

NANOGEN INC  
Form 10-Q  
November 14, 2003  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2003

OR

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

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

Commission File Number 000-23541

**NANOGEN, INC.**

(Exact name of Registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

33-0489621  
(I.R.S. Employer Identification No.)

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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  NO

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of November 13, 2003, 24,380,010 shares of the Registrant's Common Stock were outstanding.

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**NANOGEN, INC.**

**FORM 10-Q**

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**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****NANOGEN, INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share data)

	September 30, 2003	December 31, 2002
	<u>          </u>	<u>          </u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,767	\$ 9,353
Short-term investments	19,787	43,376
Receivables, net	1,696	1,754
Inventories, net	4,972	4,717
Other current assets	1,309	1,781
	<u>          </u>	<u>          </u>
Total current assets	40,531	60,981
Property and equipment, net	4,922	4,982
Acquired technology rights, net	2,761	4,544
Other assets, net	564	789
Restricted cash	14	64
	<u>          </u>	<u>          </u>
	\$ 48,792	\$ 71,360
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 390	\$ 753
Accrued liabilities	4,017	5,901
Deferred revenue	914	472
Current portion of capital lease obligations	835	805
	<u>          </u>	<u>          </u>
Total current liabilities	6,156	7,931
Capital lease obligations, less current portion	675	1,134
Other long-term liabilities	3,841	3,085
	<u>          </u>	<u>          </u>
Total long-term liabilities	4,516	4,219
Minority interest in consolidated subsidiary	223	1,817
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2003 (unaudited) and December 31, 2002		
Common stock, \$0.001 par value, 50,000,000 shares authorized; 24,380,010 and 21,981,115 shares issued and outstanding at September 30, 2003 (unaudited) and December 31, 2002, respectively	24	22
Additional paid-in capital	207,336	199,483
Accumulated other comprehensive income	1,904	4,926

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Deferred compensation	(134)	(156)
Notes receivable from officers		(513)
Accumulated deficit	(170,311)	(145,659)
Treasury stock, at cost, 500,189 and 366,857 shares at September 30, 2003 (unaudited) and December 31, 2002, respectively	(922)	(710)
	<u>          </u>	<u>          </u>
Total stockholders' equity	37,897	57,393
	<u>          </u>	<u>          </u>
	\$ 48,792	\$ 71,360
	<u>          </u>	<u>          </u>

See accompanying notes

**Table of Contents****NANOGEN, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)****(in thousands, except per share data)**

	<b>Three months ended</b>		<b>Nine months ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
<b>Revenues:</b>				
Product sales	\$ 752	\$ 957	\$ 1,642	\$ 2,873
License fees	46		46	
Sponsored research	375	354	1,125	980
Contracts and grant	568	240	1,822	1,182
<b>Total revenues</b>	<b>1,741</b>	<b>1,551</b>	<b>4,635</b>	<b>5,035</b>
<b>Operating expenses:</b>				
Cost of product sales	1,370	687	2,168	2,080
Research and development	4,280	5,328	13,473	15,220
Selling, general and administrative	3,336	5,428	11,532	15,346
Impairment of acquired technology rights	1,024	452	1,024	452
Litigation and settlement of patent matter	149	(963)	149	(165)
<b>Total operating expenses</b>	<b>10,159</b>	<b>10,932</b>	<b>28,346</b>	<b>32,933</b>
<b>Loss from operations</b>	<b>(8,418)</b>	<b>(9,381)</b>	<b>(23,711)</b>	<b>(27,898)</b>
Interest income, net	97	488	405	1,834
Other income	(46)	18	(19)	153
Gain (loss) on sale of investments	778		(2,790)	
Gain (loss) on sale of fixed assets	22		(131)	
Minority interest in loss of consolidated subsidiary	488	651	1,594	1,634
<b>Net loss</b>	<b>\$ (7,079)</b>	<b>\$ (8,224)</b>	<b>\$ (24,652)</b>	<b>\$ (24,277)</b>
<b>Net loss per share basic and diluted</b>	<b>\$ (0.33)</b>	<b>\$ (0.38)</b>	<b>\$ (1.14)</b>	<b>\$ (1.12)</b>
<b>Number of shares used in computing net loss per share basic and diluted</b>	<b>21,781</b>	<b>21,923</b>	<b>21,652</b>	<b>21,732</b>

See accompanying notes.



