 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, 2002, represents revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. Sponsored research revenue recognized during the three and nine months ended September 30, 2001, was primarily earned in connection with our two technology development programs under our research and development agreement entered into in September 1999 with Aventis, including the sale of two NanoChip® Molecular Biology Workstations to one of the Aventis programs, as well as revenue earned

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in connection with our development agreement with Hitachi. We are currently on schedule with project milestones with the Hitachi development agreement and expect to continue to receive funding under this collaboration pursuant to terms of the agreement.

Project milestones established under the research and development agreement entered into in September 1999 with Aventis were completed as of December 31, 2001 at which time the agreements expired. We do not expect to receive additional funding from Aventis under these programs.

**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.

**Cost of Product Sales and Gross Margins.** Cost of product sales totaled \$687,000 and \$2.1 million for the three and nine months ended September 30, 2002, respectively, compared to \$727,000 and \$1.1 million for the three and nine months ended September 30, 2001, respectively. Gross margins on sales revenue were 28% for the three and nine months ended September 30, 2002, compared to 29% and 28% for the three and nine months ended September 30, 2001, respectively. Cost of product sales during these periods were adversely impacted by underabsorbed overhead costs due to underutilized capacity. The cost per unit of our products remains high, as our volume of production relative to the available capacity remains low. 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 2002. In addition to underabsorbed overhead costs, cost of sales was further impacted by a reserve for obsolete inventory totaling \$6,000 and \$28,000 for the three and nine months ended September 30, 2002, respectively and \$89,000 and \$109,000 for the three and nine months ended September 30, 2001. This reserve relates primarily to excess instrument parts in our inventory as of September 30, 2002 and 2001 that could potentially become obsolete prior to their consumption. If necessary, these parts will be used as replacement parts for Nanogen Systems located both internally and at customer sites. Gross margins during these periods were further impacted by sales of NanoChip® Workstations to certain customers under various discount programs and by sales to distributors, which are generally at a discount. Gross margins in future periods may additionally be impaired by minimum product royalties or potential adjustments made to reflect the impairment of intangible assets related to products sold.

**Research and Development Expenses.** For the three and nine months ended September 30, 2002, research and development expenses totaled \$5.8 million and \$15.7 million, respectively, compared to \$4.8 million and \$14.0 million for the three and nine months ended September 30, 2001, respectively. 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, 2002 research and development activities primarily related to the development of new Analyte Specific Reagents ("ASR's"). In addition, research and development expenses includes approximately \$452,000 of costs related to the impairment of acquired technology in conjunction with the termination of our collaboration agreement with Graviton (see footnote 3) which was recorded during the three months ended September 30, 2002. The increase in research and development costs for the nine months ended September 30, 2002 when compared to the same period in 2001, is primarily a result of increased expenses relating to ASR assay development and design. We anticipate that we will continue to invest in research and product development at approximately this same level or potentially higher levels for the foreseeable future.

**Selling, General and Administrative Expenses.** For the three and nine months ended September 30, 2002, selling, general and administrative expenses totaled \$5.4 million and \$15.3 million,

respectively, compared to \$6.1 million and \$16.0 million for the three and nine months ended September 30, 2001, respectively. 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. Selling, general and administrative expenses are expected to continue at the current level for the foreseeable future as we continue to market and sell our current and potential future products.

**Litigation and Settlement of Patent Matter, Net.** For the three and nine months ended September 30, 2002, net litigation and settlement of patent matter benefits totaled \$963,000 and \$165,000 of income, respectively, compared to net expenses of \$263,000 and \$6.8 million for the three and nine months ended September 30, 2001, respectively. In September 2002, we entered into a settlement agreement with CombiMatrix and Dr. Montgomery concluding their pending litigation in the U.S. District Court for the Southern District of California. According to terms of the agreement, CombiMatrix is obligated to make cash payments to us totaling \$1.0 million that was accrued during the three month period ended September 30, 2002 net of costs incurred to defend our technology rights related to this case totaling \$337,000 and \$1.1 million for the three and nine months ended September 30, 2002, respectively, (see footnote 6 for further details and additional forms of compensation). In July 2001, a settlement agreement was reached with Motorola, Genometrix, and the MIT concluding the declaratory judgment action by us against Motorola, Genometrix and MIT as well as Motorola's counterclaim against us. In connection with the settlement, we paid a total of



\$5.0 million to the parties in the form of \$2.5 million in cash and 416,666 shares of our common stock (valued at approximately \$2.5 million based upon a per share price of \$6.00, the fair market value on the date of settlement). Amounts included for the three and nine months ended September 30, 2001 represent fees associated with the litigation and settlement of this matter. As a settlement was reached in July 2001, there were no expenses related to this matter in 2002.

