

Edgar Filing: NANOGEN INC - Form 10-K

NANOGEN INC
Form 10-K
April 02, 2001

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

FOR THE FISCAL PERIOD ENDED DECEMBER 31, 2000

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)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (858) 410-4600

Securities registered pursuant to Section 12(b) of the Act:
NONE

Securities registered pursuant to Section 12(g) of the Act:
Common Stock \$.001 par value
Preferred Stock Purchase Rights
(Title of Class)

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 / /

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405
of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and

Edgar Filing: NANOGEN INC - Form 10-K

will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon the closing sale price of the Common Stock on March 23, 2001, as reported on the Nasdaq National Market was approximately \$112,465,223. Shares of Common Stock held by each executive officer and director and by each person who owns 10 percent or more of the outstanding Common Stock have been excluded in such calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant's common stock was 20,981,900 as of March 23, 2001.

NANOGEN, INC. FORM 10-K INDEX

PART I

Item 1.	Business.....
Item 2.	Properties.....
Item 3.	Legal Proceedings.....
Item 4.	Submission of Matters to a Vote of Security Holders.....

PART II

Item 5.	Market for Registrant's Common Equity and Related Stockholder Matters.....
Item 6.	Selected Financial Data.....
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations.....
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk.....
Item 8.	Financial Statements and Supplementary Data.....
Item 9.	Change in and Disagreements with Accountants on Accounting and and Financial Disclosures.....

PART III

Item 10.	Directors and Executive Officers of the Registrant.....
----------	---

Edgar Filing: NANOGEN INC - Form 10-K

Item 11.	Executive Compensation.....
Item 12.	Security Ownership of Certain Beneficial Owners and Management.....
Item 13.	Certain Relationships and Related Transactions.....

PART IV

Item 14.	Exhibits, Financial Statement Schedules, and Reports on Form 8-K.....
----------	---

SIGNATURES.....

-i-

PART I

ITEM 1. BUSINESS

OVERVIEW

We launched our first commercial product during the second quarter of the year 2000, beginning our transformation from a research and development company to a customer-oriented company. The NanoChip(TM) Molecular Biology Workstation has been targeted toward clinical researchers performing genetic-based analyses, particularly those involving single nucleotide polymorphisms ("SNPs"), short tandem repeats ("STRs"), single point mutations ("PMs") and other genetic variations. Our first product launch marks a point of entry from which we hope to expand our product line and served markets.

Our primary differentiation stems from our ability to integrate advanced microelectronics and molecular biology into a core technology platform with potential commercial applications in the fields of genomics and biomedical research, medical diagnostics, drug discovery, forensics, agriculture, environmental testing and potentially the electronics and telecommunications industries. The first application we have developed is an integrated bioassay system, the NanoChip(TM) Molecular Biology Workstation, comprised of two automated instruments and a consumable cartridge. The NanoChip(TM) Cartridge incorporates a proprietary microchip, providing a flexible tool for the rapid identification and precision analysis of biological test samples containing charged molecules.

Through the use of microelectronics, our technology enables the active movement and concentration of charged molecules, such as DNA, to and from designated microlocations, or test sites, on our microchips. This electronic concentration of molecules greatly accelerates molecular binding at each microlocation. In addition, our technology allows the simultaneous analysis of multiple test results, or "multiplexing," from a single sample. The potential future applications for our system include microchips with preloaded arrays designed for specific applications or with arrays that can be customized by the end user. We believe that our technology platform provides an accurate, versatile and highly efficient integrated system that may shift bioassay analysis from manual and mechanical methods to microelectronic systems, thereby significantly improving the quality and reducing the overall cost of research

Edgar Filing: NANOGEN INC - Form 10-K

and healthcare.

During the year 2000, we accomplished the following:

- finalized the beta test results for our NanoChip(TM) System, reporting extremely high accuracy and flexibility in hard to score mutations;
- raised over \$76.5 million in a secondary offering;
- commercially launched the NanoChip(TM) System as our first product and shipped a total of 23 NanoChip(TM) Systems to the research laboratories of hospitals, universities, government organizations and pharmaceutical companies;
- significantly expanded our sales, marketing and field support staff and expanded our international sales and marketing efforts by opening our European office in The Netherlands;
- signed a long-term collaboration agreement with Hitachi expanding our earlier agreement and providing for the joint development of future technology;
- realigned our joint venture with Becton Dickinson to expand our licensing rights to the joint venture's proprietary amplification technique;
- received two additional government grants that provide for a total of \$2.7 million of continued funding for the development of our core technologies; and
- expanded our intellectual property portfolio by adding ten U.S. patents and seven foreign patents.

1

YEAR 2000 ACCOMPLISHMENTS

SUCCESSFUL BETA SITE TESTS

In February 2000, we announced the completion of our third and final beta site testing results for the NanoChip(TM) Molecular Biology Workstation. These tests were conducted at three commercial and academic centers: the Mayo Clinic, the University of Texas Southwestern Medical Center and the Bode Technology Group. In each case, the results indicated very high levels of accuracy for the NanoChip(TM) System. The SNP studies performed at the Mayo Clinic and the University of Texas Southwestern Medical Center both reported 100% accuracy, exceeding the performance of their current "gold standard" techniques. The STR analysis results from the Bode Technology Group showed greater than 99.5% concordance with current techniques, results which have been further improved by subsequent software upgrades.

\$76.5 MILLION SECONDARY OFFERING

In March 2000, we completed a secondary public offering of common stock that generated net proceeds of approximately \$76.5 million. As of December 31, 2000, our cash, cash equivalents and short-term investment balance was in excess of \$95 million.

COMMERCIAL LAUNCH OF THE NANOCHIP(TM) SYSTEM AND SHIPMENT OF 23 SYSTEMS

Edgar Filing: NANOGEN INC - Form 10-K

We began commercialization of our NanoChip(TM) Molecular Biology Workstation during the second quarter of 2000 in the genomics and biomedical research fields. The initial application for the technology is the analysis of SNPs including those that are hard to score, insertions and deletions, STRs, PMs and other genetic variations. We anticipate adding the analysis of gene expression as an additional application during 2001. Because of the importance of the genomics and biomedical research markets for the development and sales of future applications for the NanoChip(TM) System and for other products related to our technology, we chose to build a commercial infrastructure that would allow us to be directly involved in marketing and selling our first product. Additionally, we set up a distribution capability for our products in Japan through the distribution arm of Hitachi, Ltd., our manufacturing partner.

As of December 31, 2000, we shipped a total of 23 NanoChip(TM) Systems to customers in three countries, including the research laboratories of hospitals, universities, government organizations and pharmaceutical companies. Such customers include the National Cancer Institute, the Mayo Clinic, the Children's Research Hospital of Tokyo, Aventis, Stanford University and Beth Israel Deaconess Medical Center at Harvard. Our NanoChip(TM) System is designed to assist research in the fields of genetics, cancer and infectious and cardiovascular disease.

These 23 shipments include two sales recorded as sponsored research revenue and funded by corporate alliances, seven title transfer transactions representing sales and recorded as product revenue, and 14 non-title transfer transactions. Of the non-title transfers, one was a shipment made to a corporate collaborator pursuant to an expanded relationship. The other 13 were strategic placements made pursuant to our development site agreements. Non-title transferring transactions may include development site agreements, leases and reagent rentals. Title transferring transactions normally result in recording of full instrument revenue at the time of the transaction, while non-title transferring transactions may spread instrument revenue associated with the transaction, if any, over the life of the instrument or the agreement. We believe that the non-title transferring transactions help us establish awareness and credibility in our target markets.

EXPANDED SALES, MARKETING AND FIELD SUPPORT EFFORTS

We increased the number of employees in our sales and marketing group from three at December 31, 1999 to twenty-six at December 31, 2000. In addition, in August 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At December 31, 2000, this office employed four European-based sales executives in the United Kingdom, Germany, The Netherlands and Denmark.

2

EXPANDED HITACHI COLLABORATION

In July 2000, we 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 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 expands on the agreement executed by the Company and Hitachi in January 2000. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement,

Edgar Filing: NANOGEN INC - Form 10-K

we and Hitachi each may contribute up to \$28.5 million in cash over the ten-year period. In addition, Hitachi made an equity investment in us by purchasing 74,590 shares of our common stock worth approximately \$2.0 million pursuant to a private sale by us based on a per share price of \$26.813 (the fair market value as of the signing date of the Hitachi agreement). Hitachi has the right to be the exclusive distributor of collaboration products in Japan and, based upon the attainment of minimum sales targets to be mutually agreed upon, in other Asian countries. We retain the exclusive right to distribute collaboration products outside of these countries. The agreement is non-exclusive and excludes some clinical markets.

REALIGNED JOINT VENTURE WITH BECTON DICKINSON

In September 2000, we and Becton Dickinson modified our joint venture to permit each of us the opportunity to commercialize certain of the joint venture's technology and allow collaborations with third parties to develop and commercialize certain products in the field of infectious diseases. Pursuant to amendments to the Master Agreement, the General Partnership Agreement and the Collaborative Research and Development and License Agreement, the Partnership exclusively licensed Partnership technology developed up to that date to Becton Dickinson and Becton Dickinson exclusively sublicensed the Partnership technology to us to commercialize products in the field of infectious diseases. Becton Dickinson also agreed to non-exclusively license SDA technology to us for use and for sublicensing purposes in the field of infectious diseases. Becton Dickinson also expanded the field of use for our SDA license outside of the Partnership to not only include IN VITRO human genetic testing and IN VITRO cancer diagnostics, but also IN VITRO testing of environmental, agricultural and veterinary samples. Pursuant to the amendments, Becton Dickinson paid us \$300,000.

RECEIVED ADDITIONAL GOVERNMENT GRANTS

In August 2000, we were awarded a contract by the Space and Naval Warfare Systems Center San Diego for the Defense Advanced Research Projects Agency in an amount totaling approximately \$1.6 million over a two year period. The goal of the contract is to develop and refine electronically driven sample preparation protocols on specifically designed microelectronic chips. In October 2000, we entered into a cooperative agreement with the U.S. Army Medical Research Acquisition Activity ("USAMRAA") in an amount totaling approximately \$1.1 million over a two year period. The objective of the USAMRAA agreement is to develop an arrayable electronic system for the identification of biological warfare or infectious disease agents.

EXPANDED OUR INTELLECTUAL PROPERTY PORTFOLIO

During 2000, we expanded our intellectual property portfolio adding ten additional U.S. patents and seven additional foreign patents. As of December 31, 2000, we had a total of 20 U.S. patents and 13 foreign patents.

OUR TECHNOLOGY AND RELEVANT MARKETS

LIMITATIONS OF CURRENT ASSAY TECHNOLOGIES

Many bioassay techniques have been developed from a wide variety of different scientific disciplines for molecular biology and clinical diagnostic laboratories. Many of these techniques are technically demanding, difficult to perform, expensive or inflexible and may lack acceptable clinical accuracy. In addition, technologies well suited or targeted to one market, such as the biomedical research or drug discovery markets, often are unable to bridge the gap to serve downstream markets such as clinical diagnostics.

Despite recent advances in technology, many bioassays are too specialized or inflexible to be used throughout the various departments of a life sciences laboratory. Current bioassay tools were designed for large scale data generation, the automation of repetitious tasks such as very high throughput discovery and the narrowing of genetic targets from thousands of genes to a small set of perhaps 1 to 20 genes that function in a selected biological process. In addition, many of these systems are not useful in molecular, protein, enzyme, cell biology, and forensics laboratories. These tools fall primarily into three categories: high-density arrays; high throughput sequencing and SNP discovery tools; and gel-based methods. While these technologies each have certain advantages, they also have significant drawbacks that inhibit their broad applicability across the life sciences market.

