NANOGEN INC
Form 10-Q
May 14, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2001

OR

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

For the transition period from _____ to _____

Commission file number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

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

(858) 410-4600

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes /x/ No / /

As of May 11, 2001, 21,009,118 shares of the Registrant's Common Stock were outstanding.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2001	December 31, 2000
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,427	$ 55,330
Short-term investments	50,886	39,759
Accounts receivable	1,277	1,322
Inventory	3,471	2,289
Other current assets	2,069	1,689
Total current assets	94,130	100,389
Property and equipment, net	5,368	5,373
Acquired technology rights, net	4,879	5,179
Restricted cash	164	164
Other assets	63	63
	$ 104,604	$ 111,168

	March 31, 2001	December 31, 2000
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 990	$ 1,223
Accrued liabilities	3,642	4,595
Deferred revenue	159	360
Current portion of capital lease obligations	1,721	2,011
Total current liabilities	6,512	8,189
Capital lease obligations, less current portion	1,963	1,565
Stockholders' equity:		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2001 and December 31, 2000		
Common stock, $.001 par value, 50,000,000 shares authorized; 20,999,812 and 20,913,151 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	21	21
Additional paid-in capital	193,922	193,459
Accumulated other comprehensive income	826	270
Deferred compensation	(336)	(325)
Notes receivable from officers	(1,113)	(1,099)
Accumulated deficit	(97,191)	(90,912)
Total stockholders' equity	96,129	101,414
	$ 104,604	$ 111,168

See accompanying notes.

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

	Three months ended March 31,	
	2001	2000
Revenues:		
Sales	$ 229	$
Sponsored research	2,346	1,862
Contract and grant revenue	364	450
Total revenues	2,939	2,312
Operating expenses:		
Cost of sales	170	

	Three months ended March 31,	
Research and development	4,323	4,243
Selling, general and administrative	6,045	2,281
Total operating expenses	10,538	6,524
Loss from operations	(7,599)	(4,212)
Interest income, net	1,326	534
Loss on foreign currency transactions	(6)	
Net loss	$ (6,279)	$ (3,678)
Net loss per share Basic and diluted	$ (0.30)	$ (0.20)
Number of shares used in computing net loss per share basic and diluted	20,655	18,818

See accompanying notes.

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

	Three months ended March 31,	
	2001	**2000**
Operating activities:		
Net loss	$ (6,279)	$ (3,678)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	767	504
Amortization related to short-term investments	(19)	
Stock based compensation expense	157	452
Interest capitalized on notes receivables from officers	(14)	(10)
Changes in operating assets and liabilities:		
Accounts receivable	45	74
Inventory	(1,182)	
Other assets	(380)	65
Accounts payable	(233)	540
Accrued liabilities	(787)	(1,638)
Deferred revenue	(201)	(1,862)
Net cash used in operating activities	(8,126)	(5,553)
Investing activities:		
Purchase of short-term investments	(10,552)	

	Three months ended March 31,	
Purchase of equipment	(5)	
Net cash used in investing activities	(10,557)	
Financing activities:		
Principal payments on capital lease obligations	(349)	(581)
Issuance of common stock, net of repurchases	129	76,575
Note receivable payments from officers		164
Net cash provided by (used in) financing activities	(220)	76,158
Net (decrease) increase in cash and cash equivalents	(18,903)	70,605
Cash and cash equivalents at beginning of period	55,330	41,021
Cash and cash equivalents at end of period	$ 36,427	$ 111,626
Supplemental disclosure of cash flow information:		
Interest paid	$ 95	$ 120
Supplemental schedule of noncash investing andfinancing activities:		
Equipment acquired under capital leases	$ 457	$ 277
Unrealized gain on short-term investments	$ 556	$
Common stock issued in connection with employee benefit plan	$ 334	$

See accompanying notes.

NANOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)
March 31, 2001

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, 2001, consolidated statements of operations for the three months ended March 31, 2001 and 2000, and the consolidated statements of cash flows for the three months ended March 31, 2001 and 2000 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, 2001 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2001.

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, 2000 included in the Nanogen, Inc. Form 10-K, filed with the Securities and

Exchange Commission.

Net Loss per Share

The Company computes net income 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 per share is computed by dividing the net income for the period by the weighted average number of common shares outstanding during the period and dilutive potential common shares outstanding. 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, 2001 and 2000, 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.