**Interest Income, Net.** For the three and nine months ended September 30, 2002, net interest income totaled \$488,000 and \$1.8 million, respectively, compared to \$1.0 million and \$3.4 million for the three and nine months ended September 30, 2001, respectively. The decrease in net interest income is a result of lower average cash balances as well as lower yields on outstanding cash balances during the three and nine months ended September 30, 2002 compared to the same periods in 2001.

**Minority Interest in Loss of Consolidated Subsidiary.** For the three and nine months ended September 30, 2002, minority interest in loss of consolidated subsidiary totaled \$651,000 and \$1.6 million, respectively, compared to \$485,000 for the three and nine months ended September 30, 2001. In June 2001, we entered into agreements with 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 us and forty percent owned by Aventis. As Nanogen Recognomics was created in June 2001, the loss for the three and nine months ended September 30, 2001 reflects the early stages of operations for Nanogen Recognomics when compared to the same periods in 2002.

### Liquidity and Capital Resources

At September 30, 2002, we had \$46.4 million in cash, cash equivalents and short-term investments, compared to \$67.5 million at December 31, 2001. The decrease is primarily due to cash used in operations during the nine months ended September 30, 2002.

Net cash used in operating activities was \$20.7 million and \$25.9 million for the nine months ended September 30, 2002 and 2001, respectively. Cash used for operations during the nine months ended September 30, 2002 was primarily related to costs associated with the support of our sales and marketing organization as we continue to market our existing and potential new products, support of

our continuing research and development efforts including development of the Factor V Leiden ASR, Cystic Fibrosis ASR, the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd. and legal fees relating to establishing, maintaining and defending our intellectual property portfolio.

Net cash provided by investing activities was \$22.4 million for the nine months ended September 30, 2002 compared to cash used by investing activities totaling \$19.8 million for the nine months ended September 30, 2001. We purchase short-term investments in order to enhance the yield on our cash balances. These securities mature from time to time or are sold to fund operating expenses. For the nine months ended September 30, 2001, we maintained high average cash balances resulting in increased activity in the purchase of short-term securities. For the nine months ended September 30, 2002, these securities have matured or have been sold to fund operations. In addition, we purchase license rights to technology that is used in the development and manufacturing of our potential new products.

We funded most of our equipment acquisitions and leasehold improvements through capital leasing facilities in previous years and plan to continue this practice in the future. Currently, our existing financing sources are fully utilized and we are in the process of negotiating new equipment lease facilities.

Our manufacturing agreement with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip® Molecular Biology Workstations. As of September 30, 2002, we had commitments to purchase approximately \$2.7 million in NanoChip® Workstations through March 31, 2003. At September 30, 2002, the inventory under our purchase commitment with Hitachi is within our expected usage levels based upon our current and estimated future demands.

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-reportable 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. The four cost-per-reportable transactions entered into in the third quarter of 2002 require customer acceptance of our Cystic Fibrosis ASR as a pre-condition to this commitment. These reagent rentals and

cost-per-reportable 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. 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 the NanoChip® System, 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 at our current rate of expenditures. 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 and to enter into additional collaborative arrangements. We have incurred negative cash flow from operations since inception and do not expect to generate positive cash flow to fund our

operations for at least the next several years. We may need to raise additional capital to fund our research and development programs, to scale-up manufacturing activities and expand our sales and marketing efforts to support the commercialization of our products under development. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, we may be required to curtail 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**

##### ***Our products may not be successfully developed or commercialized, which would harm us and force us to curtail or cease operations.***

We are at an early stage of development. We currently have only three products for sale: our NanoChip® Molecular Biology Workstation, our NanoChip® Cartridge and one Analyte Specific Reagent ("ASR") for Factor V Leiden. All of our other potential products are under development. Our NanoChip® System or our other products may not be successfully developed or commercialized on a timely basis, or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of our new products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

We introduced our first two products into the marketplace in 2000 and our third product in March 2002. As of September 30, 2002 we have sold a total of forty-five NanoChip® Systems. We also place instruments at various customer sites under Development Site Agreements whereby title of the NanoChip® Molecular Biology Workstation does not pass to the customer and therefore no revenue is recognized. As of September 30, 2002, we have not yet recognized any revenue from the sale of the ASRs for Factor V Leiden and for Cystic Fibrosis.