THE NANOGEN SOLUTION

We believe that our initial product, the NanoChip(TM) Molecular Biology Workstation, or the NanoChip(TM) System, provides the accuracy, flexibility, versatility and ease-of-use features required to serve a wide range of genomic and biomedical as well as many other applications. We are promoting the NanoChip(TM) System as the research laboratory standard for molecular biologists, and eventually the industry standard for accurate, targeted genomics in both laboratory and non-laboratory settings. The NanoChip(TM) System provides the following advantages:

ACCURACY

Accuracy is critical in laboratory analysis. The NanoChip(TM) Molecular Biology Workstation, with its precision electronic addressing and high degree of stringency, exceeded the accuracy of the current "gold standard" techniques in the SNP studies conducted at the Mayo Clinic and the University of Texas Southwestern Medical Center. Nanogen's technology may have the ability to expand a customer's range of testing to include important, difficult to score mutations such as genetic deletions.

FLEXIBILITY

Nanogen's technology is highly flexible. The NanoChip(TM) System is centered around an electronics microarray containing 100 individually controllable and programmable electronic test sites. Each of the major bioassay formats, the "dot blot" and the "reverse dot blot" are conveniently handled by the NanoChip(TM) System and customers can design arrays in several different formats to meet their specific needs. Customers can combine several types of assays on one chip and multiple Loaders can be controlled by one Reader.

VERSATILITY

The NanoChip(TM) System is designed to analyze SNP's, including those that are hard to score, insertions, deletions, STRs, single point mutations and other genetic variations. Our electronic-based technology is potentially applicable to biological analyses beyond genomics and biomedical research including immunoassays, enzyme assays, cell separation and cell receptor studies.

FAST ARRAY DESIGN

Experimental design of arrays on the NanoChip(TM) Cartridge is straightforward. Customers can program NanoChip(TM) arrays in their own laboratories, allowing for faster turnaround times and higher levels of confidentiality.

Edgar Filing: NANOGEN INC - Form 10-K

EASE OF USE

Nanogen assays are easy to perform. Our fully automated Loader allows the simultaneous programming of up to four NanoChip(TM) arrays. A loaded cartridge is inserted and then analyzed on the Nanogen Reader. The NanoChip(TM) System includes proprietary software to automate assay operation and provide results in "real time." Data interpretation is clear-cut and presented in a user-friendly format.

4

THROUGHPUT

Our system's ability to program as many as 100 test sites at a time allows for higher throughput than is achievable with some competitive technologies. This throughput capacity permits highly efficient workflow for many biomedical applications in a variety of laboratory settings.

COST EFFECTIVENESS

We have designed the NanoChip(TM) System to be a cost-effective solution for most molecular biology assays. Moreover, the custom features of the system allow users to employ their own reagents in designing arrays for specific purposes. Since the NanoChip(TM) System consumes small quantities of reagents, generally at low concentration, bioassay reagent costs (such as DNA) per result are relatively low. Walk-away automation conserves direct labor, while improving the overall effectiveness of the laboratory operation. In addition, user definability allows important experiments to be done quickly, both accelerating the discovery process and simplifying the validation of important targets.

COMMERCIALIZATION STRATEGY

Our primary commercialization strategy is to research, develop, manufacture and market instruments and components, independently and in conjunction with highly regarded corporate and government partners, to facilitate breakthrough genetic analyses. Our NanoChip(TM) System is designed eventually to bridge the gap between scientific research and clinical practice. Our strategy is to make our proprietary bioassay technology platform a standard for molecular identification and analysis across a broad range of applications. Our initial commercial product is a bench-top system for use in biomedical research and genomic applications. The capabilities that are incorporated into this system are the core technology platform that will serve as the basis for expanding into other biological and non-biological areas. In addition, we believe we have the core technology that will enable us to design and deliver products incorporating molecular biology and electronics in additional formats, beyond the microchip format. These new product forms may broaden the markets we serve.

CONTINUE TO PURSUE GENOMICS AND BIOMEDICAL RESEARCH APPLICATIONS

While researchers want to use high throughput devices to discover genes and genetic mutations, they will want to explore the function and impact of these genes and mutations with a more targeted technology. Nanogen seeks to position the NanoChip(TM) System as such a technology. We intend to pursue the genomics and biomedical research markets by taking advantage of the open architecture design of our technology that allows end users to customize microchips to meet their individual research needs and help drive development of novel applications.

PURSUE MULTIPLE APPLICATIONS

Edgar Filing: NANOGEN INC - Form 10-K

We intend to use substantially the same core hardware and consumable cartridge platform across a spectrum of applications. By doing this, we believe we can establish our platform as an industry standard and also reduce development costs for follow-on applications. This approach should also allow us to achieve manufacturing economies of scale that may help reduce our per unit cost of goods sold over time. For our initial commercial market, the biomedical research market, we do not anticipate the need for Food and Drug Administration or FDA or other regulatory approval. Over time, we expect that additional features, such as genetic content-based kits, sample-to-answer capabilities and portability at reduced cost, may broaden the market potential from the research market to larger markets that include drug discovery, diagnostics, forensics, agriculture and environmental applications. Some of these applications would require FDA or other regulatory approval.

DEVELOP RECURRING REVENUE STREAM THROUGH BENCH-TOP AND CONSUMABLE PRODUCT SALES

We are selling bench-top instruments that we anticipate will lead to a recurring stream of revenue from consumable cartridge sales. We believe that widespread market penetration of our instruments and the open architecture of the system will promote sustained demand for our cartridges.

5

CONTINUE TO ESTABLISH STRATEGIC COLLABORATIONS

We intend to continue to enter into collaborations to expand applications of our technology platform and to accelerate the commercialization of our products. By partnering with multinational healthcare and technology companies, we believe that we can gain broader access to global markets without shifting our resources from the development of our core technology platform. In addition, as part of these arrangements, we believe we can better focus our efforts on tailoring our technology to expanding markets while our collaborative partners contribute their technology and expertise in areas such as sales, marketing and regulatory approvals.

OUR PLATFORM TECHNOLOGY

Our proprietary platform technology takes advantage of the fact that most biological molecules are either positively or negatively charged. Through the use of microelectronics, this technology enables the active movement and concentration of electronically charged molecules such as DNA to and from designated test sites on a semiconductor microchip or other electronics device. In the NanoChip(TM) Cartridge, these test sites are arranged in an array on our proprietary microchips. In addition, the technology allows for the simultaneous analysis of multiple test results, or "multiplexing," from a single sample. We believe these attributes make our technology well suited to unraveling complex genetic information. We have initially focused on DNA-based sample analysis in developing applications utilizing our platform.

We believe our technology may be applicable to a number of other analyses, in addition to DNA applications, including antigen-antibody, enzyme-substrate, cell-receptor, and cell separation techniques.

Our system can integrate in a single platform the following electronic operational features:

ELECTRONIC ADDRESSING

Electronic addressing is the process by which we place charged molecules at

Edgar Filing: NANOGEN INC - Form 10-K

specific test sites. Since DNA has a strong negative charge, it can be electronically moved to an area of positive charge. A group of test sites on the microchip is electronically activated with a positive charge. A solution of DNA probes is introduced onto the microchip. The negatively charged probes rapidly move to the positively charged sites, where they concentrate and are chemically bound to those sites. The microchip is then washed and another solution of distinct DNA probes can be added. Site by site, row by row, an array of specifically bound DNA probes can be addressed on the microchip. Multiplexed sites can be addressed simultaneously, allowing for speed and flexibility of array assembly. With the ability to electronically address capture probes to specific sites, the NanoChip(TM) System allows end users to build custom arrays through the placement of specific capture probes on a microchip. Alternatively, the target samples themselves can be electronically addressed to the test sites. All tests are performed using replicate probes or samples for control purposes. These microchip arrays provide research professionals with a powerful and versatile tool to process and analyze molecular information.

ELECTRONIC CONCENTRATION AND HYBRIDIZATION

Following electronic addressing, we use electronics to move and concentrate target molecules to one or more test sites on the microchip. In contrast to the passive hybridization process, the electronic concentration process has the advantage of significantly accelerating the rate of hybridization of a given target molecule with complementary capture probes. In addition, because we use buffers with low ionic strength, we improve the system's accuracy by reducing the occurrence of undesirable, non-specific hybridization. Again, the alternative method of attaching the target molecules to the test sites and then adding probes to interrogate the targets electronically is also available. All tests are performed using replicate probes or samples for control purposes.

STRINGENCY CONTROL

In addition to utilizing conventional thermal and chemical stringency techniques, the NanoChip(TM) System is capable of utilizing electronic stringency control when appropriate. Electronic stringency control can provide a means to quickly and easily remove non-complementary DNA as part of the hybridization process. Electronic stringency can provide quality control for the hybridization process and ensures that any bound pairs of DNA are truly complementary. The precision, control, and accuracy of our platform technology permits the detection of single point mutations, single base pair mismatches or other genetic mutations which have significant implications

6

in a number of disease states. Electronic control allows rapid and selective stringency conditions to be applied to individual test sites, which cannot be achieved with conventional methods. In contrast to conventional approaches, our technology can also accommodate both short and long single-stranded fragments of DNA on the same chip. This flexibility reduces the required number of probes or samples and related test sites on the microchip. Other currently marketed DNA arrays either are more difficult to control and/or require more uniformity in the preparation of the sample.

ELECTRONIC MULTIPLEXING

Our electronic multiplexing feature allows the simultaneous analysis of multiple tests from a single sample or multiple samples to be queried during the hybridization process. Electronic multiplexing is facilitated by the ability to control individual test sites (for addressing of capture probes and concentration of test sample molecules) which allows for the simultaneous use of

Edgar Filing: NANOGEN INC - Form 10-K

biochemically unrelated molecules on the same microchip. Sites on a conventional DNA array cannot be individually controlled, and therefore the same process steps must be performed on the entire array. The use of electronics in our technology provides increased versatility and flexibility over these conventional methods.

STRAND DISPLACEMENT AMPLIFICATION

Strand Displacement Amplification, or SDA, is a proprietary target amplification process whereby very low numbers of diagnostic targets in a test sample are enzymatically amplified to exponentially higher levels, greatly simplifying accurate detection of these targets. Because this process does not require thermal cycling, it is extremely fast, and complex instrumentation for thermal regulation is not required. The Nanogen/Becton Dickinson Partnership was granted rights to Becton Dickinson's patents relating to SDA in infectious disease diagnostics. During 2000, Becton Dickinson and we revised our relationship. We were granted rights to use SDA in the fields of IN VITRO human genetic testing and cancer diagnostics for use outside The Nanogen/Becton Dickinson Partnership. We believe that SDA may be an important element in the development of sample-to-answer applications for our technology platform.

THE NANOCHIP(TM) SYSTEM'S COMPONENTS

The NanoChip(TM) System consists of both a consumable cartridge containing a proprietary semiconductor microchip and a fully automated instrument that controls all aspects of microchip operations, processing, detection and reporting. The system has been designed so that after insertion of a consumable cartridge containing a test sample into the instrument, all subsequent steps are handled automatically under computer control.

CONSUMABLE CARTRIDGE

The consumable NanoChip(TM) Cartridge consists of a proprietary semiconductor microchip with electrical and fluidic connections to the instrument. We expect that over time the consumable cartridge and microchip may be manufactured in high volumes at a low cost relative to many current technologies.