2. Inventory

Inventory consists of the following (in thousands):

	March 31, 2001	December 31, 2000
Raw materials	$ 563	$ 288
Work in process	1,106	491
Finished goods	1,802	1,510
	$ 3,471	$ 2,289

Finished goods include NanoChip Molecular Biology Workstations ("NanoChip Systems") that are installed at customer sites where title has not transferred to the customer.

3. Comprehensive Loss

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

Consolidated Statements of Comprehensive Loss (Unaudited)

	Three months ended	
	March 31, 2001	March 31, 2000
Comprehensive loss:		
Net unrealized gain	$ 556	$
Net loss	(6,279)	(3,678)
Comprehensive loss	$ (5,723)	$ (3,678)

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 scale-up 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 and, depending on the attainment of certain minimum sales targets, other countries in Asia. 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 and certain other countries in Asia, subject to Hitachi's rights above. In addition, the Company seeks to develop and manufacture the NanoChip Cartridges for distribution worldwide. Except for Hitachi, Ltd.'s exclusive distribution rights of Hitachi, Ltd. produced Workstations in Japan and certain other countries in Asia, the agreement is non-exclusive and excludes some clinical markets. 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 various 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. In addition, 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 at a per share price of $26.813 (the fair market value as of the signing date of the Hitachi agreement). The agreement expands on the agreement executed by the Company and Hitachi in January 2000. 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. The agreement is non-exclusive and excludes some clinical markets.

Aventis Research and Technologies

In December 1997, the Company entered into an agreement with Aventis Research and Technologies, an affiliate of Hoechst AG ("Aventis") for, among other things, an exclusive research and development collaboration relating to the development of molecular recognition arrays. In December 1998, the Company and Aventis entered into a Collaborative Research and Development Agreement which, among other things, extended the guaranteed term of the research program from two to three years. In conjunction with this agreement, the Company issued to Aventis a warrant to purchase 120,238 shares of common stock exercisable through December 2003, which was exercised by Aventis in October 2000 at an agreed-upon exercise price of $6.17 per share. The Company has also agreed to issue to Aventis, upon the achievement of certain milestones, warrants to purchase up to approximately 360,000 additional shares of common stock at a 50 percent premium to the market price on the date the milestone is achieved. These warrants will have five-year maximum terms. The term of this collaboration agreement expired at the end of 2000. The Company is negotiating a potential new relationship with Aventis relating to the research conducted and technology developed under the December 1998 agreement.

In September 1999, the Company added two new technology development programs with Aventis which focus on the development of gene expression tools utilizing electronic bioarrays and the development of high throughput screening tools for kinase analyses. In total, these two programs may provide a maximum of $12.0 million in additional funding to the Company through December 31, 2001, including an up-front initiation fee of $2.0 million which was received in the fourth quarter of 1999.

Revenue is primarily recognized under the Aventis agreements as expenses are incurred, and totaled $2.1 million and $1.9 million for the three months ended March 31, 2001 and 2000, respectively. Funding received in advance of incurred expenses is recorded as deferred revenue until the expenses are incurred, and totaled none and $123,000 at March 31, 2001 and December 31, 2000, respectively.

4. Stock Option Program

On January 26, 2001, the Compensation Committee of the Board of Directors authorized a plan for certain employees (excluding executive officers and directors) who held options to purchase common stock whereby each holder could cancel certain of his or her vested and unvested options and receive a written commitment from the Company to issue, on a one-for-one basis, new options to be granted and priced at the fair market value on August 29, 2001. This plan applies only to options granted to employees of the Company between January 1, 2000 and February 28, 2001. These options will not be exercisable until August 29, 2001 or when they vest, whichever is later. The new options granted will contain similar vesting schedules as the cancelled options. This program resulted in the cancellation of 383,900 shares, which shares have been reserved for future issuance pursuant to the Company's written commitment to reissue the shares on August 29, 2001.

5. Pending Litigation

In April 2000, the Company filed a complaint for declaratory judgment against Motorola, Inc. ("Motorola"), Beckman Coulter, Inc. ("Beckman") and Massachusetts Institute of Technology ("MIT") in the United States District Court for the Southern District of California. Prior to the filing of the complaint, the parties had been involved in licensing discussions concerning U.S. Patent No. 5,693,939 entitled "Optical and Electrical Methods and Apparatus For Molecule Detection" (the "939 patent") which was licensed by MIT to Beckman in 1993 and to Genometrix, Inc. ("Genometrix") in 1994. Genometrix in turn granted its sublicensing rights to Motorola in 1999. The inventions claimed in the "939 patent were made with United States government funding through a grant from the Department

of the Air Force. The complaint seeks, among other things, a declaration that the Company is entitled to a license to the government funded "939 patent and that the Company is not required to obtain a license from both Motorola and Beckman. Alternatively, the complaint seeks a declaratory judgment that the claims of the "939 patent are invalid and not infringed by the Company.