We are also party to transactions known as reagent rentals and cost-per-reportable agreements. As of September 30, 2002, we entered into three reagent rental agreements and four cost-per-reportable 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. The four cost-per-reportable transactions entered into in the third quarter of 2002 require customer acceptance of our Cystic Fibrosis ASR as a pre-condition to this commitment. These reagent rentals and cost per reportable 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.***

We may not be able to develop 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

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inventory to its net realizable value. 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.

***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 or we may not derive any revenue or other benefits from these arrangements.

We have collaborative agreements with a developer and manufacturer of instrumentation products and we formed a new company with the research and development subsidiary of a pharmaceutical company. We do not know whether these 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. 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 currently have agreements with Hitachi that contemplate the commercialization of products resulting from the agreements between the parties. In addition, we have a manufacturing and distribution agreement with Hitachi. In June 2001 we formed a 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. These collaborations may not be successful.

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

We began selling our first two products in the second quarter of 2000 and our third product in March 2002, but we did not sell significant quantities of our first products during fiscal 2000, 2001 or during the nine months ended September 30, 2002. From our inception to September 30, 2002, we have incurred cumulative net losses totaling approximately \$147.5 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, some of which could be significant. The amount and timing of product revenue recognition may depend on whether potential customers for the NanoChip® System choose to enter into sales, reagent rentals, cost-per-reportable or development site transactions.

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

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We may need to raise more money to continue the research and development necessary to bring our products to market and to establish 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 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 QSR regulations, 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 may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

### ***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;

diagnostic and pharmaceutical companies;

companies developing drug discovery technologies; and

companies developing molecular 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.

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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 FDA approval or marketing technologies or products that are more effective or commercially attractive than our potential products, or that render our technologies and 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.***

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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 management personnel. We may in the future become subject

to USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.

We are aware of U.S. and European patents and patent applications owned by Oxford Gene Technology ("OGT"). We have opposed one allowed European Patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. OGT'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 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 OGT and the original claims are reinstated, or if an application relating to arrays issued in another country with claims as broad as the original European patent, we would be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

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

We anticipate that the manufacturing, labeling, distribution and marketing of any potential 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;

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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 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 products under development. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of proposed products. Regulatory clearance or approval of any proposed products may not be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Noncompliance with applicable FDA requirements can result in:

criminal prosecution, civil penalties, other administrative sanctions, or judicially imposed sanctions such as injunctions;

recall or seizure of products;

total or partial suspension of production; and

failure of the government to grant premarket clearance or premarket approval for devices or withdrawal of marketing clearances or approvals once granted.

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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.

***We depend on suppliers for materials that could impair our ability to manufacture our products.***

Outside vendors provide key components and raw materials used by us and Hitachi 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. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or Hitachi or incompatible with our or Hitachi's manufacturing processes, could harm our or Hitachi's ability to manufacture products. We or Hitachi 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 or Hitachi fail to obtain a supplier for the manufacture of components of our potential products, we may be forced to curtail or cease operations.

***We may not be able to manufacture products on a commercial scale.***

Hitachi manufactures our NanoChip® System and we manufacture our NanoChip® Cartridges and Factor V ASR. We and Hitachi 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 or Hitachi either alone, together or with subcontractors, attempt to scale up manufacturing procedures. We or Hitachi 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.

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We or Hitachi or any of our contract manufacturers could encounter manufacturing difficulties, including:

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 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 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 analyte specific reagents will be manufactured and introduced by us based on forecasted demand and will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and

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

***We currently rely on one manufacturer of our Workstation and for certain future generations of the Workstation and other hardware products, and only we manufacture our NanoChip® Cartridges, and Factor V ASR, which may delay the manufacture and shipment of our products to customers.***

We have signed an exclusive manufacturing agreement with Hitachi to manufacture our NanoChip® Workstation and a collaboration agreement to exclusively manufacture certain of our other second generation Workstations and other hardware products to be developed, subject to certain terms and conditions in each agreement. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreement 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.***

At September 30, 2002, we had thirty-one employees in our sales and marketing group. In addition, in July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At September 30, 2002, this office employed eleven European-based sales executives and support personnel in the United Kingdom, Germany, The Netherlands and Denmark.

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Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by Nanogen and certain of its 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 ASR's or other products. Nanogen may be required to increase or decrease the size of this sales and marketing force as deemed necessary and such increases or decreases in staff will require additional capital and time expenditures by Nanogen and its 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.

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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, ASR's and other products in foreign countries;

licenses, tariffs and other trade barriers;

political and economic instability;

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 US dollar and the currencies in which we do business will cause foreign currency transaction gains and losses. We cannot predict the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We currently do not engage in foreign exchange hedging transactions to manage our foreign currency exposure.

