NANOGEN INC
Form 10-Q
May 14, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

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 March 31, 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	**33-0489621**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
10398 Pacific Center Court, San Diego, CA	**92121**
(Address of principal executive offices)	(Zip code)

(858) 410-4600

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý No o

As of May 13, 2002, 21,656,172 shares of the Registrant's Common Stock were outstanding.

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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	March 31, 2002	December 31, 2001
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,126	$ 10,455
Short-term investments	52,393	57,069
Receivables, net	2,285	4,380
Inventories, net	5,879	4,688
Other current assets	1,656	2,473

	March 31, 2002	December 31, 2001
Total current assets	69,339	79,065
Property and equipment, net	4,914	5,386
Acquired technology rights, net	4,327	4,183
Other assets, net	1,147	1,158
Restricted cash	299	299
	$ 80,026	$ 90,091
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 835	$ 1,051
Accrued liabilities	3,953	4,916
Deferred revenue	458	522
Current portion of capital lease obligations	963	1,060
Total current liabilities	6,209	7,549
Capital lease obligations, less current portion	1,433	1,755
Other long-term liabilities	1,659	1,675
Total long-term liabilities	3,092	3,430
Minority interest in consolidated subsidiary	3,401	4,183
Stockholders' equity:		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2002 and December 31, 2001		
Common stock, $.001 par value, 50,000,000 shares authorized; 21,653,015 and 21,616,172 shares issued and outstanding at March 31, 2002 and December 31, 2001, respectively	22	22
Additional paid-in capital	198,563	198,387
Accumulated other comprehensive income	901	1,253
Deferred compensation	(219)	(336)
Notes receivable from officers	(998)	(984)
Accumulated deficit	(130,945)	(123,413)
Total stockholders' equity	67,324	74,929
	$ 80,026	$ 90,091

See accompanying notes.

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three months ended March 31,	
	2002	2001
Revenues:		
Sales	$ 812	$ 229
Sponsored research	313	2,346
Contract and grant	408	364
Total revenues	1,533	2,939
Operating expenses:		
Cost of sales	557	170
Research and development	4,280	4,786
Selling, general and administrative	4,972	4,784
Litigation and settlement of patent matter		798
Total operating expenses	9,809	10,538
Loss from operations	(8,276)	(7,599)
Interest income, net	729	1,320
Other income	15	
Net loss	$ (7,532)	$ (6,279)
Net loss per share basic and diluted	$ (0.35)	$ (0.30)
Number of shares used in computing net loss per share basic and diluted	21,620	20,655

See accompanying notes.

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Three months ended March 31,	
	2002	2001
Operating activities:		
Net loss	$ (7,532)	$ (6,279)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	961	767
Amortization (accretion) related to short-term investments	4	(19)

	Three months ended March 31,	
Stock based compensation expense	22	157
Interest capitalized on notes receivables from officers	(14)	(14)
Minority interest in loss of consolidated subsidiary	(561)	
Gain on sale of short-term investments	(18)	
Changes in operating assets and liabilities:		
Receivables	2,095	45
Inventories	(1,191)	(1,182)
Other assets	707	(380)
Accounts payable	(216)	(233)
Accrued liabilities	(1,114)	(787)
Deferred revenue	(64)	(201)
Net cash used in operating activities	(6,921)	(8,126)
Investing activities:		
Purchase of short-term investments	(4,321)	(10,552)
Proceeds from sale and maturities of short-term investments	8,511	
Purchase of equipment	(60)	(5)
Purchase of technology rights	(225)	
Net cash provided by (used in) investing activities	3,905	(10,557)
Financing activities:		
Principal payments on capital lease obligations, net	(443)	(349)
Issuance of common stock, net of repurchases	201	129
Net cash used in financing activities	(242)	(220)
Effect of exchange rate changes	(71)	
Net decrease in cash and cash equivalents	(3,329)	(18,903)
Cash and cash equivalents at beginning of period	10,455	55,330
Cash and cash equivalents at end of period	$ 7,126	$ 36,427
Supplemental disclosure of cash flow information:		
Interest paid	$ 39	$ 95
Supplemental schedule of noncash investing and financing activities:		
Equipment acquired under capital leases	$ 2	$ 457
Unrealized gain (loss) on short-term investments	$ (500)	$ 556
Accrued fee for purchase of technology rights	$ 225	$
Common stock issued in connection with employee benefit plan, net of forfeitures	$ 95	$ 334

See accompanying notes.