SEMICONDUCTOR MICROCHIP

Our proprietary microchip utilizes advances in the semiconductor industry and is designed and constructed using microlithography and fabrication techniques. Our microchip is mounted within the consumable cartridge and is coated with a proprietary permeation layer to which either capture probes or target samples can be attached. We have developed arrays of various sizes utilizing both passive and active CMOS microchips, as well as flip chip assembly technologies. Our initial production of consumable cartridges employs 100 different test sites on the microchip.

PERMEATION LAYER

Our proprietary permeation layer, which is critical to the proper functioning of our system, is the interface between the surface of the microchip and the biological test environment. The permeation layer isolates the

biological materials from the harsh electrochemical environment near the electrode surface and provides the chemistry necessary for attachment of capture

Edgar Filing: NANOGEN INC - Form 10-K

probes or target samples.

CAPTURE PROBES OR TARGET SAMPLES

Capture probes or target samples are electronically addressed to the desired microlocations and attached to the permeation layer. Because independent control can be applied at any test site on our microchip, different capture probes or target samples can be addressed on the same microchip, allowing multiple tests to be processed simultaneously. Our cartridges can be customized by the end user in "build-your-own-chip" applications which will allow the customer to assemble specific probes onto a microchip to perform individualized analyses. In the future, we may also offer cartridges preloaded with sets of probes or samples.

OUR INSTRUMENTS

Our fully integrated NanoChip(TM) instrument system consists of four major subsystems: (1) a freestanding microchip Loader to perform electronic addressing of blank microchips, (2) a highly sensitive, laser-based fluorescence scanner that detects molecular binding, (3) a fluid handling subsystem that controls test sample application and washing steps, (2) and (3) are, collectively, the Reader, and (4) computer hardware and software that allow the operator to select assays from a graphical user menu which controls all microchip operations, tabulates test results and prints test reports.

MICROCHIP LOADER

For biomedical research applications, our system includes a cartridge/microchip Loader that will allow users to electronically address their own target samples or probes to test sites on up to four chips simultaneously. In addition, hybridization can be performed on the Loader or on the Reader. Multiple Loaders can operate concurrently under the control of one system.

FLUORESCENT ARRAY SCANNER

The fluorescent scanner component of the system uses pattern recognition techniques and optoelectronic technology to reduce instrument cost and size and eliminate the need for complicated array positioning mechanics. In its present configuration, the scanner is able to perform high sensitivity scans of arrays of 100 test sites in less than five minutes.

FLUIDICS STATION

Within the fluorescent array scanner component of the system, the fluidics station automates the movement of the reagents and test sample onto the consumable cartridge. The fluidic subassembly of the instrument includes a panel of precision syringe pumps, a cartridge-mounted sample assembly and fluidic connections between the instrument and the consumable cartridge.

COMPUTER HARDWARE AND SOFTWARE SYSTEM

A multi-tasking operating system and microprocessor control all aspects of the systems operations, including bar-coded assay selection, assay operation, fluorescent signal detection and signal processing, calculation of assay results and report generation. Each of the individual array locations is separately controlled by the microprocessor. Fluorescent signals emanating from positive test sites are scanned, monitored and quantitated.

NANOCHIP (TM) ANALYSIS PROCESS

CARTRIDGE

An active microelectronic chip is mounted within

Edgar Filing: NANOGEN INC - Form 10-K

a plastic molded cartridge. The bar-coded cartridge is delivered in a ready-to-address format with no genetic sequences pre-attached.

8

ELECTRONIC ADDRESSING

Users design and create their own genetic arrays on the microelectronic chip with Nanogen's automated system. A 96 well or 384 well microtiter plate containing different genetic sequences is placed in the Loader instrument. The system then automatically electronically addresses the microchip to the user-defined arrays.

ELECTRONIC HYBRIDIZATION AND STRINGENCY

Users add the test samples or probes to the cartridge and insert the cartridge into the Reader. The instrument then automatically performs electronic hybridization and the appropriate stringency control. The electronically enhanced process speeds and improves the genetic analysis, allowing single-base accuracy.

SIMPLE-TO-READ OUTPUT

Within minutes of inserting the bar-coded cartridge for analysis, easy-to-read and interpret output is available. Data can be automatically downloaded to network systems and to standard software spreadsheet packages. The entire electronic addressing and data output process can be completed rapidly, allowing users to accelerate their research process by creating new genetic arrays based on previous experimental results.

PRODUCTS AND APPLICATIONS UNDER DEVELOPMENT

GENOMICS AND BIOMEDICAL RESEARCH APPLICATIONS

We began commercialization of the NanoChip(TM) System during the second quarter of 2000. Unlike the high-density arrays and sequencing technologies now in the marketplace, our focus is on the targeted analysis of data from the genomics revolution and post genomics era--helping clinical researchers define the function of genes rather than discover new genes. We believe our technology is well suited for this research, given the speed, user programmability, multiplexing capability and sensitivity of our unique platform.

Given that researchers are just beginning to move beyond gene discovery into this targeted analysis area referred to as functional genomics, our product introduction may be well suited to meet this evolving market need. An independent market research study by Strategic Directions International published in December 1999 indicated that the market potential for microarrays is anticipated to grow rapidly from \$200 million in 2000 to almost \$800 million by 2003.

Our initial strategy for entering this market is to focus on sophisticated commercial and academic users such as the research laboratories of large hospitals, academic and government institutions and genomics and pharmaceutical companies. We provide technical support and applications specialists to assist these customers in applying the technology. Our initial product offering

Edgar Filing: NANOGEN INC - Form 10-K

includes features such as the ability to perform assays on SNPs, PMs and STRs in a multiplexed format using a variety of different methods. We plan to further define and develop additional capabilities, such as gene expression, on-chip amplification and sample processing. As these capabilities are added, we expect to start expanding our customer base to a wider group that may ultimately encompass a significant percentage of the biomedical research labs in the U.S. and other parts of the world.

DIAGNOSTICS APPLICATIONS

We anticipate the introduction of array-based diagnostic testing will grow as effective technologies are introduced and validated. This multi-step process may allow for the development of relevant genetic-based tests that may

9

evolve from biomedical research, and for the awareness and confidence in electronic-based technology to extend to medical practitioners. Finally, we anticipate the need for regulatory approval of certain diagnostic tests.

- Pharmacogenomics

We believe that the ability of our technology to screen simultaneously for various DNA sequences and the ability to differentiate between SNPs has potentially wide applicability to the field of genetic testing in general and pharmacogenomics in particular.

Our NanoChip(TM) System may provide pharmaceutical and biotechnology companies with the ability to identify important genetic variations early in the drug development process. We believe our system may help stratify patients during clinical trials and identify those receiving the maximum benefit from treatment. We intend ultimately to develop a small sample-to-answer, FDA-approved diagnostic test that can be used in a doctor's office potentially while a patient is waiting. We have a development program underway to develop a more compact version of our NanoChip(TM) System.

- Infectious diseases

We believe we have the potential to apply our technology in the field of infectious disease diagnostics to develop automated tests to replace the manual and time-intensive procedures used in hospitals and reference laboratories. The role of the clinical microbiology laboratory is to detect, identify and determine antibiotic sensitivity of disease causing microorganisms. To accomplish this task, colonies of microorganisms from patient specimens are grown, or cultured, in various growth media. Following colony growth, various direct and indirect techniques are utilized to determine the identity and, as required, the sensitivity of the microorganism to specific antibiotics. Using currently available technologies, the entire process may take days or weeks to complete while the patient, requiring immediate therapy, must be treated by the clinician based upon the best clinical facts available at that time. Upon receipt of the diagnostic analysis from the laboratory, the initial patient treatment protocol may need to be modified in order to treat the patient more effectively.

Current culture-based methods detect a single microorganism at one time. Because a particular infectious episode may be caused by one of many microorganisms or several microorganisms together, multiple tests may be required to determine the correct diagnosis. "Single tube" (one at a time) DNA probe diagnostics, which were first introduced to the marketplace in the mid-1980's, have been unsuccessful in displacing culture based diagnostic tests

Edgar Filing: NANOGEN INC - Form 10-K

in part due to their inability to identify several organisms simultaneously. Our technology addresses these shortcomings by allowing the simultaneous analysis of multiple microorganisms from a single patient sample. We believe our technology and integrated system may speed the time-to-result for diagnostic tests and patient treatment and offer our customers the opportunity to lower their costs and improve productivity by automating all or a significant portion of their labor-intensive testing.

- Other genetic testing applications

As the Human Genome Project opportunity and other public and private genetic sequencing efforts yield increasing amounts of genetic information, the demand for genetic predisposition testing will continue to grow. Because many important genetic diseases are ideally suited to diagnosis in multiplexed arrays, we believe that our technology platform could contribute significantly to the expansion of testing in this area. For example, in cancer diagnostics, certain mutations are indicative of a predisposition to certain types of cancer. Although many diseases involve multiple mutations, the ability to analyze all possible mutations has previously been expensive and impracticable. Our stringency control feature potentially permits rapid and accurate testing for these single point mutations. While our development efforts in this area with respect to specific genetic tests are still at an early stage, our core technology platform for other diagnostic applications may be well suited for these opportunities.

DRUG DISCOVERY APPLICATIONS

We believe we have a powerful tool which will help clarify appropriate pathways for therapeutic intervention, identify and evaluate lead compounds and simultaneously assess the efficacy and toxicology of these compounds in model systems. It is estimated that the preclinical drug discovery process takes an average of six and one-half years.

10

Consequently, we believe there is a significant demand for improved tools which accelerate the drug discovery process.

We believe the microelectronic array format and independent test site control of our system are well suited for applications in drug discovery. In addition, we believe the use of electronics beyond the microchip format may provide a valuable tool for the high throughput screening of compounds. One such application is the high throughput screening of drug candidates acting on protein kinases. Protein kinases are particularly important in signal transduction pathways and are thought to be key elements in many forms of cancer. Nanogen's electronic, fluorescent assays are free of antibodies and have the potential of improving the cost and quality of the screening process.

To advance our efforts in this area of drug discovery and optimization, we entered into a research and development collaboration with Aventis in 1998. This collaboration was focused on the development of novel electronic combinatorial approaches toward drug screening and discovery and was concluded at the end of 2000. We are negotiating a potential new relationship with Aventis relating to the research conducted and technology developed under this 1998 agreement. In 1999, we entered into an additional collaboration agreement with Aventis for two additional projects. Nanogen and Aventis have met all of the objectives to date for these two projects.

FORENSIC APPLICATIONS

Edgar Filing: NANOGEN INC - Form 10-K

STRs are the genetic sequences chosen by the U.S. government and various foreign governments to populate their national criminal identification databases. These databases are intended to provide nationwide tools for identifying repeat criminals by comparing a given piece of evidence or sample from a suspect with the sequences stored in the database. We believe our NanoChip(TM) System may be useful in human identity testing.

NON-BIOLOGICAL APPLICATIONS

We are applying our core microelectronics biochip technology to potential applications in non-biological areas which include nanotechnology, data storage and semiconductor manufacturing. Based on the intrinsic self-assembly and programmable qualities of DNA, our technology uses electrical current to direct the heterogeneous integration of a number of molecular and nonmolecular components onto a microelectronic chip. Our integrated "host substrate" or "motherboard" array capability could serve to provide researchers with useful new tools that permit them to take advantage of these valuable components.