***We may have significant product liability exposure.***



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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. We may not be able to obtain insurance for such potential liability on acceptable terms with adequate coverage, or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance, once obtained, may not be renewed at a cost and level of coverage comparable to that then in effect.

***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 nine months ended September 30, 2002 the rate of turnover at all levels of the Company was 24%. For the years ended December 31, 2001 and 2000 the turnover rates of the Company were 31% and 19%, respectively. Turnover at these rates may, and if they continue, adversely affect the Company.

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In October 2002, the Company reduced its workforce by approximately 10%. A one-time severance charge of approximately \$300,000 will be recognized in the fourth quarter of fiscal 2002 related to this event. Continued layoffs could have an adverse effect on the Company.

***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.

***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.***

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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.

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***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, ASR's 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 and other stocks in general;

purchases by the Company pursuant to the stock repurchase program; and

changes in estimates of our performance by securities analysts.

***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 by our board of directors and may have the effect of deterring hostile takeover attempts.

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***If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.***

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. We currently have no commitments or agreements with respect to any material acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired business, technology, service or product may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to certain intangible assets, which could adversely affect our results of operations and financial condition.

### **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 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 Netherlands and German subsidiaries is the U.S. dollar and euro, respectively. The German subsidiary's accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. The net tangible assets of our subsidiaries, excluding intercompany balances, is \$2.1 million at September 30, 2002.

### **Item 4. Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act Filings and Reports is recorded, processed, summarized and reported within the timelines specified in the Security and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Executive Chairman who functions as our chief executive officer ("Chief Executive Officer") and Chief Financial Officer, to allow timely disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that, as of the date of their evaluation, our disclosure controls and procedures were effective.

There have been no significant changes in our internal controls or in other factors that could significantly affect these controls subsequent to the date we carried out this evaluation.

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## PART II OTHER INFORMATION

### Item 1. Legal Proceedings

Please see discussion of legal proceedings at note 6 in the Notes to the Consolidated Financial Statements included elsewhere in this report.

### Item 6. Exhibits and Reports on Form 8-K

(a)  
Exhibits

- 10.1 Settlement Agreement, dated September 30, 2002 by and between the Company, CombiMatrix Corporation and Dr. Donald Montgomery
- 99.1 Chief Executive Officer and Chief Financial Officer Certification Letter, dated November 13, 2002

(b)  
Reports on Form 8-K

There were no reports on Form 8-K filed during the three months ended September 30, 2002.

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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 13, 2002 /s/ Howard C. Birndorf

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Howard C. Birndorf  
*Chairman of the Board and Executive  
Chairman*  
(Principal Executive Officer)

Date November 13, 2002 /s/ Gerard A. Wills

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Gerard A. Wills  
*Vice President, Chief Financial Officer  
and Treasurer*  
(Principal Financial and Accounting  
Officer)

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#### Chief Executive Officer Certification

I, Howard C. Birndorf, Chairman of the Board and Executive Chairman of Nanogen, Inc. certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Nanogen, Inc. (the "registrant");

(2) Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

(3) Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

(4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-14 and 15D-14) for the registrant and have:

(i) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

(ii) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Quarterly Report (the "Evaluation Date"); and

(iii) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):

(i) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

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(6) The registrant's other certifying officers and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated November 13, 2002

/s/ Howard C. Birndorf

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Howard C. Birndorf  
Chairman of the Board and  
Executive Chairman of Nanogen, Inc.  
(Principal Executive Officer)

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### Chief Financial Officer Certification

I, Gerard A. Wills, Vice President, Chief Financial Officer and Treasurer of Nanogen, Inc. certify that:

(1) I have reviewed this Quarterly Report on Form 10-Q of Nanogen, Inc. (the "registrant");

(2) Based on my knowledge, this Quarterly Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Quarterly Report;

(3) Based on my knowledge, the financial statements, and other financial information included in this Quarterly Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Quarterly Report;

(4) The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-14 and 15D-14) for the registrant and have:

(i) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Quarterly Report is being prepared;

(ii) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Quarterly Report (the "Evaluation Date"); and

(iii) presented in this Quarterly Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):

(i) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

(6) The registrant's other certifying officers and I have indicated in this Quarterly Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated November 13, 2002

/s/ Gerard A. Wills

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Gerard A. Wills  
Vice President, Chief Financial Officer and  
Treasurer of Nanogen, Inc.  
(Principal Financial and Accounting Officer)

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**NANOGEN, INC.  
EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
10.1	Settlement Agreement, dated September 30, 2002 by and between the Company, CombiMatrix Corporation and Dr. Donald Montgomery
99.1	Chief Executive Officer and Chief Financial Officer Certification Letter, dated November 13, 2002

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