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

	<b>Nine months ended September 30,</b>	
	<b>2003</b>	<b>2002</b>
<b>Operating activities:</b>		
Net loss	\$ (24,652)	\$ (24,277)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,256	3,067
Asset impairment and other non-cash charges	1,029	452
Loss on disposal of fixed assets	131	
Amortization related to short-term investments	169	44
Stock-based compensation expense	152	64
Interest capitalized on notes receivables from officers		(43)
Minority interest in loss of consolidated subsidiary	(1,594)	(1,634)
Loss (gain) on sale of short-term investments	2,790	(182)
Changes in operating assets and liabilities:		
Receivables	58	2,984
Inventories	(796)	(926)
Other assets	471	(744)
Accounts payable	(363)	(344)
Accrued liabilities	(1,263)	528
Deferred revenue	442	340
<b>Net cash used in operating activities</b>	<b>(20,170)</b>	<b>(20,671)</b>
<b>Investing activities:</b>		
Purchase of short-term investments	(12,856)	(12,303)
Proceeds from sale and maturities of short-term investments	30,270	35,686
Purchase of equipment	(1,139)	(131)
Proceeds on disposal of equipment	42	
Purchase of patents and technology rights	(3)	(835)
<b>Net cash provided by investing activities</b>	<b>16,314</b>	<b>22,417</b>
<b>Financing activities:</b>		
Principal payments on capital lease obligations	(594)	(1,108)
Proceeds from development partner	749	1,373
Proceeds from restricted cash balances	50	235
Issuance of common stock, net of repurchases	6,869	313
<b>Net cash provided by financing activities</b>	<b>7,074</b>	<b>813</b>
Effect of exchange rate changes	196	326
<b>Net increase decrease in cash and cash equivalents</b>	<b>3,414</b>	<b>2,885</b>



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Cash and cash equivalents at beginning of period	9,353	10,455
Cash and cash equivalents at end of period	<u>\$ 12,767</u>	<u>\$ 13,340</u>
<b>Supplemental disclosure of cash flow information:</b>		
Interest paid	<u>\$ 136</u>	<u>\$ 140</u>
<b>Supplemental schedule of noncash investing and financing activities:</b>		
Equipment acquired under capital leases	<u>\$ 164</u>	<u>\$ 435</u>
Inventory transferred to fixed assets	<u>\$ 541</u>	<u>\$ 1,007</u>
Unrealized loss on short-term investments	<u>\$ 3,216</u>	<u>\$ 783</u>
Accrued fee for purchase of technology rights	<u>\$</u>	<u>\$ 225</u>
Warrant accrued for research and development collaboration	<u>\$ 700</u>	<u>\$</u>
Acquisition of treasury stock in exchange for cancellation of officer note receivable	<u>\$ 212</u>	<u>\$</u>
Equity instruments issued in connection with employee benefit plan, non-employees services, and purchase of license rights, net	<u>\$ 121</u>	<u>\$ 988</u>
Repayment of note receivable	<u>\$ 300</u>	<u>\$</u>

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**NANOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**September 30, 2003**

**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, 2003, consolidated statements of operations for the three and nine months ended September 30, 2003 and 2002, and the consolidated statements of cash flows for the nine months ended September 30, 2003 and 2002 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, 2003 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2003.

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, 2002 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2002, filed with the Securities and Exchange Commission.

***Use of Estimates***

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

***Net Loss per Share***

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net income (loss) per share is computed by dividing the net income (loss) available to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period and in the periods they are dilutive, common equivalent shares for outstanding stock options and warrants computed using the treasury stock method. The weighted average common shares outstanding during the period does not include those shares issued pursuant to the exercise of stock options prior to vesting and shares issued under the Company's 401K benefit plan prior to vesting. In loss periods, common stock equivalents are excluded from the computation of diluted net loss per share as their effect would be anti-dilutive.

***Recent Accounting Pronouncements***

In December 2002, the FASB issued Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method on reported results. The adoption of any transition alternative to changes to the fair value based method of accounting for stock-based compensation will have a material impact on the Company's consolidated results of operations.

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## NANOGEN, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

September 30, 2003

*Stock-Based Compensation*

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

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

	Three months ended September 30,		Nine months ended September 30,	
	(unaudited)		(unaudited)	
	2003	2002	2003	2002
Net loss:				
As reported	\$ (7,079)	\$ (8,224)	\$ (24,652)	\$ (24,277)
Stock-based compensation expense under fair value based method	(1,345)	(1,671)	(3,329)	(5,120)
Pro forma net loss	\$ (8,424)	\$ (9,895)	\$ (27,981)	\$ (29,397)
Loss per common share:				
As reported	\$ (0.33)	\$ (0.38)	\$ (1.14)	\$ (1.12)
Pro forma	\$ (0.39)	\$ (0.45)	\$ (1.29)	\$ (1.35)

The pro forma effect on net loss for the three and nine months ended September 30, 2003 and 2002, respectively, is not necessarily indicative of potential pro forma effects on results for future years.

*Warranty*

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The Company provides product warranty coverage under direct sale and reagent rental transactions of NanoChip® Molecular Biology Workstations. Additionally, the Company provides warranty coverage on products that are placed at customer sites under programs such as development site arrangements. A liability is recorded at the time products are shipped. Changes in the Company's warranty liability were as follows (in thousands):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>(unaudited)</b>		<b>(unaudited)</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
Balance at beginning of period	\$ 237,000	\$ 248,000	\$ 190,000	\$ 142,000
Warranty additions	153,000	83,000	334,000	357,000
Cash payments	(187,000)	(39,000)	(321,000)	(207,000)
Balance at end of period	<b>\$ 203,000</b>	<b>\$ 292,000</b>	<b>\$ 203,000</b>	<b>\$ 292,000</b>

### *Reclassification*

Certain prior period amounts have been reclassified to conform to current period presentation. For the three and nine months ended September 30, 2002, \$452,000 in expense has been reclassified from research and development to impairment of acquired technology rights.