Our electronic "pick and place" technology may have several advantages compared to the more difficult conventional processes. Our technology could facilitate the movement and assembly of microelectronic components ranging in size from molecular scale to micron scale, something traditional assembly methods cannot achieve. Also, using electric field specificity control, we may have the ability to form novel integrated devices in a more timely and cost-effective fashion. For example, we have evaluated the use of this platform technology to facilitate integration of different size components for the development of new photonic or electronic devices.

COLLABORATIVE ALLIANCES

We have established collaborative alliances in the areas of drug discovery and genomics as part of our strategy to expand the applications and accelerate the commercialization of products derived from our technology. During 1999, we expanded our relationship with Aventis by increasing the number of collaborative research and development projects from one to three. In January 2000 we entered into a manufacturing, development and distribution agreement with Hitachi, Ltd. In July 2000, we entered into an additional 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. We anticipate being directly involved with marketing our first product line to the biomedical research and genomics market. Additionally, we may distribute products in Japan and selected Asian markets through the distribution arm of Hitachi, Nissei Sangyo Co., Ltd.

11

AVENTIS

In December 1997, we entered into a Letter Agreement with Aventis for an exclusive research and development collaboration relating to new drug discovery tools and immunodiagnosics research. In connection with the Letter Agreement, we entered into a definitive Collaborative Research and Development Agreement with an effective date of January 1, 1998. The arrangements for the commercialization of products, if any, developed as a result of the collaboration will be negotiated by the parties. The term of this collaboration agreement expired at the end of 2000. We are negotiating a potential new relationship with Aventis relating to the research conducted and technology developed under this 1998 agreement. In addition, in September 1999 we entered

Edgar Filing: NANOGEN INC - Form 10-K

into an additional collaboration agreement with Aventis that involves two new research and development programs focused on gene expression arrays and on an electronics-based high throughput screening system. We retain full commercialization rights for any products resulting from these new projects, while Aventis retains the right to use the technology for internal research and development.

As part of our 1998 collaboration, 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.

HITACHI

In January 2000, we executed an agreement with Hitachi, Ltd., effective as of December 15, 1999, for the full-scale commercial manufacturing and distribution of the NanoChip(TM) 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(TM) Molecular Biology Workstation's components.

Under this agreement, Hitachi, Ltd. has the right to be the sole distributor of Hitachi, Ltd. produced NanoChip(TM) Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip(TM) Cartridges in Japan. We retained the right to distribute, directly or through others, Hitachi, Ltd. produced NanoChip(TM) Molecular Biology Workstations outside of Japan. In addition, we currently develop and manufacture the NanoChip(TM) Cartridges for distribution worldwide. Except for Hitachi, Ltd.'s exclusive distribution rights of Hitachi, Ltd. produced Workstations in Japan, the agreement is non-exclusive and excludes certain clinical markets. We also retain the right to form other manufacturing and distribution agreements.

In July 2000, we 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 products based on the parties' proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and Nanogen each may contribute up to \$28.5 million in cash over the ten-year period. In addition, Hitachi made an equity investment in Nanogen by purchasing 74,590 shares of Nanogen's common stock worth approximately \$2.0 million pursuant to a private sale by Nanogen based on 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 us 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. We retain the exclusive right to distribute collaboration products outside of these countries. The agreement is non-exclusive and excludes some clinical markets.

BECTON DICKINSON

In connection with Nanogen's joint venture with Becton Dickinson in October 1997, The Nanogen/Becton Dickinson Partnership, or the Partnership, a Delaware

Edgar Filing: NANOGEN INC - Form 10-K

general partnership was established. The Partnership was formed to develop and commercialize products in the field of IN VITRO nucleic acid-based diagnostic and monitoring technologies in infectious diseases.

12

In September 2000, we and Becton Dickinson modified the joint venture to permit the partners the opportunity to commercialize certain of the Partnership's technology and allow them to collaborate with third parties to develop and commercialize certain products in the field of infectious diseases. Pursuant to amendments to the Master Agreement, the General Partnership Agreement and the Collaborative Research and Development and License Agreement, the Partnership exclusively licensed other Partnership technology developed up to that date to Becton Dickinson and Becton Dickinson exclusively sublicensed the Partnership technology to Nanogen to commercialize products in the field of infectious diseases. Becton Dickinson also agreed to non-exclusively license SDA technology to Nanogen for its use and for sublicensing purposes in the field of infectious diseases. Becton Dickinson also expanded the field of use for our SDA license outside of the Partnership to not only include IN VITRO human genetic testing and IN VITRO cancer diagnostics, but also IN VITRO testing of environmental, agricultural and veterinary samples. Pursuant to the amendments, Becton Dickinson paid us \$300,000. We do not expect to receive any additional funding from Becton Dickinson.

ELAN

In December 1997, we entered into an agreement with Elan Corporation, plc ("Elan") for a non-exclusive research and development agreement for the development of genomics and gene expression research tools. We and Elan have not agreed upon specific program objectives with respect to the nonexclusive research and development program. In 1999 and 1998, revenues earned by us pursuant to this agreement were approximately \$568,000 and \$929,000, respectively. No revenue was recognized under the agreement during 2000. We do not expect to receive any additional funding from Elan.

RESEARCH AND PRODUCT DEVELOPMENT

In the near term, Nanogen is working to develop its NanoChip(TM) System to provide gene expression analysis capabilities, a key component in realizing the potential of the post genomics era. Nanogen seeks to further develop the NanoChip(TM) System, integrating new features and broadening the applications of the currently marketed system, including enhancing chip design and capabilities to simplify instrument design. Nanogen's scientists will investigate new opportunities, while customers may create new assays by taking advantage of the flexible format of the system.

We also intend to pursue new opportunities utilizing electronics beyond the current microchip concept. Future technologies may include integration of sample processing and DNA amplification. The NanoChip(TM) System may be designed to provide analysis of other charged molecules and antigen-antibody, enzyme substrate, cell-receptor, and cell-separation techniques. The NanoChip(TM) System eventually may also become a portable lab on a chip for use in the field, away from the laboratory bench.

Nanogen may also continue to develop leading edge technologies such as micro electro-mechanical systems ("MEMS"), micro-fluidics, miniaturized capillary electrophoresis and the application of electronics to high throughput screening.

One mechanism to fund and implement new technologies or applications is

Edgar Filing: NANOGEN INC - Form 10-K

through the government grant system. In 2000, Nanogen's scientists received grants from the Space and Naval Warfare Systems Center San Diego to develop an integrated electronics-based sample to answer technology and from the U.S. Army to develop technology to identify biological warfare compounds if used in combat against U.S. troops. The development of these new technologies represent important elements in Nanogen's long-term platform development strategy.

PROPRIETARY TECHNOLOGY AND PATENTS

As of December 31, 2000, we have twenty issued U.S. patents, thirteen foreign issued patents and a number of pending patent applications filed in the U.S. and abroad. In addition to pursuing patents and patent applications relating to our platform technology, we may enter into other license arrangements to obtain rights to third-party intellectual property where appropriate.

13

Our or our licensors' patent applications may not be issued. Issued patents may not be found valid if challenged. In addition, intellectual property rights licensed by us may not be successfully integrated into commercial products. Others may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future product development and, consequently, our business, financial condition and results of operations.

We seek to protect our inventions through filing U.S. patents and foreign counterpart applications in selected other countries. Because patent applications in the U.S. are maintained in secrecy for at least eighteen months after the applications are filed and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications or that we were the first to file for protection of inventions set forth in such patent applications. Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case continued development and marketing of the products would require a license. Required licenses may not be available to us on acceptable terms, if at all. If we do not obtain these licenses, we could encounter delays in product introductions while we attempt to design around the patents, or could find that the development, manufacture or sale of products requiring these licenses is foreclosed.

We are aware of U.S. and corresponding foreign patents and applications which are assigned to Affymax Technologies, N.V., and Affymetrix which relate to certain devices having 1,000 or more groups of oligonucleotides occupying a total area of less than 1 cm² and 400 different oligonucleotides per cm² on a substrate. In the event that we proceed with the development of arrays with more than 400 groups of oligonucleotides, we expect to design our devices through, among other things, the selection of the physical dimensions, methods of binding and selection of support materials 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. (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

Edgar Filing: NANOGEN INC - Form 10-K

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.

In addition to the patent litigation with Motorola and MIT, and with CombiMatrix and Dr. Montgomery described in Item 3 herein, other litigation may be necessary to defend against or assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the scope and validity of the proprietary rights of others. In addition, interference proceedings declared by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patent applications. Litigation or interference proceedings could result in substantial costs to and diversion of our effort, and could have a material adverse effect on our business, financial condition, and results of operations. Any such efforts may not be successful.

We may rely on trade secrets to protect our technology. Trade secrets are difficult to protect. We seek to protect our proprietary technology and processes by confidentiality agreements with our employees and certain consultants and contractors. These agreements may be breached, we may not have adequate remedies for any breach and our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees or our consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions. We are currently in litigation concerning trade secret issues against CombiMatrix and Dr. Montgomery as described in Item 3.

14

MANUFACTURING

In January 2000 we formed a collaboration with Hitachi for the manufacture of our NanoChip(TM) Molecular Biology Workstation instruments. In July 2000, we executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan to develop, manufacture and distribute products based on the parties' proprietary technologies. For the manufacture of the NanoChip(TM) Cartridge, we perform many of the proprietary assembly steps in-house. We believe our technology allows for large-scale microchip production at a relatively low cost. We believe that the implementation of this scalability and low cost will help promote the rapid acceptance of our proprietary semiconductor-based platform technology as an industry standard. However, achieving these efficiencies will require substantial commercial volumes and there can be no assurance we will be successful in generating sufficient demand to scale up manufacturing capacity to levels that will allow our products to be priced competitively.

SALES AND MARKETING

We began commercializing the NanoChip(TM) Molecular Biology Workstation during the second quarter of 2000. We have built a commercial structure which allows us to sell directly in certain markets, while selling through distributors and partners in other markets. Our commercial organization includes direct sales representatives and sales management, field support personnel and marketing. We began selling our product directly to customers in the United

Edgar Filing: NANOGEN INC - Form 10-K

States, Canada and selected European countries such as Germany and the United Kingdom. Hitachi's distribution company, Nissei Sangyo Co. Ltd. began distributing our product in Japan during the second half of 2000. We expect to augment our commercial selling process by adding distributor partners in other countries. To support the commercial efforts in Europe, in August 2000 we established Nanogen Europe B.V., a company with limited liability, in The Netherlands. This wholly-owned subsidiary operates as our primary European sales and marketing office. In San Diego, we are supporting world-wide field activities with a customer applications laboratory. This laboratory will be used to assist in early customer demonstrations, protocol development and training.

COMPETITION

As we develop applications of our technology, we expect to encounter intense competition from a number of companies that offer products competing in our targeted applications. We anticipate that our competitors in these areas will include health care companies that manufacture laboratory-based tests and analyzers, diagnostic and pharmaceutical companies, as well as companies developing drug discovery technologies. To the extent we are successful in developing products in these areas, we will face competition from established and development-stage companies.

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 we. Moreover, competitors may offer broader product lines and have greater name recognition than we, and may offer discounts as a competitive tactic. In addition, several development stage companies are making or developing products that compete with our potential products. There can be no assurance that our competitors will not succeed in developing or marketing technologies or products that are more effective or commercially attractive than our potential products, or that would render our technologies and products obsolete. Also, we may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Our success will depend in large part on our ability to maintain a competitive position with respect to our technologies. Rapid technological development by others may also result in competing products or technologies.