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 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 footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The consolidated balance sheet as of March 31, 2002, consolidated statements of operations for the three months ended March 31, 2002 and 2001, and the consolidated statements of cash flows for the three months ended March 31, 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 months ended March 31, 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. Form 10-K, 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. Weighted average common shares outstanding during the period does not include 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. Due to the losses incurred by the Company during the three months ended March 31, 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 142 for fiscal years beginning after December 15, 2001. 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. Companies are required to adopt FAS 144 for fiscal years beginning after December 15, 2001, but early adoption is permitted. The adoption of these standards did not have a material impact on the Company's results of operations and financial position.

2. Inventories

Inventories consist of the following (in thousands):

	March 31, 2002	December 31, 2001
Raw materials	$ 984	$ 796
Work in process	1,885	1,436
Finished goods	4,824	3,956
	7,693	6,188
Reserve for obsolescence	(1,814)	(1,500)
	$ 5,879	$ 4,688

Finished goods includes $2.7 million and $2.0 million of NanoChip® Molecular Biology Workstations ("NanoChip® Workstations") at March 31, 2002 and December 31, 2001, respectively, that are installed at customer sites where title has not transferred to the customer.

The Company's manufacturing agreement with Hitachi, Ltd. ("Hitachi") requires that the Company provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of March 31, 2002, the Company has commitments to purchase approximately $3.1 million in NanoChip® Workstations through March 31, 2003.

3. Comprehensive Loss

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 March 31,	
	2002	2001
Comprehensive loss:		
Net unrealized gain (loss) on sale of investments	$ (500)	$ 556
Cumulative currency translation adjustment	147	
Net loss	(7,532)	(6,279)
Comprehensive loss	$ (7,885)	$ (5,723)

4. Collaborative Alliances

Hitachi, Ltd.

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 Hitachi, Ltd. produced NanoChip® Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip® Cartridges in Japan. The Company retains the right to distribute, directly or through others, Hitachi, Ltd. produced NanoChip® Molecular Biology Workstations outside of Japan. In addition, the Company seeks to develop and manufacture the NanoChip® Cartridges for distribution worldwide. The Company also retains the right to form other manufacturing and distribution agreements.

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 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 Company is liable to repay fifty percent of all funding provided by Hitachi over an indefinite period of time. Payment 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.

Sponsored research revenue recognized under this agreement totaled $313,000 and $250,000 for the three months ended March 31, 2002 and 2001, respectively. The amount owed to Hitachi for proceeds received under this agreement was $1.6 million at March 31, 2002 and December 31, 2001.

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 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 is primarily recognized under these agreements as expenses are incurred, and totaled $2.1 million for the three months ended March 31, 2001. No revenue was recognized during 2002 as these projects were complete 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"). The company 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 the new company and also contributed intellectual property in the form of eighteen patents. The Company is 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. 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 the new company 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, is equal to $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 results of operations for Nanogen Recognomics are fully consolidated in the financial statements included herein, as such, there is no off-balance sheet component. The total operating loss of Nanogen Recognomics is reflected as a reduction of the "minority interest in consolidated subsidiary" liability account and totaled $561,000 and none for the three months ended March 31, 2002 and 2001, respectively.

5. 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 939 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, as determined using the Black-Scholes valuation model) to the parties involved. The settlement does not 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 months ended March 31, 2001 costs associated with the litigation of the Motorola patent matter totaled $798,000.

In November 2000, the Company filed a complaint against CombiMatrix Corp. ("CombiMatrix") and Dr. Donald Montgomery in the United States District Court for the Southern District of California. Dr. Montgomery is a former company employee now affiliated with CombiMatrix. The Company's complaint alleges that the naming of Dr. Montgomery as the sole inventor on U.S. Patent No. 6,093,302, entitled "Electrochemical Solid Phase Synthesis" (the " 302 patent"), and assignment of the 302 patent to CombiMatrix were incorrect and that the invention was made by company employees. The complaint also alleges that inventions disclosed in the patent were the Company's trade secrets and that CombiMatrix and Dr. Montgomery misappropriated these trade secrets by their actions, including publishing those trade secrets in patent applications. The Company's complaint seeks correction of inventorship, assignment of rights in the patent to the Company, an injunction preventing disclosure of trade secrets and damages for trade secret misappropriation.

In December 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss the Company's complaint. In January 2001, the motion was denied as to all claims except a claim for conversion, as to which the motion was granted without prejudice. The Company elected not to amend its complaint as to the conversion claim. In March 2001, CombiMatrix and Dr. Montgomery answered the Company's complaint, asserted various affirmative defenses and filed a counterclaim for breach of contract against the Company for unspecified damages allegedly arising from the filing of the complaint at a time when CombiMatrix had announced its intent to make an initial public offering of its shares. The counterclaim asserts that the Company, by filing its complaint, breached a settlement agreement entered into

between the Company and Dr. Montgomery in 1995. In May 2001, the Company filed a motion to dismiss CombiMatrix's counterclaim, which was denied on July 27, 2001.