**Table of Contents****NANOGEN, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(unaudited)****September 30, 2003****2. Inventories**

Inventories consist of the following (in thousands):

	<b>September 30, 2003</b>	<b>December 31, 2002</b>
	<u>                    </u>	<u>                    </u>
	<b>(unaudited)</b>	
Raw materials	\$ 1,356	\$ 1,062
Work in process	1,329	1,485
Finished goods	4,808	4,428
	<u>                    </u>	<u>                    </u>
	7,493	6,975
Reserve for excess and obsolete	(2,521)	(2,258)
	<u>                    </u>	<u>                    </u>
	<b>\$ 4,972</b>	<b>\$ 4,717</b>
	<u>                    </u>	<u>                    </u>

Finished goods includes \$2.2 million and \$3.2 million of NanoChip<sup>®</sup> Molecular Biology Workstations ( NanoChip<sup>®</sup> Workstations ) at September 30, 2003 and December 31, 2002, 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<sup>®</sup> Workstation is placed at a customer site for a period normally between six and twelve months for the purpose of developing content and optimizing assays which may result in the creation or enhancement of intellectual property that the Company may license in the future. The customer has the option to purchase the NanoChip<sup>®</sup> Workstation during the period of the arrangement or at its expiration. The Company provides warranty for these NanoChip<sup>®</sup> Workstations as well as insures them during the development site period. Development site customers are normally required to purchase any cartridges to be used on the instrument from the Company during the development site period. As of September 30, 2003, the Company had a total of 22 NanoChip<sup>®</sup> Workstations under agreements whereby the Company retains title to the Workstation. The Company classifies this inventory as consignment inventory and includes this within finished goods. The Company accrues refurbishment costs for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. This reserve totaled \$372,000 and \$489,000 at September 30, 2003 and December 31, 2002, respectively. In addition, the Company has recorded a reserve related to the older production units that may be deemed obsolete or may be sold to the customer at a discount due to the depreciation of the unit during the development site period. This reserve totaled \$962,000 at September 30, 2003 and \$1.6 million at December 31, 2002.

The Company's manufacturing agreement with Hitachi, Ltd. ( Hitachi ) requires that the Company provide annual purchase commitments to Hitachi for NanoChip<sup>®</sup> Workstations. As of September 30, 2003, the Company had commitments to purchase approximately \$204,000 in NanoChip<sup>®</sup> Workstations from Hitachi for shipments of product through December 31, 2003. A reserve of \$118,000 recorded during the three months ended September 30, 2003 relating to this purchase commitment is included as a reduction of inventory as of September 30, 2003.

### 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 September 2003, the Company recognized \$1.0 million in impairment related to two previously acquired licenses as a result of a decision to restructure or terminate the agreements. It was determined that minimum future royalty payments on such licenses significantly limit the financial viability of bringing the licensed technology to market. As a result, an impairment loss was recorded for the carrying amount of the technology acquired under the two licenses.

**Table of Contents****NANOGEN, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(unaudited)****September 30, 2003****4. Comprehensive Loss**

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

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>(unaudited)</b>		<b>(unaudited)</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
Comprehensive loss:				
Net unrealized gain / (loss)	\$ 1,032	\$ (156)	\$ (3,216)	\$ (783)
Foreign currency translation adjustment	4	(45)	194	581
Net loss	(7,079)	(8,224)	(24,652)	(24,277)
<b>Comprehensive loss</b>	<b>\$ (6,043)</b>	<b>\$ (8,425)</b>	<b>\$ (27,674)</b>	<b>\$ (24,479)</b>

**5. Collaborative Alliances*****Hitachi, Ltd.******Manufacturing Agreements***

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.



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Pursuant to the agreement, Hitachi, Ltd. has the right to be the sole distributor of NanoChip<sup>®</sup> Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip<sup>®</sup> Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip<sup>®</sup> Molecular Biology Workstations sold by Hitachi, Ltd. in Japan. The Company retained the right to distribute, directly or through others, NanoChip<sup>®</sup> Molecular Biology Workstations outside of Japan. In addition, the Company manufactures NanoChip<sup>®</sup> Cartridges at its San Diego, California facility for distribution worldwide. The Company also retained 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<sup>®</sup> Workstations. As of September 30, 2003, the Company had a commitment to purchase approximately \$204,000 in NanoChip<sup>®</sup> Workstations from Hitachi for shipments of product through December 31, 2003.

In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of a new clinical instrument being developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the new clinical instrument, when development is completed, exclusively for the Company for worldwide distribution. Once production instruments are received by the Company, the Company will be required to meet certain annual purchase commitments for the new instrument.

### *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

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**NANOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**September 30, 2003**

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 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.

