

NANOGEN INC
Form 10-Q
August 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 June 30, 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
(State or other jurisdiction of
incorporation or organization)

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

10398 Pacific Center Court, San Diego, CA
(Address of principal executive offices)

92121
(Zip code)

(858) 410-4600

(Registrant's telephone number, including area code)

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

As of August 9, 2001, 21,426,999 shares of the Registrant's Common Stock were outstanding.

**NANOGEN, INC.
FORM 10-Q**

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

(in thousands, except share data)

	<u>June 30, 2001</u>	<u>December 31, 2000</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,419	\$ 55,330
Short-term investments	57,938	39,759
Accounts receivable	1,413	1,322
Inventory	4,234	2,289

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	June 30, 2001	December 31, 2000
Other current assets	3,332	1,689
Total current assets	87,336	100,389
Property and equipment, net	5,444	5,373
Acquired technology rights, net	4,579	5,179
Restricted cash	164	164
Other assets	203	63
	<u>\$ 97,726</u>	<u>\$ 111,168</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 622	\$ 1,223
Accrued liabilities	5,419	4,095
Deferred revenue	151	360
Current portion of capital lease obligations	1,514	2,011
Total current liabilities	7,706	7,689
Capital lease obligations, less current portion	2,186	1,565
Other long-term liabilities	3,000	500
Total long-term liabilities	5,186	2,065
Stockholders' equity:		
Convertible preferred stock, \$.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2001 and December 31, 2000		
Common stock, \$.001 par value, 50,000,000 shares authorized; 21,057,583 and 20,913,151 shares issued and outstanding at June 30, 2001 and December 31, 2000, respectively		
Additional paid-in capital	21	21
	194,198	193,459
Accumulated other comprehensive income	862	270
Deferred compensation	(175)	(325)
Notes receivable from officers	(1,131)	(1,099)
Accumulated deficit	(108,941)	(90,912)
Total stockholders' equity	84,834	101,414
	<u>\$ 97,726</u>	<u>\$ 111,168</u>

See accompanying notes.

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

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	Three months ended June 30,		Six months ended June 30,	
	2001	2000	2001	2000
Revenues:				
Sales	\$ 302	\$ 164	\$ 531	\$ 164
Sponsored research	2,055	1,704	4,401	3,566
Contract and grant revenue	358	484	723	934
Total revenues	2,715	2,352	5,655	4,664
Operating expenses:				
Cost of sales	230	12	400	12
Research and development	4,414	4,515	9,199	8,758
Selling, general and administrative	5,406	3,344	10,192	5,625
Litigation and settlement of patent matter	5,511		6,309	
Total operating expenses	15,561	7,871	26,100	14,395
Loss from operations	(12,846)	(5,519)	(20,445)	(9,731)
Interest income, net	1,092	1,406	2,418	1,940
Gain (loss) on foreign currency transactions	4		(2)	
Net loss	\$ (11,750)	\$ (4,113)	\$ (18,029)	\$ (7,791)
Net loss per share basic and diluted	\$ (0.56)	\$ (0.20)	\$ (0.87)	\$ (0.40)
Number of shares used in computing net loss per share basic and diluted	20,847	20,208	20,802	19,513

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Six months ended June 30,	
	2001	2000
Operating activities:		
Net loss	\$ (18,029)	\$ (7,791)
Adjustments to reconcile net loss to net cash used in operating activities:		

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	Six months ended June 30,	
Accrual for settlement of litigation	5,000	
Depreciation and amortization	1,542	1,121
Amortization related to short-term investments	(35)	
Stock based compensation expense	294	670
Interest capitalized on notes receivables from officers	(32)	(31)
Changes in operating assets and liabilities:		
Accounts receivable	(91)	(208)
Inventory	(1,945)	
Other assets	(1,783)	(1,183)
Accounts payable	(601)	166
Accrued liabilities	(1,176)	(1,722)
Deferred revenue	(209)	(2,555)
Net cash used in operating activities	(17,065)	(11,533)
Investing activities:		
Purchase of short-term investments	(17,552)	
Purchase of equipment	(30)	
Purchase of technology rights		(5,000)
Net cash used in investing activities	(17,582)	(5,000)
Financing activities:		
Principal payments on capital lease obligations	(859)	(1,078)
Issuance of common stock, net of repurchases	595	76,880
Note receivable payments from officers		185
Net cash provided by (used in) financing activities	(264)	75,987
Net (decrease) increase in cash and cash equivalents	(34,911)	59,454
Cash and cash equivalents at beginning of period	55,330	41,021
Cash and cash equivalents at end of period	\$ 20,419	\$ 100,475
Supplemental disclosure of cash flow information:		
Interest paid	\$ 198	\$ 222
Supplemental schedule of noncash investing and financing activities:		
Equipment acquired under capital leases	\$ 983	\$ 391
Unrealized gain on short-term investments	\$ 592	\$
Common stock issued in connection with employee benefit plan, net of forfeitures	\$ 144	\$

See accompanying notes.