GOVERNMENT REGULATION

For our initial commercial market, the biomedical research market, we do not anticipate the need for FDA or other regulatory approval. We have not applied for FDA or other regulatory approvals with respect to any of our products under development. We anticipate, however, that the manufacturing, labeling, distribution and marketing of some or all of the diagnostic products we may develop and commercialize in the future will be subject to regulation in the U.S. and in other countries. In addition to clinical diagnostic markets, we also may pursue forensic, agricultural, environmental, laboratory and industrial applications for our products which may be subject to different government regulation. Aspects of our manufacturing and marketing activities may also be subject to federal, state and local regulation by various governmental authorities.

In the U.S., the FDA regulates, as medical devices, most diagnostic tests and IN VITRO reagents that are marketed as finished test kits and equipment. Pursuant to the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, design, manufacture, labeling, distribution and promotion of medical devices. We

Edgar Filing: NANOGEN INC - Form 10-K

will not be able to commence marketing or commercial sales in the U.S. of new medical devices that fall within the FDA's jurisdiction until we receive clearance or approval from the FDA, which can be a lengthy, expensive, and uncertain process. Noncompliance with applicable requirements can result in, among other things, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing clearances or approvals, or criminal prosecution.

In the U.S., medical devices are generally classified into one of three classes (I.E., Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, premarket notification, and adherence to Quality System Regulation, or QSR). Class II devices are subject to general and special controls (e.g., performance standards, postmarket surveillance, patient registries and FDA guidelines). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting, and implantable devices or new devices which have been found not to be substantially equivalent to a legally marketed devices). Before a new device can be introduced in the market, the manufacturer must generally obtain FDA clearance of a 510(k) notification or approval of a PMA application. Our products will vary significantly in the degree of regulatory approvals required. We believe that certain of our products for research, genomics, drug discovery and industrial applications will not require regulatory approvals or clearance. Some diagnostic products will require 510(k) approvals while other diagnostic and genetic testing products will require PMA approvals.

A 510(k) clearance will generally only be granted if the information submitted to the FDA establishes that the device is "substantially equivalent" to a legally marketed predicate device. For any devices that are cleared through the 510(k) process, significant modifications or enhancements in the design or intended use that could significantly affect safety or effectiveness will require new 510(k) submissions. It generally takes at least nine to twelve months from submission to obtain 510(k) premarket clearance but the process may take longer.

The PMA approval process is more expensive, uncertain, and lengthy than the 510(k) clearance process. A PMA must prove the safety and effectiveness of the device to the FDA's satisfaction, which typically requires extensive data, including but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate the safety and effectiveness of the device. Although clinical investigations of most devices are subject to the investigational device exemption requirements, clinical investigations of IN VITRO diagnostic tests, such as our products and products under development, are exempt from the investigational device exemption requirements, including the need to obtain the FDA's prior approval, provided the testing is noninvasive, does not require an invasive sampling procedure that presents a significant risk, does not introduce energy into the subject, and is not used as a diagnostic procedure without confirmation by another medically established test or procedure. In addition, the IN VITRO diagnostic tests must be labeled for research use only or investigational use only, and distribution controls must be established to assure that IVDs distributed for research or clinical investigation are used only for those purposes.

The FDA may determine that we must adhere to the more costly, lengthy, and uncertain PMA approval process for our potential products. Significant modifications to the design, labeling or manufacturing process of an approved device may require approval by the FDA of a PMA supplement or a new PMA application.

Edgar Filing: NANOGEN INC - Form 10-K

After a PMA is accepted for filing, the FDA begins its review of the submitted information, which generally takes between one and two years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA will be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. We may not be able to obtain necessary approvals on a timely basis, if at all, and delays in obtaining or failure to obtain such approvals, the loss of previously obtained approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

16

Manufacturers of medical devices for marketing in the U.S. are required to adhere to the QSR requirements (formerly Good Manufacturing Practices), which include testing, control and documentation requirements. Manufacturers must also comply with Medical Device Reporting requirements that a manufacturer report to the FDA any incident in which its product may have caused or contributed to a death or serious injury, or in which its product malfunctioned and would be likely to cause or contribute to a death or serious injury upon recurrence. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

We may become subject to routine inspection by the FDA and certain state agencies for compliance with QSR requirements, medical device reporting requirements and other applicable regulations. The recently finalized QSR requirements include design controls that will likely increase the cost of compliance. We may incur significant costs to comply with laws and regulations in the future and these laws and regulations may have a material adverse effect upon our business, financial condition and results of operation.

Any of our customers using our potential future diagnostic devices for clinical use in the U.S. may be regulated under the Clinical Laboratory Improvement Amendments of 1988 or CLIA. CLIA is intended to ensure the quality and reliability of clinical laboratories in the U.S. by mandating specific standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections. The regulations promulgated under CLIA establish three levels of diagnostic tests ("waived," "moderately complex" and "highly complex"), and the standards applicable to a clinical laboratory depend on the level of the tests it performs. CLIA requirements may prevent some clinical laboratories from using our diagnostic products. Therefore, CLIA regulations and future administrative interpretations of CLIA may have a material adverse impact on us by limiting the potential market for our products.

The Food and Drug Administration Modernization Act of 1997 makes changes to the device provisions of the FD&C Act or the Act and other provisions in the Act affecting the regulation of devices. Among other things, the changes will affect the Investigational Device Exemption, 510(k) and PMA processes, and also will affect device standards and data requirements, procedures relating to humanitarian and breakthrough devices, tracking and postmarket surveillance, accredited third-party review, and the dissemination of off-label information. We cannot predict how or when these changes will be implemented or what effect the changes will have on the regulation of our products. There can be no assurance that the new legislation will not impose additional costs or lengthen review times for our products.

Edgar Filing: NANOGEN INC - Form 10-K

Additionally, should we develop food pathogen products, they will be subject to the regulations of various domestic and foreign government agencies which regulate food safety and food adulteration, including the U.S. Department of Agriculture.

EMPLOYEES

As of December 31, 2000, we had 175 full-time employees, of whom 39 hold Ph.D. degrees and 25 hold other advanced degrees. Approximately 89 are involved in research and development, 31 in operations, manufacturing and quality assurance, 30 in sales and marketing, and 25 in finance, legal and other administrative functions. Our success will depend in large part upon our ability to attract and retain employees. We face competition in this regard from other companies, research and academic institutions, government entities and other organizations. None of our employees is covered by a collective bargaining agreement, and we believe that we maintain good relations with our employees.

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(TM) Molecular Biology Workstation and our NanoChip(TM) Cartridge. All of our other products are under development.

17

Our NanoChip(TM) 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. Neither the products we have developed nor those we develop in the future may 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

Edgar Filing: NANOGEN INC - Form 10-K

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 future 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 of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue 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, Elan 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. During the year ended, December 31, 2000, Becton Dickinson agreed to pay \$300,000 related to amendments of existing Partnership agreements. We do not expect to receive any additional funds from Becton Dickinson. We have not agreed upon specific program objectives with respect to our research and development agreement with Elan. We do not expect to receive any additional funds from Elan.

WE HAVE A HISTORY OF NET LOSSES. WE EXPECT TO CONTINUE TO INCUR NET LOSSES AND WE MAY NOT ACHIEVE OR MAINTAIN PROFITABILITY.

18

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. From our inception to December 31, 2000, we have incurred cumulative net losses totaling approximately \$90.9 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(TM) 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

Edgar Filing: NANOGEN INC - Form 10-K

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 we. Moreover, these competitors may offer broader product lines and have greater name recognition than we 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 for or marketing technologies or products that are more effective or commercially attractive than our potential products, or that render our technologies and

Edgar Filing: NANOGEN INC - Form 10-K

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 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

Edgar Filing: NANOGEN INC - Form 10-K

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

20

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 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.

WE ARE INVOLVED IN INTELLECTUAL PROPERTY LITIGATION THAT IS AND MAY CONTINUE TO BE COSTLY, TIME-CONSUMING AND MAY IMPACT OUR COMPETITIVE POSITION.

In April 2000, we 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 we are entitled to a license to the government funded '939 patent and 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.

Edgar Filing: NANOGEN INC - Form 10-K

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.

21

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.

Edgar Filing: NANOGEN INC - Form 10-K

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

22

- 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

Edgar Filing: NANOGEN INC - Form 10-K

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 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 (TM) SYSTEM.

Edgar Filing: NANOGEN INC - Form 10-K

We increased the number of employees in our sales and marketing group from three at December 31, 1999 to twenty-six at December 31, 2000. In addition, in July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At December 31, 2000, this office employed four European-based sales executives 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(TM) 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 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 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(TM) System in foreign countries;
- licenses, tariffs and other trade barriers;
- political and economic instability;
- difficulties in staffing and managing foreign offices;
- potentially adverse tax consequences; and
- the burden and significant expense of complying with a wide variety of complex foreign laws and treaties.

Our international sales and marketing efforts will also be subject to the risks associated with the imposition of legislation and regulations relating to the import or export of high technology products. We cannot predict whether tariffs or restrictions upon the importation or exportation of our products will be implemented by the United States or other countries.

We may lose money when we exchange foreign currency received from international sales into U.S. dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which we do business will cause foreign currency translation gains and losses.

Edgar Filing: NANOGEN INC - Form 10-K

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 do not currently engage in foreign exchange hedging transactions to manage our foreign currency exposure.

24

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

Edgar Filing: NANOGEN INC - Form 10-K

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.

25

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;

Edgar Filing: NANOGEN INC - Form 10-K

- the announcement by us or our competitors of technological innovations or new products;
- the announcement by us of acquisitions by customers of our NanoChip(TM) 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

26

- 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

Edgar Filing: NANOGEN INC - Form 10-K

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 2. PROPERTIES

We currently lease an approximately 45,000 square foot facility in San Diego, California, under a lease expiring in 2005. We have an option to renew the lease on this facility for two additional five-year terms. The facility currently houses our administrative offices and research and development laboratories, and is expected to be sufficient to meet our currently anticipated facilities needs at least through 2002.

ITEM 3. LEGAL PROCEEDINGS

In April 2000, we 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 we are entitled to a license to the government funded '939 patent and 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

27

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.

Edgar Filing: NANOGEN INC - Form 10-K

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.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

There were no matters submitted to a vote of security holders during the quarter ended December 31, 2000.

28

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

(a) Changes in Securities

In October 2000, we sold 120,238 shares of our common stock to Aventis Research and Technologies at a per share price of \$6.17. We relied on the exemption from registration provided by Section 4(2) of the Securities Act of 1933 in making the sale, based in part on the institutional nature of the purchaser and representations and warranties of the purchaser.

In November 1998, our Board of Directors adopted a Stockholder Rights Plan which provides for a dividend of one Preferred Stock Purchase Right for each share of common stock to stockholders of record on November 30, 1998. Each Right will entitle stockholders to buy one one-thousandth of a share of Series A Participating Preferred Stock of the Company at an exercise price of \$50.00, subject to antidilution adjustments. The Rights will become exercisable only if a person or group becomes the beneficial owner of 15% or more of the common stock, or commences a tender or exchange offer which would result in the offeror beneficially owning 15% or more of common stock, which is not approved by our

Edgar Filing: NANOGEN INC - Form 10-K

Board of Directors. The Board of Directors is entitled to redeem the Rights at \$0.01 per Right at any time prior to the public announcement of the existence of a 15% holder. If not earlier terminated or redeemed, the Rights will expire on November 17, 2008.