In August 2003, the Company received written notice from Hitachi exercising its right to terminate the collaborative research agreement in accordance with terms of the agreement. Hitachi's exercise of its right to terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Neither Nanogen nor Hitachi has terminated any of the other agreements between the companies. Based on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new clinical instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new clinical instrument. Hitachi is responsible for world-wide manufacturing of the instrument and will have distribution rights for the new instrument in Japan. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

Sponsored research revenue recognized under this agreement totaled \$375,000 and \$1.1 million for the three and nine months ended September 30, 2003, respectively, and \$354,000 and \$1.0 million for the three and nine months ended September 30, 2002, respectively. The Company has recognized \$4.0 million in sponsored research revenue under this agreement since inception and through the period ended September 30, 2003. 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 \$3.7 million and \$3.0 million at September 30, 2003 and December 31, 2002, respectively. The current portion of the long-term liability remains immaterial as payment amounts due under this obligation are determined as a percentage of the Company's gross NanoChip® Cartridge sales which have not been significant to date. As such, the Company has classified the entire balance of this obligation as a long-term liability.

*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 sale or placement by the Company with the Company's customers. The Company pays Hitachi for annual service on each Workstation covered under the agreement and amortizes the cost of the warranty 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.

*Aventis Research and Technologies*

In June 2001, the Company entered into agreements with Hoechst AG ( Aventis ) to create a new company, Nanogen Recognomics GmbH ( Nanogen Recognomics ). Nanogen Recognomics was established to develop new

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**NANOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**September 30, 2003**

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 million dollars. 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 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 June 2003, pursuant to the joint venture agreement, the Company accrued for the issuance of a second warrant to Aventis to purchase 323,850 shares of the Company's common stock exercisable through June 2008 at an agreed upon price of \$5.618 per share. At present, the Company does not believe that it is obligated to issue the second warrant. However, the Company is discussing this with Aventis. The value of this accrued warrant, as determined by the Black-Scholes valuation model, was \$700,000 and is included in other assets in the accompanying consolidated financial statements and is being amortized over a seven month period, the remaining 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 yield of 0%, expected volatility of 84%, risk-free interest rate of 2.3%, expected life of 5 years, stock price of \$3.70 per share, and an exercise price of \$5.618 per share. In the event Nanogen Recognomics should run out of funds, the Company is required pursuant to the agreement to take over reorganization costs and the Company may restructure Nanogen Recognomics to hold the original patents contributed by Aventis and any jointly owned patents. The restructured company will collect royalties, if any, and pay the equity owners accordingly. Our exclusive commercialization license will continue for 10 years after restructuring.

The results of operations for Recognomics are fully consolidated in the Company's financial statements. The total operating loss of Recognomics is reflected as a reduction of the minority interest in consolidated subsidiary liability account. The operating loss of Recognomics totaled \$488,000 and \$1.6 million for the three and nine months ended September 30, 2003, respectively, and \$651,000 and \$1.6 million for the three and nine months ended September 30, 2002, respectively.

**6. Litigation**

In September 2002, the Company entered into a settlement agreement with CombiMatrix Corp. ( CombiMatrix ) and Dr. Donald Montgomery concluding pending litigation in the U.S. District Court for the Southern District of California. Pursuant to the settlement agreement, Nanogen agreed to drop its claims against CombiMatrix and Dr. Montgomery that include certain causes of action relating to U.S. patent Nos. 6,093,302 and 6,280,595 (the patented technology ) that were assigned by Dr. Montgomery, an ex-Nanogen employee, to CombiMatrix in 1995 and assertions relating to other matters. In exchange, CombiMatrix agreed to pay \$1.0 million as a reimbursement of legal costs; issue 4,016,346 shares of CombiMatrix tracking common stock that as of December 18, 2002 became publicly tradable on the Nasdaq National Market and were

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initially valued upon receipt at \$10.8 million, which represents seventeen and one-half percent (17.5%) of its outstanding common stock; and make royalty payments of twelve and

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**NANOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(unaudited)**

**September 30, 2003**

one-half percent (12.5%) on sales of products by either CombiMatrix or its affiliates that incorporate the patented technology. Of the \$1.0 million due the Company, \$500,000 was paid in October 2002 and the remaining \$500,000 was paid in September 2003. 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.

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, 2003, no amounts were due the Company relating to the settlement agreement.

In December, 2002, Oxford Gene Technologies ( OGT ) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that Nanogen infringes U.S. Patent No. 6,054,270 (the 270 Patent ) entitled Analyzing Polynucleotide Sequences. In April 2003, Nanogen filed an answer to the complaint that denies that it infringes the 270 Patent. In October, 2003, the Company and OGT entered into a settlement agreement pursuant to which the lawsuit was dismissed by OGT without prejudice. For the three and nine months ended September 30, 2003, litigation and settlement of patent matter costs totaled \$149,000.

**7. Stock Transactions**

In January 2003, the Compensation Committee of the Board of Directors approved the issuance of common stock pursuant to the Company's Stock Bonus Plan. During the nine months ended September 30, 2003, the Company issued 71,610 shares of common stock under the Plan valued at approximately \$112,000 based on the value of the shares at the date of issuance.