In May 2000, the Company reached a settlement with Beckman and dismissed Beckman from the lawsuit without prejudice. In connection with the settlement, the Company secured a license to the "939 patent from Beckman.

The action continues against Motorola and MIT. Motorola filed a counterclaim against the Company in May 2000, claiming infringement of the "939 patent and seeking monetary damages and injunctive relief. Motorola's counterclaim asserts that it has exclusive rights to certain claims in the "939 patent. In October 2000, the Company's motion for leave to amend the complaint to add Genometrix as a defendant was granted. Fact discovery was substantially completed in early March 2001. The pretrial conference is currently scheduled for October 2001. No assurance can be given that a license to the "939 patent will be available from Motorola on commercially acceptable terms, or at all, or that the Company will prevail in the lawsuit. The Company has expended, and will continue to expend considerable financial resources and managerial efforts prosecuting the lawsuit and defending against Motorola's counterclaim, and against Motorola's, MIT's and Genometrix's affirmative defenses. The Company may not prevail in the action, which could have a material adverse effect on the Company.

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 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, containing fourteen claims, 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.

On December 15, 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss Nanogen's complaint. On January 29, 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. 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. 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 may have to expend 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. 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. 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

We integrate advanced microelectronics and molecular biology into a core technology platform with potentially broad and diverse commercial applications in the fields of genomics, biomedical research, medical diagnostics, drug discovery, forensics, agriculture, environmental testing and potentially the electronics and telecommunications industries. 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 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, and, since early 2000, to our commercial launch of the NanoChip System. We have incurred losses since inception and, as of March 31, 2001, had an accumulated deficit of $97.2 million. We expect to incur significant losses over at least the next several years as we expand our research and product development efforts and attempt to further commercialize our products.

We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, the achievement of milestones under our collaborative agreements, whether and when new products are successfully developed and introduced by us or our competitors, market acceptance of the NanoChip System and potential products under development, and the type of acquisition program our potential customers choose. Payments 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.

Results of Operations

Revenues. Sales of $229,000 for the three months ended March 31, 2001, include the sale of one NanoChip Molecular Biology Workstation through an outright sales transaction where the title of the instrument passed to the customer in addition to the sale of NanoChip Cartridges. There were no comparable sales in the prior year three month period as these products had not yet been commercially launched. We offer our products to customers under several different types of acquisition programs, some of which do not pass title to the customer, and for which no revenue is recorded at the time of delivery. In these cases, revenue, if any, will be recorded ratably over the rental period. Our sales revenue may vary from quarter to quarter due to, among other things, the types of acquisition programs our potential customers may choose.

Revenue from sponsored research totaled $2.3 million and $1.9 million for the three months ended March 31, 2001 and 2000, 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 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 entered into in July 2000 with Hitachi. Sponsored research revenue recognized during the three months ended March 31, 2000, was earned in connection with the research and development agreements entered into in December 1998 and September 1999 with Aventis.

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.

Continuation of sponsored research agreements, contracts and grants is dependent upon us achieving specific contractual milestones. The recognition of revenue under sponsored research agreements, contracts and grants may vary from quarter to quarter and may result in significant fluctuations in operating results from year to year.

Cost of Sales. Cost of sales were $170,000 for the three months ended March 31, 2001. There were no cost of sales recorded for the three months ended March 31, 2000 as we had not recorded any product sales during this period. Cost of sales during the three months ended March 31, 2001 were impacted by underabsorbed overhead costs due to underutilized capacity. As we are still in the early stages of our first product launch, we expect to continue to incur significant costs associated with excess production capacity during 2001.

Research and Development Expenses. Research and development expenses were $4.3 million and $4.2 million for the three months ended March 31, 2001 and 2000, respectively. During these periods, research and development expenses included salaries for scientific, engineering and operations personnel, costs associated with improving and refining our current products as well as development of potential new products, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities. Research and development spending may increase over the next several years as our research and product development efforts continue.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $6.0 million and $2.3 million for the three months ended March 31, 2001 and 2000, respectively. The increase is primarily due to costs associated with the expansion of our sales and marketing organization, increased legal fees associated with enhancing and maintaining our intellectual property portfolio, and costs related to patent litigation. Selling, general and administrative expenses are expected to continue at this level for the foreseeable future as we continue to market and sell our current products, continue to enhance our intellectual property portfolio, and as litigation continues.