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

June 30, 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 June 30, 2001, consolidated statements of operations for the three and six months ended June 30, 2001 and 2000, and the consolidated statements of cash flows for the six months ended June 30, 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 and six months ended June 30, 2001 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2001.

Certain prior year amounts have been reclassified to conform to the current year presentation.

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 and six months ended June 30, 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):

	June 30, 2001	December 31, 2000
Raw materials	\$ 705	\$ 288
Work in process	1,075	491
Finished goods	2,454	1,510
	<u>\$ 4,234</u>	<u>\$ 2,289</u>

Finished goods include NanoChip Molecular Biology Workstations ("NanoChip Systems") 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 Molecular Biology Workstations. As of June 30, 2001, the Company has commitments to purchase approximately

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\$5.4 million in NanoChip Molecular Biology Workstations through March 31, 2002.

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 June 30,		Six months ended June 30,	
	2001	2000	2001	2000
Comprehensive loss:				
Net unrealized gain	\$ 36	\$	\$ 862	\$
Net loss	(11,750)	(4,113)	(18,029)	(7,791)
Comprehensive loss	\$ (11,714)	\$ (4,113)	\$ (17,167)	\$ (7,791)

4. Collaborative Alliances

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 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 funding to the Company through December 31, 2001. As of June 30, 2001, the Company had received an aggregate of \$9.2 million in funding for these programs, including an up-front initiation fee of \$2.0 million which was received in the fourth quarter of 1999.

Revenue is primarily recognized under these agreements as expenses are incurred, and totaled \$1.8 million and \$3.9 million for the three and six months ended June 30, 2001, respectively, and \$1.7 million and \$3.6 million for the three and six months ended June 30, 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 June 30, 2001 and December 31, 2000, respectively.

In June 2001, the Company entered into agreements with Aventis to create a new company, Nanogen Recognomics GmbH ("Nanogen Recognomics"). The joint venture 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 will provide the funding for the operations of the new company and has contributed intellectual property in the form of eighteen patents. In addition, Nanogen Recognomics will own several patent applications filed jointly by the Company and Aventis. The Company has licensed certain aspects of its

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NanoChip technology to the new company and will commercialize new products and applications developed by the joint venture. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of the joint venture. 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 \$9.83.

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 some claims of the '939 Patent. In exchange, the Company will make a one-time payment of \$2.5 million in cash and issue 416,666 shares of the Company's common stock (valued at approximately \$2.5 million based upon a per share price of \$6.00, the fair market value on the date of settlement) to the parties involved. The settlement does not include any

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cross-licensing provisions of the Company's technology to Motorola, Genometrix or MIT. The lawsuit and the counterclaim have now been dismissed. As of June 30, 2001, these amounts have been accrued for in the Company's financial statements.

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.

On December 15, 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss the Company'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 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. On May 14, 2001, the Company filed a motion to dismiss CombiMatrix's counterclaim, which was denied on July 27, 2001.

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.

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

This report includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties that could cause our actual results to vary materially from those reflected in the forward-looking statements. 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 June 30, 2001, had an accumulated deficit of \$108.9 million. We expect to incur significant losses over at least the next several years as we continue 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. For the three and six months ended June 30, 2001 sales totaled \$302,000 and \$531,000, respectively, compared to \$164,000 for the three and six months ended June 30, 2000. Sales revenue during the three months ended June 30, 2001 includes the sale of two NanoChip Molecular Biology Workstations through outright sales transactions where the title of the instrument passed to the customer as well as sales of NanoChip Cartridges. For the six months ended June 30, 2001, sales revenue includes sales of three NanoChip Molecular Biology Workstations in addition to sales of NanoChip Cartridges. Sales revenue for the three and six months ended June 30, 2000 was comprised of the sale of our first NanoChip Molecular Biology Workstation as well as our first sales of NanoChip Cartridges. 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.

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For the three and six months ended June 30, 2001 revenues from sponsored research totaled \$2.1 million and \$4.4 million, respectively, compared to \$1.7 million and \$3.6 million for the three and six months ended June 30, 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 and six months ended June 30, 2001, was primarily earned in connection with our technology development programs under our research and development agreement entered into in September 1999 with Aventis. Sponsored research revenue recognized during these periods in 2001 also includes revenue earned in connection with our development program entered into in July 2000 with Hitachi. Additionally, sponsored research revenue recognized during the three and six months ended June 30, 2001 includes the sale of two NanoChip Molecular Biology Workstations to one of the Aventis programs. Sponsored research revenue recognized during the three and six months ended June 30, 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. Our current technology programs under our research and development agreement with Aventis are anticipated to conclude prior to December 31, 2001. 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.