In April 2003, the Compensation Committee of the Board and the Board itself approved a revised compensation program for Board members to be in effect after the Annual Meeting of Stockholders of the Company held in June 2003. During the nine months ended September 2003, the Company issued, to independent Board Members, 24,388 shares of common stock valued at approximately \$100,000 based on the value of the shares at the date of issuance.

In September 2003, the Company entered into agreements to sell common stock and warrants to several accredited investors for aggregate potential gross proceeds of approximately \$16 million. During the initial closing in September 2003, Nanogen received \$7 million in gross proceeds through the sale of 2,121,211 newly issued shares of its common stock at a negotiated discount price of \$3.30 per share. The investors received warrants to purchase additional shares of common stock as follows: 1,103,032 shares at an exercise price of \$4.14 per share exercisable until March 18, 2004; 530,305 shares at an exercise price of \$4.75 per share exercisable until September 18, 2004; and 424,243 shares at an exercise price of \$4.75 per share exercisable until September 18, 2008. As of September 30, 2003, none of the warrants had been exercised.

**8. Related Party Transactions**

In December 2002, the Company entered into a separation agreement with its then Chief Executive Officer. Under the terms of the agreement, the Company made a net severance payment of \$58,000 in January 2003 to settle all outstanding obligations between the two parties, including indebtedness to the Company of approximately \$167,000.

Also in December 2002, Nanogen's then President resigned effective in January 2003. In connection with the former President's resignation, the Company made a net payment of approximately \$384,000 in January 2003 to settle all outstanding obligations between the two parties, including indebtedness to the Company of approximately \$300,000.

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**September 30, 2003**

In May 2003, the Company entered into a separation agreement with its then Chief Financial Officer. Under the terms of the agreement, the Company accrued approximately \$165,000 relating to the severance costs. As of September 30, 2003 there were no amounts owed to the former Chief Financial Officer.

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

**9. Investment in CombiMatrix**

As the result of a settlement agreement between the Company and CombiMatrix, the Company received 4,016,346 shares of CombiMatrix tracking common stock in 2002. The Company sold 3,000,000 of CombiMatrix common stock in February 2003 for net proceeds totaling \$4.5 million and 583,600 shares in September 2003 for net proceeds totaling \$2.3 million. During the three and nine months ended September 30, 2003, the Company recognized a realized gain of \$758,000 and a realized loss of approximately \$2.8 million, respectively, relating to the sale of these shares. During October 2003, the Company sold all remaining shares of CombiMatrix common stock. The Company received net proceeds totaling \$2.0 million and recorded an unrecognized loss of \$801,000 and a realized gain of \$852,000.



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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 indicate forward-looking statements. The forward-looking statements contained in this Form 10-Q may include, but are not limited to, statements about matters including the following: (i) the development of the markets and demand for our products and services; (ii) our product development plans and anticipated activities designed to pursue these plans, including collaborations and other corporate partnering arrangements; (iii) our ability to derive substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements; (iv) the ability of our product platform to affect the market and become an industry standard; (v) our ability to generate license and other fee revenue in the future; (vi) the amounts we invest in research and development activities in the future; (vii) future levels of selling, general and administrative expenses and other expenses associated with our business, including the related impact on these expenses as the result of our April 2003 restructuring; (viii) future levels of interest income; (ix) any amounts we may be able to realize from the liquidation of our investments, including our investments in short-term securities; (x) operating results of joint ventures and other corporate partnering arrangements; (xi) the amounts and timing of our contractual obligations and capital commitments and (xii) our future capital needs and our ability to fund those needs. 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, 2002. 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 mission to become a leading provider of molecular diagnostic tests and services. 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, biodefense, forensics and drug discovery. The Company's current commercially available products include (1) the NanoChip® Molecular Biology Workstation, an automated, multi-purpose instrument primarily used for DNA-based analyses, (2) the NanoChip® Cartridge, which incorporates the NanoChip® Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules, (3) various Analyte Specific Reagents (ASRs) for detecting gene mutations associated with diseases such as cystic fibrosis and Alzheimer's disease, and (4) the Assay Toolbox product designed to help customers develop their own assays on the NanoChip® System. The Company also has several other ASRs and applications of its proprietary technology under development including new instrumentation products. The Company provides technical support and field applications assistance to its customers.

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, 2003, had an accumulated deficit of \$170.3 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.

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We introduced our first two products into the marketplace in 2000. While we recognized revenue from product sales during the nine months ended September 30, 2003 and the years ended December 31, 2002, 2001, and 2000, significant revenues during these periods were earned under our sponsored research agreements, contracts and grants and, in 2002, a license fee valued at \$10.8 million received from a litigation settlement with CombiMatrix Corp. We believe that in future periods, however, our revenue base will shift to being more product driven as a result of our sales strategy to place our products in research and clinical laboratory environments. Additionally, revenue associated with our research collaboration agreement with Hitachi will end in April 2004 and we do not expect to immediately, if ever, replace this source of revenue. 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<sup>®</sup> System; other products currently being sold by the Company 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 remaining milestones under our collaborative agreement 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 judgments, including those related to bad debts, inventories, investments, intangible assets, service obligations and contingencies. We base our estimates and judgments on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

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

#### ***Revenue recognition***

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 Staff Accounting Bulletin 101 - Revenue Recognition in Financial Statements and record revenues as follows.