Interest Income, Net. Net interest income was $1.3 million and $534,000 for the three months ended March 31, 2001 and 2000, respectively. The increase in net interest income is a result of higher average cash balances during the three months ended March 31, 2001 compared to the same period in 2000 as a result of cash proceeds received in conjunction with our follow-on offering of common stock in March 2000.

Liquidity and Capital Resources

At March 31, 2001, we had $87.3 million in cash, cash equivalents and short-term investments, compared to $95.1 million at December 31, 2000. The decrease is primarily due to cash used in operations during the three months ended March 31, 2001.

Net cash used in operating activities was $8.3 million and $5.6 million for the three months ended March 31, 2001 and 2000, respectively. Cash used for operations during the three months ended March 31, 2001 was primarily related to costs associated with our expanded sales and marketing organization as the launch of our initial products progresses, an increase of $1.2 million in inventory pursuant to our manufacturing arrangement with Hitachi, Ltd., legal fees relating to establishing and maintaining our intellectual property portfolio, supporting our continued research and development efforts, and patent litigation.

We fund most of our equipment acquisitions and leasehold improvements through capital leasing facilities. During the first three months of 2001, we received proceeds from equipment financing of $457,000, compared to $277,000 of proceeds received during the same period in 2000. We anticipate that we will continue to use capital equipment leasing or debt facilities to fund most of our equipment acquisitions and leasehold improvements.

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 and contracts and grants will be sufficient to support our planned operations through at least the next two years. 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, 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 two 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 other products or applications 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, which would harm us and force us to curtail or cease operations.

We are at an early stage of development. We currently have only two products for sale, our NanoChip Molecular Biology Workstation and our NanoChip Cartridge. All of our other 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.

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. 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, licensors, licensees and others. Our success depends in part upon the performance by these collaborators and potential collaborators 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 health care company, pharmaceutical companies and a developer and manufacturer of instrumentation products. We do not know whether these companies 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 Aventis, Becton Dickinson, Élan and Hitachi, Ltd. that contemplate the commercialization of products resulting from research and development collaboration agreements between the parties. In addition, we have a manufacturing and distribution agreement with Hitachi. 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, but we did not sell significant quantities of our first products during fiscal 2000 or during the three months ended March 31, 2001. From our inception to March 31, 2001, we have incurred cumulative net losses totaling approximately $97.2 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 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; and
- companies developing drug discovery technologies.

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 which 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. Besides the patent involved in litigation with Motorola, MIT and Genometrix, and CombiMatrix and Dr. Montgomery described below, 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 litigation with Motorola, MIT and Genometrix 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 corresponding foreign patents and applications which are assigned to Affymax Technologies, N.V., and Affymetrix, Inc. which relate to certain devices having 1,000 or more groups of oligonucleotides occupying a total area of less than 1 cm^2, 400 different oligonucleotides per cm^2 on a substrate, and for gene expression, more than 100 different oligonucleotides at a density greater than

about 60 different oligonucleotides per 1 cm^2. In the event that we proceed with the development of arrays with more than 400 groups of oligonucleotides, or for gene expression, with more than 100 different oligonucleotides, we expect to design our devices through, among other things, the selection of the physical dimensions, methods of binding, selection of support materials and intended uses of the device to avoid infringing these patents. We may not be able to design around these patents. We are aware of U.S. and European patents and patent applications owned by Isis Innovations Ltd. or Isis Innovations (E. M. Southern). We have opposed one allowed European patent which had broad claims to array technology for analyzing a predetermined polynucleotide sequence. Isis Innovations' position with respect to the opposed patent is that the claims relate to what it terms the "diagnostic mode." Those claims have now all been narrowed to the point that if the claims are accepted by the European Patent Office, they would not be infringed by our technology. On May 5, 1998, the Opposition Division of the European Patent Office issued a provisional nonbinding opinion that the claims should be revoked. If the claims of the original European patent survive the opposition or if an application relating to arrays issues in another country with claims as broad as the original European patent, we would be subject to infringement claims that could delay or preclude sales of some or all of our anticipated diagnostic products.