In April 2002, the Company filed a motion for leave to amend its complaint to add a cause of action against Dr. Montgomery for fraudulent inducement to enter into a 1996 settlement agreement with the Company and to add to its claims against CombiMatrix and Dr. Montgomery an additional patent that was recently issued to CombiMatrix. Discovery is currently ongoing.

No assurances can be given that the Company will prevail in the lawsuit or that it can successfully defend itself against the counterclaim. The Company is expending considerable financial resources and managerial efforts prosecuting the lawsuit and defending against Dr. Montgomery's and CombiMatrix's counterclaim. The Company may not prevail in the action, which could have a material adverse effect on the Company.

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 Form 10-Q and which are described in our 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 March 31, 2002, had an accumulated deficit of $130.9 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.

We introduced our first two products into the marketplace in 2000 and our third product in March 2002. 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 months ended March 31, 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 our instrument and consumable revenues grow. 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, such as an Analyte Specific Reagent ("ASR") for Cystic Fibrosis, expected to be launched by the end of the second quarter of 2002, 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 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, contingencies and litigation. 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

Revenue from the sale of NanoChip® Molecular Biology Workstations and of NanoChip® Cartridges is generally recognized upon shipment and transfer of title. 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 generally sold with a one year maintenance contract. The fair value of the maintenance service is recorded as deferred revenue and recognized ratably over the period earned. We provide for the estimated cost of product maintenance at the time revenue is recognized. We also recognize revenue from the sale of our NanoChip® System under reagent rental transactions whereby customers pay to either a financing company or directly to us, higher prices for our consumable cartridges over a number of years to cover the cost of the system. Under these arrangements, the customer typically commits to purchasing a fixed number of consumable cartridges on a periodic basis, which in turn represents payment under the reagent rental agreement. Revenue under reagent rental transactions is recognized in line with scheduled payments over the term of the agreement, generally two to five years. We also offer our NanoChip® Molecular Biology Workstations to customers under programs, such as Development Site arrangements, where title of the product does not transfer to the customer. Sales under these types of programs do not result in the recognition of revenue. 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 debt

We maintain allowances 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.

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 based upon assumptions about future demand, supply, market conditions and new product introductions. If actual future demand, supply or market conditions are less favorable than those projected by us, additional inventory write-downs may be required. The timing of introduction of new products or new uses for products may also impact the carrying value of inventory.

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. 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 months ended March 31, 2002 sales totaled $812,000 compared to $229,000 for the three months ended March 31, 2001. Sales revenue during the three months ended March 31, 2002 includes the sale of five NanoChip® Molecular Biology Workstations as well as sales of NanoChip® Cartridges. In addition, we recognized royalty revenue for two NanoChip® Workstations which were sold in Japan by our distributor, Hitachi Ltd. Sales revenue for the three months ended March 31, 2001 was comprised of the sale of one NanoChip® Molecular Biology Workstation as well as sales of NanoChip® Cartridges. 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 months ended March 31, 2002 revenues from sponsored research totaled $313,000 compared to $2.3 million for the three months ended March 31, 2001. 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 months ended March 31, 2002, primarily consists of revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. Sponsored research revenue recognized during the three months ended March 31, 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 a NanoChip® Molecular Biology Workstation to one of these programs, and the development program with Hitachi.

All 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.

Contract 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 $408,000 and $364,000 for the three months ended March 31, 2002 and 2001, respectively.

Cost of Sales and Gross Margins. Cost of sales totaled $557,000 for the three months ended March 31, 2002 compared to $170,000 for the three months ended March 31, 2001. Gross margins on sales revenue were 31% and 26% for the three months ended March 31, 2002 and 2001, respectively. Cost of sales during these periods were adversely impacted by underabsorbed overhead costs due to underutilized capacity. The cost per unit of our products remained high, as our volume of production

relative to the available capacity remained low. In 2002, cost of sales was further impacted by a reserve for obsolete inventory. 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.

Research and Development Expenses. For the three months ended March 31, 2002, research and development expenses totaled $4.3 million compared to $4.8 million for the three months ended March 31, 2001. 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. The decrease in research and development costs for the three months ended March 31, 2002 when compared to the same period in 2001, is primarily a result of reduced expenses due to the completion of our technology development programs with Aventis as of December 31, 2001 as well as a cognizant effort to reduce overall costs. We anticipate that we will continue to invest in research and product development at approximately this same level for the foreseeable future.