We offer our NanoChip<sup>®</sup> Molecular Biology Workstations under various commercial programs such as direct sales, lease arrangements, reagent rental programs and cost-per-test 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 and the transfer of title (f.o.b. shipping point), as we do not sell consumables with a right of return.

Revenue from the direct sale of NanoChip<sup>®</sup> 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<sup>®</sup> 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

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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<sup>®</sup> System under reagent rental transactions whereby the customer commits to purchasing a fixed minimum number of consumable products on a periodic basis for a specified period of time (i.e. a certain number of cartridges for a certain number of years). Generally, these

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transactions require the customer to validate a test that they have developed utilizing our instrument and reagents. Recognition of revenue begins after the customer has completed validation. Revenue for the Workstation, consumables and warranty under reagent rental transactions is then 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 reclassify 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. We provide product warranty coverage for the Workstation over the period of the contract. 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<sup>®</sup> Molecular Biology Workstations at customer sites under programs, such as development site arrangements, where title of the NanoChip<sup>®</sup> Workstation does not transfer to the customer. No revenues are recognized at the time of placement under these agreements. These arrangements are for a period normally between six and twelve months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that we may license in the future. In addition, a primary intent of the program is for the customer to purchase the NanoChip<sup>®</sup> Workstation during the period of the arrangement or at its expiration. We provide a warranty for these NanoChip<sup>®</sup> 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 \$372,000 and \$489,000 at September 30, 2003 and December 31, 2002, 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<sup>®</sup> 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, 2003, we converted six development site agreements to sales.

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.

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.

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

*Bad debts*

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

*Inventory*

We reduce the carrying value of our inventory, including NanoChip® Molecular Biology Workstations placed under development site arrangements, for estimated obsolescence or non-marketability after considering future

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purchase commitments, the potential impact of next generation instruments, and based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

### *Intangible Assets*

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

### **Results of Operations**

**Product Revenues.** For the three and nine months ended September 30, 2003, sales totaled \$752,000 and \$1.6 million, respectively, compared to \$957,000 and \$2.9 million for the three and nine months ended September 30, 2002, respectively. Product sales revenue during the three and nine months ended September 30, 2003 included the sale of five and nine and one-half (a partial unit) NanoChip<sup>®</sup> Molecular Biology Workstations, respectively, as well as sales of NanoChip<sup>®</sup> Cartridges, reagents and warranty revenue. Sales revenue during the three and nine months ended September 30, 2002 included the sale of six and nineteen, respectively, of NanoChip<sup>®</sup> Molecular Biology Workstations as well as sales of NanoChip<sup>®</sup> Cartridges. The decline in the sale of the number of NanoChip<sup>®</sup> Molecular Biology Workstations for the three and nine months ended September 30, 2003 compared to the same time periods in 2002 is due to the Company's strategy to target clinical laboratories with our ASR products. Many clinical laboratory customers purchase product via reagent rental contracts that result in a multi year revenue stream versus research institutions that generally purchase systems. Additionally, the time required for clinical laboratories to develop and validate assays delays product revenue when compared to research sales. The sale of instruments was the major source of product revenue in both of these periods. All revenue recorded related to sales of our NanoChip<sup>®</sup> Molecular Biology Workstation for the nine months ended September 20, 2003 and 2002 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, 2003, revenues from sponsored research totaled \$375,000 and \$1.1 million, respectively, compared to \$354,000 and \$1.0 million for the three and nine months ended September 30, 2002, 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, 2003 and 2002 represents revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. We are currently on schedule with project milestones and expect sponsored research revenues from the collaboration to continue at their current level through the first quarter of 2004. During August 2003, the Company received written notification from Hitachi that Hitachi is terminating the research collaboration agreement in accordance with the terms of that agreement. Funding by Hitachi under the collaboration agreement is expected to terminate in April of 2004.

**Contracts and Grants.** We fund some of our research and development efforts through contracts and grants awarded by various federal and state agencies. Revenues are recognized under these contracts and grants as expenses are incurred, and totaled \$568,000 and \$1.8 million, respectively, and \$240,000 and \$1.2 million, respectively, for the three and nine months ended September 30, 2003 and 2002. The increase in revenues for the three and nine months ended September 30, 2003 compared to 2002 is primarily related to additional revenue recognized on

existing contracts and grants.