On December 12, 2000, our Board of Directors amended the Rights Plan to allow Citigroup Inc. and its affiliates and associates to acquire the beneficial ownership of up to 25% of the outstanding common stock of the Company without triggering the ability of our stockholders to exercise the rights governed by the Rights Plan. The Board of Directors required Citigroup to maintain its status as a filer on Schedule 13G with respect to its beneficial ownership of our common stock to take advantage of this exception.

(c) Market Information

Our common stock began trading on the National Association of Securities Dealers Automated Quotation ("Nasdaq") National Market on April 14, 1998, under the symbol "NGEN." Prior to that date, there was no established trading market for our common stock. The following table sets forth the range of high and low sales prices as reported for our common stock by Nasdaq for the periods indicated:

Fiscal 1999:	High	Low
1st Quarter	\$ 9.64	\$ 3.89
2nd Quarter	\$ 9.75	\$ 6.25
3rd Quarter	\$ 8.64	\$ 5.75
4th Quarter	\$ 24.50	\$ 6.50
Fiscal 2000:		
1st Quarter	\$ 101.94	\$ 18.00
2nd Quarter	\$ 43.00	\$ 14.50
3rd Quarter	\$ 43.00	\$ 17.25
4th Quarter	\$ 20.44	\$ 7.69

As of March 23, 2001, there were approximately 200 shareholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below with respect to our consolidated financial statements has been derived from the audited financial statements. The data set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and notes thereto appearing elsewhere

Edgar Filing: NANOGEN INC - Form 10-K

herein:

	YEARS ENDED DECEMBER 31		
	2000	1999	1998
	(IN THOUSANDS, EXCEPT PER SHARE)		
CONSOLIDATED STATEMENT OF OPERATIONS DATA:			
Revenues:			
Product	\$ 919	\$ --	\$ --
Sponsored research	8,457	5,688	5,461
Contract and grant	1,856	2,431	2,172
	-----	-----	-----
Total revenues	11,232	8,119	7,633
Operating expenses:			
Cost of sales	599	--	--
Research and development	18,905	25,284	23,002
General and administrative	15,267	9,097	6,420
Acquired in-process technology	--	--	1,193
	-----	-----	-----
Total operating expenses	34,771	34,381	30,615
	-----	-----	-----
Loss from operations	(23,539)	(26,262)	(22,982)
Equity in loss of joint venture	--	(996)	(610)
Interest income, net	5,257	2,059	2,650
	-----	-----	-----
Net loss	\$ (18,282)	\$ (25,199)	\$ (20,942)
	=====	=====	=====
Net loss per share--basic and diluted	\$ (.92)	\$ (1.39)	\$ (1.60)
	=====	=====	=====
Number of shares used in computing net loss per share--basic and diluted	19,944	18,069	13,097
	=====	=====	=====
CONSOLIDATED BALANCE SHEET DATA:			
Cash, cash equivalents and short-term investments	\$95,089	\$41,021	\$62,245
Working capital	92,200	33,508	57,701
Total assets	111,168	50,785	72,704
Capital lease obligations, less current portion	1,565	2,831	4,176
Accumulated deficit	(90,912)	(72,630)	(47,431)
Total stockholders' equity	101,414	38,121	61,051

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Form 10-K 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,"

Edgar Filing: NANOGEN INC - Form 10-K

"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 previously under the caption "Factors that May Affect Results" and elsewhere in this Form 10-K. 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(TM) System, is an integrated bioassay system consisting of the NanoChip(TM) Molecular Biology Workstation and the NanoChip(TM) Cartridge. The NanoChip(TM)

30

Workstation is comprised of two automated instruments and the NanoChip(TM) Cartridge, a consumable cartridge, which incorporates a proprietary microchip. The NanoChip(TM) System provides a flexible tool for the rapid identification and precision analysis of biological test samples containing charged molecules.

Since commencing operations in 1993, we have applied substantially all of our resources to our research and development programs. We have incurred losses since inception and, as of December 31, 2000, had an accumulated deficit of \$90.9 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 introduced our first two products into the marketplace in the second quarter of 2000. While we recognized revenue from product sales during the year ended December 31, 2000, our main sources of revenues during fiscal 2000 were payments under our sponsored research agreements, contracts and grants. 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(TM) 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

YEARS ENDED DECEMBER 31, 2000, 1999 AND 1998

REVENUES

Total revenues for the year ended December 31, 2000 include \$919,000 from the sale of our NanoChip(TM) Molecular Biology Workstations and NanoChip(TM) Cartridges. During the year ended December 31, 2000, all revenue recorded related to sales of our NanoChip(TM) Molecular Biology Workstation resulted from outright sales transactions where title of the instrument passed to the customer. We offer our products to customers under several different types of

Edgar Filing: NANOGEN INC - Form 10-K

acquisition programs, some of which pass title of the instrument to the customer and some of which do not pass title to the customer. Our sales revenue may vary from year to year due to, among other things, the types of acquisition programs our potential customers may choose.

For the year ended December 31, 2000, revenue from sponsored research totaled \$8.5 million compared to \$5.7 million and \$5.5 million for the years ended December 31, 1999 and 1998, 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 year ended December 31, 2000 was earned in connection with our research and development agreements entered into in December 1998 and September 1999 with Aventis, the joint venture agreement with Becton Dickinson as amended in September 2000, and the development program entered into in July 2000 with Hitachi, Ltd. Sponsored research revenue recognized during the year ended December 31, 1999 was earned in connection with our research and development agreements with Aventis, our joint venture collaboration with Becton Dickinson, and our nonexclusive research and development agreement with Elan. Sponsored research revenue recognized during the year ended December 31, 1998 was earned in connection with our research and development agreement with Aventis entered into in December 1998, our joint venture collaboration with Becton Dickinson, and our nonexclusive research and development agreement with Elan. We are negotiating a potential new relationship with Aventis relating to the research conducted and technology developed under the December 1998 agreement. In September 2000, we and Becton Dickinson modified the joint venture to, among other things, permit the partners the opportunity to commercialize certain of the Partnership's technology and to allow them to collaborate with third parties in developing and commercializing certain products and technologies. We do not expect to receive any additional funding from Becton Dickinson. We and Elan have not agreed upon specific program objectives with respect to the nonexclusive research and development program, and we do not expect to receive any additional funding from Elan.

31

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

For the year ended December 31, 2000, cost of sales were \$599,000. Cost of sales during the year ended December 31, 2000 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 within our manufacturing facility in 2001.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses decreased to \$18.9 million during the year ended December 31, 2000 from \$25.3 million and \$23.0 million for the years ended December 31, 1999 and 1998, respectively. During these periods, research and development expenses included salaries for scientific, engineering and

Edgar Filing: NANOGEN INC - Form 10-K

operations personnel, product design and prototype development costs, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities. The changes in research and development expenses resulted primarily from the different development stages of our NanoChip(TM) Molecular Biology Workstation from period to period. During the years ended December 31, 1999 and 1998, our NanoChip(TM) Molecular Biology Workstation was in an advanced stage of prototype design and development. During this stage, we incurred significant expenditures both internally and with outside vendors related to engineering prototypes, as well as other costs associated with testing and refining the product. In comparison, during the year ended December 31, 2000, many costs associated with the manufacturing of the workstation were absorbed by our manufacturing partner, Hitachi, Ltd. Research and development spending may increase over the next several years as our research and product development efforts continue.

GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses totaled \$15.3 million in 2000 compared to \$9.1 million in 1999 and \$6.4 million in 1998. The year-to-year increases from 1998 through 2000 are primarily due to increased legal fees associated with enhancing and maintaining our intellectual property portfolio, costs related to patent litigation, increased personnel costs as we expanded our administrative, sales and marketing organizations, and the expansion of activities related to marketing and selling our products. General and administrative expenses are expected to continue to increase as we continue to expand our sales and marketing organization and continue to enhance and maintain our intellectual property portfolio.

ACQUIRED IN-PROCESS TECHNOLOGY

During the first quarter of 1998, we issued 200,000 shares of our Series D Convertible Preferred Stock at \$6.00 per share in exchange for all of the outstanding shares of Nanotronics, Inc. This Series D Preferred Stock converted into 132,334 shares of common stock at our initial public offering. The in-process technology acquired relates generally to nanotechnology and molecular electronics. We recorded \$1.2 million in expenses relating to acquired in-process technology during the year ended December 31, 1998.

EQUITY IN LOSS OF JOINT VENTURE

We recognized a loss of \$996,000 and \$610,000 for the years ended December 31, 1999 and 1998, respectively, from the joint venture formed in 1997 with Becton Dickinson, based on the loss allocation described in the Partnership Agreement stating that losses will be allocated in proportion to and not to exceed required cash contributions. There was no loss recognized during 2000 as no cash contributions were required to be made by us to the joint venture during that period. In September 2000, we and Becton Dickinson modified the joint venture to, among other things, permit the partners the opportunity to commercialize certain of the Partnership's technology and

32

to allow them to collaborate with third parties in developing and commercializing certain products and technologies. We do not anticipate any additional funding to the joint venture.

INTEREST INCOME, NET

We had net interest income of \$5.3 million in 2000 compared to net interest income of \$2.1 million and \$2.7 million, in 1999 and 1998, respectively. The

Edgar Filing: NANOGEN INC - Form 10-K

significant increase in 2000 compared to 1999 and 1998 can be primarily attributed to higher average cash balances in 2000 resulting from net proceeds received in conjunction with our secondary public offering of common stock in March 2000. The decrease in net interest income for 1999 compared to 1998 can be attributed to lower cash balances during 1999 compared to 1998, as a result of cash used in operations.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2000, we had \$95.1 million in cash, cash equivalents and short-term investments, compared to \$41.0 million at December 31, 1999. This increase is primarily due to the completion of our secondary public offering of common stock in March 2000 generating net proceeds of \$76.5 million, offset by net cash used in operations and for the acquisition of technology rights during the year ended December 31, 2000.

Net cash used in operating activities was \$19.3 million, \$18.6 million and \$15.2 million for 2000, 1999 and 1998, respectively. Cash used for operations during 2000 was primarily related to costs associated with entering the commercialization stage of our initial products including the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd. and expansion of our sales and marketing organization, support of our continuing research and development efforts, costs associated with legal fees relating to establishing and maintaining our intellectual property portfolio, and patent litigation. Cash used for operations during 1999 and 1998 was primarily related to the costs associated with developing prototypes of our initial product, the support of our expanding operations, including higher personnel costs, and legal fees relating to establishing and maintaining our intellectual property rights.

During the year ended December 31, 2000, we paid \$5.1 million to acquire rights to technologies in order to enable us to further develop and commercialize our products. In addition, \$39.5 million of cash was used to invest in short-term securities in an effort to maximize our return while preserving our cash balance.

We fund most of our equipment acquisitions and leasehold improvements through capital leasing facilities. During 2000, we received proceeds from equipment and leasehold improvement financing of \$944,000, compared to \$881,000 and \$5.7 million of proceeds received during 1999 and 1998, respectively. The significantly higher amount of proceeds received during 1998 is due to the expansion of our facility during that year. We anticipate that we will continue to use capital equipment leasing or debt facilities to fund most of our equipment acquisitions and leasehold improvements. As of December 31, 2000, we had \$3.8 million of available funding under our equipment lease lines.

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(TM) System, sponsored research agreements, 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

Edgar Filing: NANOGEN INC - Form 10-K

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 products under development. Additional capital may not be available on terms acceptable to us, or at all. If adequate

33

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.