Selling, General and Administrative Expenses. For the three months ended March 31, 2002, selling, general and administrative expenses totaled $5.0 million compared to $4.8 million for the three months ended March 31, 2001. 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. For the three months ended March 31, 2002 and 2001, litigation and settlement of a patent matter totaled none and $798,000, respectively. In July 2001, a settlement agreement was reached with Motorola, Inc., Genometrix, Inc. and the Massachusetts Institute of Technology 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 months ended March 31, 2001 represent legal fees associated with the settlement. As the events of this transaction concluded during fiscal 2001 there were no costs related to this matter for the three months ended March 31, 2002.

Interest Income, Net. For the three months ended March 31, 2002, net interest income totaled $729,000 compared to $1.3 million for the three months ended March 31, 2001. 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 months ended March 31, 2002 compared to the same period in 2001.

Liquidity and Capital Resources

At March 31, 2002, we had $59.5 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 three months ended March 31, 2002.

Net cash used in operating activities was $6.9 million and $8.1 million for the three months ended March 31, 2002 and 2001, respectively. Cash used for operations during the three months ended March 31, 2002 was primarily related to costs associated with 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, 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 $3.9 million for the three months ended March 31, 2002 compared to cash used by investing activities totaling $10.6 million for the three months ended March 31, 2001. The change in uses of cash in investing activities is primarily a result of our efforts to maximize the yield on our cash balances through the purchases of short-term investments. These securities will mature from time to time or will be sold to fund operating expenses.

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. However, as existing financing sources are fully utilized we will cease using debt facilities to fund most of our equipment acquisitions and leasehold improvements until we are able to negotiate new debt facilities under terms which we deem acceptable.

Our manufacturing agreement with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip® Molecular Biology Workstations. As of March 31, 2002, we have commitments to purchase approximately $3.1 million in NanoChip® Workstations through March 31, 2003.

The Company is a party to Development Site Agreements with various entities whereby the Company may be obligated to pay license fees or 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 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 approximately two years 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 Analytic 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 March 31, 2002 we have sold a total of thirty-four 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 March 31, 2002, we have not yet recognized any revenue from the sale of the ASR for Factor V Leiden.

Our success will depend upon our ability to overcome significant technological challenges and successfully introduce our products into the marketplace. A number of applications envisioned by us will 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 our inventory of our products in a timely fashion and at anticipated price levels, we may not become profitable. In addition, we may have to take accounting charges and reduce the value of our product inventory to its net realizable value. 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 three months ended March 31, 2002. From our inception to March 31, 2002, we have incurred cumulative net losses totaling approximately $130.9 million. Moreover, our negative cash flow and losses from operations will continue to increase 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 title transfer or non-title transfer transactions.

To develop and sell our products successfully, we will need to increase our spending levels in research and development, as well as in selling, marketing and administration. We will 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.

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 preclinical studies and 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.

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.

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, besides our current litigation with CombiMatrix and Dr. Montgomery described below, 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 Isis Innovations Ltd. (E.M. Southern). We have opposed one allowed European Patent which has broad claims to array technology for analyzing a predetermined polynucleotide sequence. Isis Innovation'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. If the decision of the Opposition Division is successfully appealed by Isis Innovations 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.

We were and are currently involved in intellectual property litigation that was and is costly, time-consuming and may impact our competitive position.

In July 2001, we entered into a settlement agreement with Motorola, Genometrix and MIT concluding the declaratory judgment action by us against Motorola, Genometrix and MIT and Motorola's counterclaim against us. In connection with the settlement, we have secured a license from Motorola to certain claims of the "939 Patent. In exchange, Nanogen paid the parties involved a total of $2.5 million in cash and $2.5 million in Nanogen common stock (equal to 416,666 shares based upon a per share price of $6.00, the fair market value on the date of settlement). The settlement does not include any cross-licensing provisions of Nanogen technology to Motorola, Genometrix or MIT. Nanogen's lawsuit and Motorola's counterclaim have now been dismissed.