**Cost of Product Sales and Gross Margins.** Cost of product sales totaled \$1.4 million and \$2.2 million for the three and nine months ended September 30, 2003, respectively, compared to \$687,000 and \$2.1 million for the three and nine months ended September 30, 2002, respectively. Gross margins on product sales revenue were a negative 82% and a negative 32% for the three and nine months ended September 30, 2003, respectively, compared to 28% for the three and nine months ended September 30, 2002, respectively. Costs of product sales during the three and nine months ended September 30, 2003 were negatively impacted by a reserve for excess instrument inventory and related accessory items, lower sales volume, underabsorbed overhead costs due to underutilized capacity, and

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manufacturing scrap as a result of lower yields on new products released into production. 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 2003. Costs of product sales for the three and nine months ended September 30, 2003 included a reserve for excess and obsolete inventory totaling \$829,000 and \$862,000, respectively. This reserve relates primarily to excess instruments and accessory items in our inventory that could potentially not be saleable or could become obsolete. For the nine months ended September 30, 2002, gross margins were impacted by sales of NanoChip® Workstations to certain customers under various discount programs, totaling \$145,000, and by sales to distributors that are at a discount. Gross margins in future periods may be further impaired by minimum product royalties or potential adjustments made to reflect the impairment of intangible assets related to products sold. The sale of NanoChip® Workstations is directly related to the successful validation of assays developed and implemented by clinical laboratories based on our ASRs. Should the successful validation or rate of adoption by clinical laboratories vary from our estimates, gross margins could be impacted by additional reserves for obsolete and slow moving inventory.

**Research and Development Expenses.** For the three and nine months ended September 30, 2003, research and development expenses totaled \$4.3 million and \$13.5 million, respectively, compared to \$5.3 million and \$15.2 million for the three and nine months ended September 30, 2002, 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, 2003 research and development activities primarily related to the development of new ASRs and new instrumentation products. Based on restructuring that occurred in April 2003, we anticipate research and product development costs to decline from amounts experienced during the nine months ended September 30, 2003.

**Selling, General and Administrative Expenses.** For the three and nine months ended September 30, 2003, selling, general and administrative expenses totaled \$3.3 million and \$11.5 million, respectively, compared to \$5.4 million and \$15.3 million for the three and nine months ended September 30, 2002, 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. The decline in selling, general, and administrative expense for the three and nine months ended September 30, 2003 as compared to the same period during the prior year is primarily the result of decreased expenditures associated with the launch of products, reduced costs related to maintaining and enhancing our intellectual property portfolio, and other cost reduction measures taken during the year. Based on the reduction in force that occurred in April 2003, we anticipate selling, general and administrative expenses to continue to decline from amounts experienced during the nine months ended September 30, 2003.

**Litigation and Settlement of Patent Matter, Net.** For the three and nine months ended September 30, 2003, litigation expenses totaled \$149,000 which related to Oxford Gene Technologies. 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. The net benefits incurred in 2002 related to a dispute with CombiMatrix and Dr. Montgomery. As a settlement between all parties was reached in September 2002, there were no benefits or expenses related to this matter in 2003.

**Impairment of Acquired Technology Rights.** For the three and nine months ended September 30, 2003, impairment of acquired technology rights totaled \$1.0 million as a result of a decision to restructure or terminate two license agreements. For the three and nine months ended September 30, 2002, impairment of acquired technology rights totaled \$452,000 and resulted from the termination of a collaboration agreement. The impairment losses recognized during these periods represented the difference between the assets carrying values and their estimated fair values.

**Interest Income, Net.** For the three and nine months ended September 30, 2003, net interest income totaled \$97,000 and \$405,000, respectively, compared to \$488,000 and \$1.8 million, respectively, for the three and nine months ended September 30, 2002. The decrease in net interest income is a result of lower average cash and investment balances as well as lower yields on outstanding cash and investment balances during the three and nine months ended September 30, 2003. Based on the continued consumption of cash and short-term investments to augment operating activities, we expect net interest income to continue to decline during the remainder of 2003.





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**Minority Interest in Loss of Consolidated Subsidiary.** We had losses relating to our majority-owned subsidiary, Nanogen Recognomics GmbH, for the three and nine months ended September 30, 2003, of \$488,000 and \$1.6 million, respectively, compared to \$651,000 and \$1.6 million for the three and nine months ended September 30, 2002, respectively. Since this subsidiary is primarily engaged in research and does not generate any significant revenue, we expect to experience continued losses with the majority-owned subsidiary similar to levels incurred during 2002. These losses are funded by the investment from minority interest investors and are therefore offset against the minority interest balance in the respective balance sheet.

## **Liquidity and Capital Resources**

At September 30, 2003, we had \$32.6 million in available cash, cash equivalents and short-term investments, compared to \$52.7 million at December 31, 2002. The decrease is primarily due to cash used in operations during the nine months ended September 30, 2003 totaling \$20.2 million and realized and unrealized losses in short-term investments of \$6.0 million related principally to CombiMatrix securities offset by net proceeds of \$6.9 million received from the issuance of common stock. While the CombiMatrix securities are included within short-term investments, we do not expect significant market value fluctuations in this investment that had a market value of \$2.0 million at September 30, 2003 since this investment has subsequently been liquidated (see Note 9 of Notes to Consolidated Financial Statements).