NET OPERATING LOSS CARRYFORWARDS

As of December 31, 2000, we had federal and California net operating loss, or NOL, carryforwards of \$83.6 million and \$10.8 million, respectively, and \$3.7 million and \$2.1 million of research and development, or R&D, tax credits available to offset future federal and state income taxes, respectively. The federal and California NOL carryforwards are subject to alternative minimum tax limitations and to examination by the tax authorities. The federal tax loss carryforwards will begin expiring in 2006, unless previously utilized, and the California tax loss carryforwards will continue to expire in 2001, unless previously utilized. The federal and California R&D tax credit carryforwards will begin expiring in 2007 unless previously utilized. We believe that our initial public offering combined with the concurrent private placement, which occurred in April 1998, may constitute a "change of ownership" under federal income tax regulations. We also experienced a "change of ownership" in 1995 and 1997. As such, we may be limited in the amount of NOLs incurred prior to our initial public offering, which may be utilized to offset future taxable income. Similar limitations may also apply to utilization of R&D tax credits to offset taxes payable. However, we do not believe such limitations will have a material impact on our ability to utilize the NOLs. See Note 8 of Notes to Financial Statements.

ITEM 7A. 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 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 \$718,000 at December 31, 2000.

Edgar Filing: NANOGEN INC - Form 10-K

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Refer to the Index on Page F-1 of the Financial Report included herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

34

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information regarding Directors is incorporated by reference to the section entitled "Election of Directors" in the Nanogen, Inc. definitive Proxy Statement to be filed with the Securities and Exchange Commission in connection with the Annual Meeting of Stockholders to be held on June 13, 2001 (the "Proxy Statement"). Information regarding Executive Officers is incorporated by reference to the Proxy Statement under the heading "Executive Officers." Information regarding Section 16(a) reporting compliance is incorporated by reference to the Proxy Statement under the heading "Section 16(a) Beneficial Ownership Reporting Compliance."

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to the Proxy Statement under the heading "Executive Compensation."

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference to the Proxy Statement under the heading "Security Ownership of Certain Beneficial Owners and Management."

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference to the Proxy Statement under the heading "Certain Transactions."

35

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) (1) Financial Statements:

Our financial statements are included herein as required under Item 8 of this Annual Report on Form 10-K. See Index on page F-1.

(2) Financial Statement Schedules

Edgar Filing: NANOGEN INC - Form 10-K

Financial statement schedules have been omitted since they are either not required, not applicable, or the information is otherwise included.

(3) Exhibits

EXHIBIT NUMBER	DESCRIPTION OF DOCUMENT
2.1(1)	Agreement and Plan of Merger among Registrant, Nanotronics, Inc. ("Nanotronics") and the shareholders of Nanotronics, dated as of December 18, 1997 (2.1).
3.(i)1(3)	Restated Certificate of Incorporation. (3.(i)1)
3.(i)2(3)	Certificate of Designation, as filed with the Delaware Secretary of State on November 23, 1998. (3.(ii)2)
3.(ii) (1)	Amended and Restated Bylaws of Registrant. (3.(ii)2)
4.1(1)	Form of Common Stock Certificate (4.1).
4.2(2)	Rights Agreement dated as of November 17, 1998, between Registrant and BankBoston, N.A (4.2).
4.3(10)	Amendment No. 1 to Rights Agreement, dated as of December 11, 2000 between Registrant and FleetBoston, N.A.
10.1(7) (A)	1997 Stock Incentive Plan of Nanogen, Inc. ("1997 Plan"), as amended. (10.1)
10.2(7) (A)	Form of Incentive Stock Option Agreement under the 1997 Plan, as amended. (10.2)
10.3(7) (A)	Form of Nonqualified Stock Option Agreement under the 1997 Plan, as amended. (10.3)
10.4(1) (A)	Nanogen, Inc. Employee Stock Purchase Plan. (10.6)
10.5(1) (A)	Form of Indemnification Agreement between Registrant and its directors and executive officers. (10.7)
10.6(1) (+)	Agreement between Registrant and Elan Corporation, plc, dated December 19, 1997. (10.8)
10.7(1) (+)	Agreement between Registrant and Syntro Corporation, dated of November 24, 1997. (10.10)
10.8(1) (+)	Master Agreement between Registrant and Becton, Dickinson and Company ("BD"), dated as of October 1, 1997, with related attachments. (10.11)
10.9(9)	First Amendment of Master Agreement between

Edgar Filing: NANOGEN INC - Form 10-K

- Registrant and BD, dated as of September 25, 2000 (10.1)
- 10.10(9)(+) First Amendment of Collaborative Research and Development and License Agreement between Registrant and BD, dated as of September 25, 2000 (10.2)
- 10.11(9)(+) First Amendment of General Partnership Agreement between Registrant and BD, dated as of September 25, 2000 (10.3)
- 10.12(9)(+) First Amendment of License Agreement between Registrant and BD, dated as of September 25, 2000 (10.4)
- 10.13(9)(+) Partnership Product Commercialization License Agreement, dated as of September 25, 2000 (10.5)
- 36
- 10.14(11)(+) Letter Agreement between Registrant and Hoechst AG, dated December 4, 1997 (10.16)
- 10.15(12)(+) Collaborative Research and Development Agreement between Registrant and Hoechst, dated December 3, 1998
- 10.16(4)(+) Collaborative Research and Development Agreement by and between Aventis Research & Technologies GMBH & Co. KG and Nanogen, Inc. dated as of September 27, 1999.
- 10.17(9) Warrant to Purchase Common Stock between Registrant and Aventis Research and Technologies Verwaltungs, GmbH, dated September 22, 2000 (10.9)
- 10.18(6)(+) Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement by and between Registrant and Hitachi, Ltd. dated as of December 15, 1999
- 10.19(9)(+) First Amendment to Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement between Registrant and Hitachi, Ltd., dated July 26, 2000 (10.7)
- 10.20(9)(+) Collaboration Agreement between Registrant and Hitachi, Ltd., Nissei Sangyo Co. Ltd. And Hitachi Instruments Service Co. Ltd., (collectively, the "Hitachi Parties"), dated July 26, 2000 (10.6)
- 10.21(9) Common Stock Purchase Agreement between Registrant and the Hitachi Parties, dated July 26, 2000 (10.8)
- 10.22(5)(+) License Agreement between Registrant and Billups-Rothenberg, Inc., dated as of March 31, 1998 (10.34(1))

Edgar Filing: NANOGEN INC - Form 10-K

- 10.23(8) (+) License Agreement between Registrant and Beckman Coulter, Inc., dated May 19, 2000 (10.1)
- 10.24(1) Amended and Restated Investors' Rights Agreement between Registrant and certain security holders set forth therein, dated as of May 5, 1997, as amended. (10.18)
- 10.25(1) Master Lease Agreement between Registrant and Mellon US Leasing, dated September 11, 1997. (10.19)
- 10.26(1) Master Lease Agreement between Registrant and LMP Properties, Ltd., dated June 29, 1994. (10.20)
- 10.27(1) Lease Agreement between Registrant and Lease Management Services, Inc., dated April 26, 1994, as amended on December 13, 1994 and June 13, 1996. (10.21)
- 10.28(1) (A) Form of Nanogen, Inc. Restricted Stock Issuance Agreement between Registrant and certain of its directors and executive officers, dated as of November 7, 1997. (10.22)
- 10.29(1) (A) Form of Promissory Note between Registrant and certain of its executive officers, dated August 22, 1996. (10.23)
- 10.30(1) (A) Form of Promissory Note between Registrant and certain of its executive officers, dated June 30, 1995. (10.24)
- 10.31(1) (A) Form of Common Stock Purchase Agreement. (10.25)
- 10.32(1) (A) Form of Performance Stock Option Agreement. (10.26)
- 10.33(5) (A) Agreement between Registrant and Kieran T. Gallahue, dated October 29, 1999.
- 10.34(5) (A) Agreement between Registrant and Michael J. Heller, dated October 29, 1999.
- 10.35(5) (A) Agreement between Registrant and Howard C. Birndorf, dated October 29, 1999.
- 10.36(5) (A) Agreement between Registrant and Clare "Bud" Bromley, dated October 29, 1999.
- 10.37(5) (A) Agreement between Registrant and W.J. Kitchen, dated December 31, 1999.
- 10.38(A) Secured Promissory Note between Registrant and Kieran T. Gallahue, dated April 23, 1998.
- 10.39(8) (A) Agreement between Registrant and Michael D. Moore, dated June 15, 2000 (10.2)
- 10.40(8) (A) Agreement between Registrant and George E. Bers, dated June 5, 2000 (10.3)

Edgar Filing: NANOGEN INC - Form 10-K

37

- 10.41(9) (A) First Amendment to Agreement between Registrant and Howard C. Birndorf, dated as of July 28, 2000 (10.10)
- 10.42(9) (A) First Amendment to Agreement between Registrant and Kieran T. Gallahue, dated as of July 28, 2000 (10.11)
- 10.43(9) (A) First Amendment to Agreement between Registrant and Michael D. Moore, dated as of July 28, 2000 (10.12)
- 10.44(9) (A) First Amendment to Agreement between Registrant and George E. Bers, dated as of July 28, 2000 (10.14)
- 10.45(9) (A) First Amendment to Agreement between Registrant and Michael J. Heller, dated as of July 28, 2000 (10.15)
- 10.46(A) Agreement between Registrant and Vera P. Pardee, dated as of November 1, 2000
- 10.47(A) Agreement between Registrant and James P. O'Connell, dated as of October 4, 2000
- 10.48(A) Agreement between Registrant and Harry J. Leonhardt, dated as of December 1, 2000
- 10.49(A) First Amendment to Agreement between Registrant and Clare "Bud" Bromley, dated as of July 28, 2000
- 10.50(5) Master Loan and Security Agreement between Registrant and Transamerica Business Credit Corporation dated June 14, 1999.
- 23.1 Consent of Ernst & Young LLP, independent auditors.

-
- (1) Incorporated by reference to Registrant's Registration Statement on Form S-1 (File No. 333-42791). Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
 - (2) Incorporated by reference to Registrant's Registration Statement on Form 8-A, filed on November 24, 1998. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
 - (3) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 1998. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.

Edgar Filing: NANOGEN INC - Form 10-K

- (4) Incorporated by reference to Exhibit 10.13 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999.
- (5) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 1999. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed
- (6) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (7) Incorporated by reference to the Registrant's Form S-8 filed on June 15, 2000. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
- (8) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2000. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
- (9) Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
- (10) Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 12, 2000.
- (11) Incorporated by reference to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on February 9, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
- (12) Incorporated by reference to Exhibit 10.1 to Amendment No. 2 to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2000, filed on March 13, 2001.
- (A) Indicates management compensatory plan or arrangement.
- (+) Confidential treatment has been requested for certain portions of these agreements.

38

- (b) Reports on Form 8-K

On December 12, 2000, we filed a report on Form 8-K to disclose an amendment to the Company's Stockholder Rights Plan approved by the Company's Board of Directors on December 12, 2000.

39

Edgar Filing: NANOGEN INC - Form 10-K

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NANOGEN, INC.

Date: March 28, 2001

By: /s/ HOWARD C. BIRNDORF

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

Pursuant to the requirements to the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ HOWARD C. BIRNDORF ----- Howard C. Birndorf	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	March 28,
/s/ KIERAN T. GALLAHUE ----- Kieran T. Gallahue	President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 28,
/s/ VAL BUONAIUTO ----- Val Buonaiuto	Director	March 28,
/s/ CAM L. GARNER ----- Cam L. Garner	Director	March 28,
/s/ REGINA E. HERZLINGER ----- Regina E. Herzlinger	Director	March 28,
/s/ DAVID G. LUDVIGSON ----- David G. Ludvigson	Director	March 28,
/s/ THOMAS G. LYNCH ----- Thomas G. Lynch	Director	March 28,
/s/ STELIOS B. PAPADOPOULOS	Director	March 28,

Stelios B. Papadopoulos

40

NANOGEN, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Ernst & Young LLP, Independent Auditors.....
Consolidated Balance Sheets.....
Consolidated Statements of Operations.....
Consolidated Statements of Stockholders' Equity.....
Consolidated Statements of Cash Flows.....
Notes to Consolidated Financial Statements.....