In November 2000, we filed a complaint against CombiMatrix Corp. ("CombiMatrix") and Dr. Donald Montgomery in the United States District Court for the Southern District of California. Dr. Montgomery is a former Nanogen employee now affiliated with CombiMatrix. The Nanogen complaint alleges that the naming of Dr. Montgomery as the sole inventor on U.S. Patent No. 6,093,302, entitled "Electrochemical Solid Phase Synthesis" (the " 302 patent"), and assignment of the 302 patent to CombiMatrix were incorrect and that the invention was made by Nanogen employees. The complaint also alleges that inventions disclosed in the patent were Nanogen trade secrets and that CombiMatrix and Dr. Montgomery misappropriated these trade secrets by their actions, including publishing those trade secrets in patent applications. Nanogen's complaint seeks correction of inventorship, assignment of rights in the patent to Nanogen, an injunction preventing disclosure of trade secrets and damages for trade secret misappropriation.

In December 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss Nanogen's complaint. In January 2001, the motion was denied as to all claims except a claim for conversion, as to which the motion was granted without prejudice. We elected not to amend our complaint as to the conversion claim. On March 9, 2001, CombiMatrix and Dr. Montgomery answered Nanogen's complaint, asserted various affirmative defenses and filed a counterclaim for breach of contract against Nanogen for unspecified damages allegedly arising from the filing of the complaint at a time when CombiMatrix had announced its intent to make an initial public offering of its shares. The counterclaim asserts that Nanogen, by filing its complaint, breached a settlement agreement entered into between Nanogen and Dr. Montgomery in 1995. On May 14, 2001, Nanogen filed a motion to dismiss CombiMatrix's counterclaim, which was denied on July 27, 2001.

In April 2002, the Company filed a motion for leave to amend its complaint to add a cause of action against Dr. Montgomery for fraudulent inducement to enter into a 1996 settlement agreement with the Company and to add to its claims against CombiMatrix and Dr. Montgomery an additional patent that was recently issued to CombiMatrix. Discovery is currently ongoing.

No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the counterclaim. We are expending considerable financial resources and managerial efforts prosecuting the lawsuit and defending against Dr. Montgomery's and CombiMatrix's counterclaim. We may not prevail in the action, which could have a material adverse effect on us.

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;

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.

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.

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 materials, components and our products vary significantly which could lead to excess inventory levels as well as shortages of critical components or products if our supply forecasts are inaccurate.

We anticipate that our products will be manufactured based on forecasted demand and will seek to purchase components and materials in anticipation of the actual receipt of purchase orders for our products from customers. Lead times for materials, components and our products vary significantly and 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, components and products at any given time. 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 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 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.

Energy shortages may adversely impact our operations.

California had been experiencing shortages of electrical power and other energy sources. This condition has periodically resulted in rolling brownouts, or the temporary and generally unannounced loss of the primary electrical power source. Our laboratory facility in San Diego is powered by electricity. We do not have secondary electrical power sources to mitigate the impacts of temporary or longer-term electrical outages. It is not anticipated that the power shortages will abate soon, and therefore, our operating facilities may experience brown-outs, black-outs, or other consequences of the shortage, and may be subject to usage restrictions or other energy consumption regulations that could adversely impact or disrupt our research and development, manufacturing and other activities.

The number of our sales and marketing employees may not result in corresponding numbers of sales or placements of the NanoChip® System.

At March 31, 2002, we had twenty-seven 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 March 31, 2002, this office employed nine European-based sales executives and support personnel in the United Kingdom, Germany, The Netherlands and Denmark.

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.

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 US 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.

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 years ended December 31, 2001 and 2000 the rates of turnover at all levels of the Company were 31% and 19%, respectively. Turnover at these rates may, and if they continue, adversely affect 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.

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

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

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

- the results of our premarket studies and clinical trials or those of our collaborators or competitors or for DNA testing in general;
- evidence of the safety or efficacy of our potential products or the products of our competitors;
- the announcement by us or our competitors of technological innovations or new products;
- the announcement by us of acquisitions by customers of our NanoChip® System, ASR's or our other products;
- announcements by us of government grants or contracts;
- announcements or developments relating to our litigation against Combimatrix and Dr. Montgomery;
- developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;
- loss of key 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 in general; 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.

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 $1.5 million at March 31, 2002.

PART II OTHER INFORMATION

Item 1. Legal Proceedings

Please see discussion of legal proceedings at note 5 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
Indemnification Agreement between the Company and Randy J. Berholtz, dated January 28, 2002

(b)
Reports on Form 8-K
There were no reports on Form 8-K filed during the three months ended March 31, 2002.

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 May 13, 2002 /s/ HOWARD C. BIRNDORF

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

Date May 13, 2002 /s/ GERARD A. WILLS

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

NANOGEN, INC.
EXHIBIT INDEX

Exhibit No.	Description
10.1	Indemnification Agreement between the Company and Randy J. Berholtz, dated January 28, 2002

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