Gross Margins. Gross margins for the three and six months ended June 30, 2001 were 23.8% and 24.7%, respectively, and were impacted by the sale of a NanoChip Molecular Biology Workstation to a distributor at a discount from list price. In addition, gross margins during these periods in 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. For the three and six months ended June 30, 2000, gross margins were 92.7% and were impacted by the sale of one NanoChip Molecular Biology Workstation for which the cost had been recognized as research and development expense in a prior period as the Workstation was a prototype unit.

Research and Development Expenses. For the three and six months ended June 30, 2001 research and development expenses totaled \$4.4 million and \$9.2 million, respectively, compared to \$4.5 million and \$8.8 million for the three and six months ended June 30, 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. For the three and six months ended June 30, 2001 selling, general and administrative expenses totaled \$5.4 million and \$10.2 million, respectively, compared to \$3.3 million and \$5.6 million for the three and six months ended June 30, 2000, respectively. The increase is primarily due to costs associated with the expansion and development of our sales and marketing organization. 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.

Litigation and Settlement of Patent Matter. For the three and six months ended June 30, 2001 litigation and settlement of a patent matter totaled \$5.5 million and \$6.3 million, respectively. There were no comparable expenses for the three and six months ended June 30, 2000. Costs incurred during

the three and six month period ended June 30, 2001 primarily consist of the settlement fee of \$5 million in addition to legal fees incurred related to the litigation process. 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 agreed to pay a total of \$5 million to the parties in the form of \$2.5 million in cash and \$2.5 million in our common stock (approximately 416,666 shares).

Interest Income, Net. For the three and six months ended June 30, 2001 net interest income totaled \$1.1 million and \$2.4 million, respectively, compared to \$1.4 million and \$1.9 million for the three and six months ended June 30, 2000, respectively. The decrease in net interest income for the quarter is a result of lower average cash balances during the three months ended June 30, 2001 compared to the same period in 2000. Cash proceeds received in conjunction with the follow-on offering of our common stock in March 2000 resulted in an increase in net interest income for the six months ended June 30, 2001 when compared to the same period in 2000.

Liquidity and Capital Resources

At June 30, 2001, we had \$78.4 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 six months ended June 30, 2001.

Net cash used in operating activities was \$17.1 million and \$11.5 million for the six months ended June 30, 2001 and 2000, respectively. Cash used for operations during the six months ended June 30, 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 \$1.9 million in inventory pursuant to our manufacturing arrangement with Hitachi, Ltd., \$1.3 million in patent litigation fees, legal fees related to establishing, maintaining and defending our intellectual property portfolio, and supporting our continued research and development efforts.

We fund most of our equipment acquisitions and leasehold improvements through capital leasing facilities. During the first six months of 2001, we financed approximately \$983,000 of capital equipment, compared to approximately \$391,000 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.

Our manufacturing agreement with Hitachi, Ltd. ("Hitachi") requires that we provide annual purchase commitments to Hitachi for NanoChip Molecular Biology Workstations. As of June 30, 2001, we have commitments to purchase approximately \$5.4 million in NanoChip Molecular Biology Workstations through March 31, 2002.

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 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 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 two products for sale, our NanoChip Molecular Biology Workstation and our NanoChip Cartridge. 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.

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 health care company, a pharmaceutical company and a developer and manufacturer of instrumentation products and we entered into a joint venture with the research and development subsidiary of a pharmaceutical company. We do not know whether the collaborators 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 and Hitachi, Ltd. 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 also entered into a joint venture, 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, but we did not sell significant quantities of our first products during fiscal 2000 or during the six months ended June 30, 2001. From our inception to June 30, 2001, we have incurred cumulative net losses totaling approximately \$108.9 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 obtaining necessary regulatory clearances or approvals;

filing, prosecuting, defending and enforcing patent claims and litigation; and

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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 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.

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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 cm², 400 different oligonucleotides per cm² on a substrate, and for gene expression, more than 100 different oligonucleotides at a density greater than about 60 different oligonucleotides per 1 cm². 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.

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We were and are currently involved in intellectual property litigation that was and is 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 sought, 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 sought a declaratory judgment that the claims of the '939 patent were 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 continued 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 asserted that it had 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.

In July 2001, we reached a settlement with Motorola, Genometrix and MIT. Pursuant to the settlement, Nanogen secured from Motorola a license to and freedom to operate under Claims 16 and 39 of the '939 Patent. In exchange, Nanogen agreed to pay the parties involved a total of \$2.5 million in cash and \$2.5 million in Nanogen common stock. 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. We have expended considerable financial resources and managerial efforts prosecuting, defending and settling the lawsuit and counterclaim.

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