Net cash used in operating activities was \$20.2 million and \$20.7 million for the nine months ended September 30, 2003 and 2002, respectively. Cash used for operations during the nine months ended September 30, 2003 and 2002 was primarily related to costs associated with commercializing our products, including the expansion, development and support of our sales and marketing organization; the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd; support of our continuing research and development efforts including development of the ASRs which may be used by customers to develop tests for the detection of mutations in the CFTR gene associated with cystic fibrosis, the ASRs for mutations in the HFE gene associated with the hereditary hemochromatosis, and the other ASRs and other products recently introduced by Nanogen; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio.

Net cash provided by investing activities was \$16.3 million and \$22.4 million for the nine months ended September 30, 2003 and 2002, respectively. 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.

We have funded some of our equipment acquisitions and leasehold improvements through capital leasing facilities. Our equipment lease lines expired in September 2003. We are in the process of seeking new equipment lease financing. If we are unable to obtain such financing, we will need to fund new equipment purchases from our existing cash resources which will further reduce cash available for other operating activities.

Net cash provided by financing activities was \$7.1 million and \$813,000 for the nine months ended September 30, 2003 and 2002, respectively. Cash provided by financing activities during 2003 primary related to the issuance of common stock to several private accredited investors in September 2003 resulting in net proceeds of \$6.5 million. Proceeds received from our development partner totaled \$749,000 and \$1.4 million during the nine months ended September 30, 2003 and 2002, respectively. As our development partner, Hitachi, has provided written notification to cancel the research collaboration agreement, we expect to receive development partner proceeds in accordance with the agreement through April 2004 at levels similar to those experienced during 2003.

Our manufacturing agreement for the Molecular Biology Workstation with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip<sup>®</sup> Molecular Biology Workstations. As of September 30, 2003, we had commitments to purchase approximately \$204,000 in NanoChip<sup>®</sup> Workstations from Hitachi for shipments of product through December 31, 2003.

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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.

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We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a workstation at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. Many of our reagent rentals and cost-per-test agreements entered into to date require customer acceptance of our CFTR ASRs as a pre-condition to this commitment. These reagent rentals and cost-per-test agreements might have 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, which is typically three to five years, as reagents are shipped to the customer.

We expect that our existing capital resources, combined with anticipated revenues from potential product sales, reagent rentals, leases or other types of acquisition programs for 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. 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 our ability 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, to expand our sales and marketing efforts to support the commercialization of our products under development and otherwise to fund operations beyond the one-year period referenced above. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through entering into collaborative agreements or other arrangements on unfavorable terms. Our failure to raise capital on acceptable terms when needed could have a material adverse effect on our business, financial condition or results of operations.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

**Foreign currency rate fluctuations.** The functional currency for our 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 \$2.7 million at September 30, 2003.

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

(a) Evaluation of Disclosure Controls and Procedures.

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The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. The Company believes that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

(b) Change in Internal Control over Financial Reporting.

No change in the Company's internal control over financial reporting occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents****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 2. Changes in Securities**

(c)(2) In September 2003, the Company entered into agreements to sell common stock and warrants to several accredited investors for aggregate potential gross proceeds of approximately \$16 million. Following the initial closing on September 19, 2003, Nanogen received \$7 million in gross proceeds through the sale of 2,121,211 newly issued shares of its common stock at a negotiated discount price of \$3.30 per share. The investors received warrants to purchase additional shares of common stock as follows: 1,103,032 shares at an exercise price of \$4.14 per share exercisable until March 18, 2004; 530,305 shares at an exercise price of \$4.75 per share exercisable until September 18, 2004; and 424,243 shares at an exercise price of \$4.75 per share exercisable until September 18, 2008. As of September 30, 2003, none of the warrants had been exercised. The offer, issuance or sale of the securities was within the exemptions from regulation requirements provided by Sections 4(2) of the Securities Act of 1933, as amended, Regulation D and rule 506 thereunder, certain State Securities laws and certain Rules and Regulations promulgated pursuant thereto.

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

(a) Exhibits

Exhibit No.	Description
31.1	Certifications of Chief Executive Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certifications of Chief Financial Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended. (This exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
32.2	Certifications of Chief Financial Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended. (This exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)

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### (b) Reports on Form 8-K

(i) On July 31, 2003, we furnished a Current Report on Form 8-K to the SEC, including the Company's press release announcing financial results for the quarter ended June 30, 2003.

(ii) On September 22, 2003, we furnished a Current Report on Form 8-K to the SEC, announcing the completion of a financing transaction.



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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.**

Date November 13, 2003

**NANOGEN, INC.**

**HOWARD C. BIRNDORF**

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**Howard C. Birndorf**

**Chairman of the Board,**

**Executive Chairman and Chief**

**Executive Officer**

**(Principal Executive Officer)**

Date November 13, 2003

**DAVID LUDVIGSON**

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**David Ludvigson**

**Executive Vice President, Chief**

**Financial Officer and**

**Treasurer**

**(Principal Financial and**

**Accounting Officer)**

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**NANOGEN, INC.**

**EXHIBIT INDEX**

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