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

In April 2000, we filed a complaint for declaratory judgment against Motorola, Beckman and MIT in the United States District Court for the Southern District of California. Prior to the filing of the complaint, the parties had been involved in licensing discussions concerning U.S. Patent No. 5,693,939 entitled "Optical and Electrical Methods and Apparatus For Molecule Detection" (the "939 patent") which was licensed by MIT to Beckman in 1993 and to Genometrix, Inc. or Genometrix in 1994. Genometrix subsequently granted its sublicensing rights to Motorola in 1999. The inventions claimed in the "939 patent were made with United States government funding through a grant from the Department of the Air Force. The complaint seeks, among other things, a declaration that we are entitled to a license to the government funded "939 patent and, in the event we proceed to take a license, that we are not required to obtain a license from both Motorola and Beckman. Alternatively, the complaint seeks a declaratory judgment that the claims of the "939 patent are invalid and not infringed by us.

In May 2000, we reached a settlement with Beckman and dismissed Beckman from the lawsuit without prejudice. In connection with the settlement, we secured a license to the "939 patent from Beckman.

The action continues against Motorola and MIT. Motorola filed a counterclaim against us in May 2000, claiming infringement of the "939 patent and seeking monetary damages and injunctive relief. Motorola's counterclaim asserts that it has exclusive rights to certain claims in the "939 patent. In October 2000, our motion for leave to amend the complaint to add Genometrix as a defendant was granted. Fact discovery was substantially completed in early March 2001. The pretrial conference is currently scheduled for October 2001. No assurance can be given that a license to the "939 patent will be available from Motorola on commercially acceptable terms, or at all, or that we will prevail in the lawsuit. We have expended and will continue to expend considerable financial resources and managerial efforts prosecuting the lawsuit and defending against Motorola's counterclaim, and against Motorola's,

MIT's, and Genometrix's affirmative defenses. We may not prevail in the action, which could have a material adverse effect on us.

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, containing fourteen claims, 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.

On December 15, 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss Nanogen's complaint. On January 29, 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. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the counterclaim. We may have to expend 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 a number of any diagnostic products 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 *in vitro* reagents that are marketed for human 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 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 which 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.

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.

Energy shortages may adversely impact our operations.

California is currently 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. Currently, 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 increase in the number of our sales and marketing employees may not result in increases in sales or placements of the NanoChip System.

We increased the number of employees in our sales and marketing group from 26 at December 31, 2000 to 31 at March 31, 2001. In addition, in July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At March 31, 2001, this office employed seven 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 increased sales or placements of the NanoChip System nor increased product revenues associated with such sales or placements. 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 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 US 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.

If we fail to manage our growth, our business could be impaired.

We expect to continue to experience growth in the number of our employees and the scope of our operating and financial systems. This growth has resulted in an increase in responsibilities for both existing and new management personnel. Our ability to manage growth effectively will require us to continue to implement and improve our operational, financial and management information systems and to recruit, train, motivate and manage our employees. We may not be able to manage our growth and expansion, which would impair our business.

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 and management 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.

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 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 or our other products;

announcements or developments relating to our litigation against Motorola, MIT and Genometrix and 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;

changes or announcements in reimbursement policies;

developments with our 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 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 goodwill and other intangible assets, which could adversely affect our results of operations and financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We invest our excess cash in short-term, interest-bearing investment-grade securities that 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.

The functional currency for our Netherlands subsidiary is the U.S. dollar. In certain instances, our subsidiary conducts its business with customers and vendors in Euros or other in 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 subsidiary, excluding intercompany balances, is $899,000 at March 31, 2001.

NANOGEN, INC.
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 5. Other Information

On April 15, 2001, Thomas G. Lynch, Executive Vice President and Chief Financial Officer of Élan Corporation, plc voluntarily resigned from the Board of Directors. On April 26, 2001, Randy White, Ph.D., Executive Vice President Technical Operations and Research and Development at American Medical Laboratories, Inc., was appointed to the Board of Directors. On April 26, 2001, Gerard A. Wills joined the Company as its Vice President, Chief Financial Officer and Treasurer.

Item 6. Exhibits and Reports on Form 8-K

(a)

Exhibits

10.1

Employment Agreement between Kieran Gallahue and Nanogen, Inc., dated January 26, 2001.

(b)

Reports on Form 8-K

No Reports on Form 8-K were filed during the three months ended March 31, 2001.

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 May 14, 2001 /s/ HOWARD C. BIRNDORF

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

Date May 14, 2001 /s/ GERARD A. WILLS

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

NANOGEN, INC.
EXHIBIT INDEX

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QuickLinks