F-1

REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Stockholders
Nanogen, Inc.

We have audited the accompanying consolidated balance sheets of Nanogen, Inc., as of December 31, 2000 and 1999, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in

Edgar Filing: NANOGEN INC - Form 10-K

all material respects, the consolidated financial position of Nanogen, Inc. at December 31, 2000 and 1999 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

San Diego, California
January 26, 2001

F-2

NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE DATA)

	DECEMBER 31,	
	2000	1999
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 55,330	\$ 41,021
Short-term investments	39,759	--
Receivables	2,376	1,641
Inventory	2,289	--
Other current assets	635	679
	100,389	43,341
Property and equipment, net	5,373	6,154
Acquired technology rights, net	5,179	1,005
Restricted cash	164	219
Other assets	63	66
	\$ 111,168	\$ 50,785
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,223	\$ 598
Accrued liabilities	4,595	3,726
Deferred revenue	360	3,373
Current portion of capital lease obligations	2,011	2,136
	-----	-----

Edgar Filing: NANOGEN INC - Form 10-K

Total current liabilities	8,189	9,833
Capital lease obligations, less current portion	1,565	2,831
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, \$.001 par value, 5,000,000 shares authorized at December 31, 2000 and 1999; no shares issued and outstanding at December 31, 2000 and 1999	--	--
Common stock, \$.001 par value, 50,000,000 shares authorized at December 31, 2000 and 1999; 20,913,151 and 18,990,799 shares issued and outstanding at December 31, 2000 and 1999, respectively	21	19
Additional paid-in capital	193,459	113,574
Accumulated other comprehensive income	270	--
Deferred compensation	(325)	(1,473)
Notes receivable from officers	(1,099)	(1,369)
Accumulated deficit	(90,912)	(72,630)
Total stockholders' equity	101,414	38,121
	\$ 111,168	\$ 50,785
	=====	=====

See accompanying notes.

F-3

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
Revenues:			
Product	\$ 919	\$ --	\$ --
Sponsored research	8,457	5,688	5,461
Contract and grant	1,856	2,431	2,172
Total revenues	11,232	8,119	7,633
Operating expenses:			
Cost of sales	599	--	--
Research and development	18,905	25,284	23,002
General and administrative	15,267	9,097	6,420
Acquired in-process technology	--	--	1,193

Edgar Filing: NANOGEN INC - Form 10-K

Total operating expenses	34,771	34,381	30,615
Loss from operations	(23,539)	(26,262)	(22,982)
Equity in loss of joint venture	--	(996)	(610)
Interest income, net	5,257	2,059	2,650
Net loss	\$ (18,282)	\$ (25,199)	\$ (20,942)
Net loss per share--basic and diluted	\$ (0.92)	\$ (1.39)	\$ (1.60)
Number of shares used in computing net loss per share--basic and diluted	19,944	18,069	13,097

See accompanying notes.

F-4

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS)

	CONVERTIBLE PREFERRED STOCK		COMMON STOCK	
	SHARES	AMOUNT	SHARES	AMOUNT
Balance at December 31, 1997	13,684	\$ 14	3,184	\$ 3
Issuance of common stock	--	--	555	1
Repurchase of common stock	--	--	(123)	--
Issuance of convertible preferred stock	232	--	--	--
Sale of common stock under initial public offering, net of expenses	--	--	3,900	4
Sale of common stock in private placement in conjunction with initial public offering	--	--	1,909	2
Conversion of preferred stock upon the completion of initial public offering	(13,916)	(14)	9,277	9
Deferred compensation related to stock options	--	--	--	--
Amortization of deferred compensation	--	--	--	--
Exercise of stock options in exchange for Notes receivable and accrued interest	--	--	133	--
Net loss	--	--	--	--
Balance at December 31, 1998	--	--	18,835	19
Issuance of common stock	--	--	94	--
Repurchase of common stock	--	--	(73)	--

Edgar Filing: NANOGEN INC - Form 10-K

Cancellation of notes receivable related to Unvested restricted stock	--	--	(116)	--
Restricted stock awards	--	--	251	--
Stock based compensation expense	--	--	--	--
Amortization of deferred compensation	--	--	--	--
Payments received and accrued interest on Notes receivable from officers	--	--	--	--
Net loss	--	--	--	--
	-----	-----	-----	-----
Balance at December 31, 1999	--	--	18,991	19
Components of comprehensive loss:				
Net loss	--	--	--	--
Unrealized gain on short-term investments	--	--	--	--
 Total comprehensive loss				
Issuance of common stock	--	--	462	--
Repurchase of common stock	--	--	(58)	--
Sale of common stock under secondary public Offering, net of expenses	--	--	1,500	2
Sale of common stock in private placement	--	--	75	--
Cancellation of notes receivable related to Unvested restricted stock	--	--	(57)	--
Stock based compensation expense	--	--	--	--
Amortization of deferred compensation	--	--	--	--
Payments received and accrued interest on Notes receivable from officers	--	--	--	--
	-----	-----	-----	-----
Balance at December 31, 2000	--	\$ --	20,913	\$ 21
	=====	=====	=====	=====

	ACCUMULATED OTHER COMPREHENSIVE INCOME	DEFERRED COMPENSATION	NOTES RECEIVABLE FROM OFFICERS	ACCUMULATED DEFICIT
	-----	-----	-----	-----
Balance at December 31, 1997	\$ --	\$ (2,323)	\$ (1,129)	\$ (26)
Issuance of common stock	--	--	--	--
Repurchase of common stock	--	--	90	--
Issuance of convertible preferred stock	--	--	--	--
Sale of common stock under initial public Offering, net of expenses	--	--	--	--
Sale of common stock in private placement in Conjunction with initial public offering	--	--	--	--
Conversion of preferred stock upon the The completion of initial public offering	--	--	--	--
Deferred compensation related to stock options	--	(1,370)	--	--
Amortization of deferred compensation	--	2,181	--	--
Exercise of stock options in exchange for Notes receivable and accrued interest	--	--	(475)	--
Net loss	--	--	--	(20)
	-----	-----	-----	-----
Balance at December 31, 1998	--	(1,512)	(1,514)	(47)
Issuance of common stock	--	--	--	--

Edgar Filing: NANOGEN INC - Form 10-K

Repurchase of common stock	--	86	--	
Cancellation of notes receivable related to Unvested restricted stock	--	--	104	
Restricted stock awards	--	(1,820)	--	
Stock based compensation expense	--	--	--	
Amortization of deferred compensation	--	1,773	--	
Payments received and accrued interest on Notes receivable from officers	--	--	41	
Net loss	--	--	--	(25)
	-----	-----	-----	-----
Balance at December 31, 1999	--	(1,473)	(1,369)	(72)
Components of comprehensive loss:				
Net loss	--	--	--	(18)
Unrealized gain on short-term investments	270	--	--	
 Total comprehensive loss				
Issuance of common stock	--	--	--	
Repurchase of common stock	--	201	--	
Sale of common stock under secondary public Offering, net of expenses	--	--	--	
Sale of common stock in private placement	--	--	--	
Cancellation of notes receivable related to Unvested restricted stock	--	--	56	
Stock based compensation expense	--	504	--	
Amortization of deferred compensation	--	443	--	
Payments received and accrued interest on Notes receivable from officers	--	--	214	
	-----	-----	-----	-----
Balance at December 31, 2000	\$ 270	\$ (325)	\$ (1,099)	\$ (90)
	=====	=====	=====	=====

See accompanying notes.

F-5

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
	-----	-----	-----
OPERATING ACTIVITIES:			
Net loss	\$(18,282)	\$(25,199)	\$(20,942)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquisition of in-process technology	--	--	1,193

Edgar Filing: NANOGEN INC - Form 10-K

Equity in loss of joint venture	--	996	610
Net (gain) loss from sale of property and equipment	--	24	(13)
Depreciation and amortization	2,553	1,709	1,168
Amortization related to short-term investments	29	--	--
Amortization of deferred compensation	443	1,773	2,181
Stock based compensation expense	504	237	--
Interest capitalized on notes receivable from officers	(57)	(74)	(75)
Changes in operating assets and liabilities:			
Accounts receivable	(735)	(94)	(941)
Inventory	(2,289)	--	--
Other assets	47	(88)	(1,350)
Accounts payable	625	(468)	469
Accrued liabilities	869	2,293	424
Deferred revenue	(3,013)	308	2,053
	-----	-----	-----
Net cash used in operating activities	(19,306)	(18,583)	(15,223)
INVESTING ACTIVITIES:			
Purchase of short-term investments	(39,461)	--	--
Purchase of technology rights	(5,000)	--	--
Purchase of equipment	(59)	(32)	(72)
Investment in joint venture	--	(996)	(610)
Proceeds from sale of assets	--	6	29
	-----	-----	-----
Net cash used in investing activities	(44,520)	(1,022)	(653)
FINANCING ACTIVITIES:			
Decrease in restricted cash	55	51	89
Principal payments on capital lease obligations	(2,335)	(2,003)	(1,561)
Issuance of common stock	80,139	218	60,052
Note receivable payments from officers	276	115	--
Issuance of convertible preferred stock, net of issuance costs	--	--	43
	-----	-----	-----
Net cash provided by (used in) financing activities	78,135	(1,619)	58,623
	-----	-----	-----
Net increase (decrease) in cash and cash equivalents	14,309	(21,224)	42,747
Cash and cash equivalents at beginning of year	41,021	62,245	19,498
	-----	-----	-----
Cash and cash equivalents at end of year	\$ 55,330	\$ 41,021	\$ 62,245
	=====	=====	=====
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:			
Interest paid	\$ 461	\$ 580	\$ 466
	=====	=====	=====
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES:			
Equipment acquired under capital leases	\$ 944	\$ 881	\$ 5,652
	=====	=====	=====
Common stock issued in exchange for notes receivables from officers	\$ --	\$ --	\$ 310
	=====	=====	=====
Issuance of convertible preferred stock and warrants in exchange for in-process technology	\$ --	\$ --	\$ 1,193
	=====	=====	=====
Exchange of notes receivable for acquired technology rights	\$ --	\$ 1,005	\$ --
	=====	=====	=====
Deferred compensation related to stock options and restricted stock awards, net	\$ --	\$ 1,734	\$ 1,370

Edgar Filing: NANOGEN INC - Form 10-K

	=====	=====	=====
Unrealized gain on short-term investments	\$ 270	\$ --	\$ --
	=====	=====	=====
Cancellation of notes receivable related to unvested restricted stock	\$ (56)	\$ (104)	\$ --
	=====	=====	=====
Cancellation of unvested restricted stock	\$ 201	\$ 86	\$ --
	=====	=====	=====

See accompanying notes.

F-6

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2000

1. ORGANIZATION

ORGANIZATION AND BUSINESS ACTIVITY

Nanogen, Inc. ("Nanogen" or the "Company") was incorporated in California on November 6, 1991 and, in November 1997, the Company reincorporated in Delaware. The Company was established to develop products which integrate advanced microelectronics and molecular biology into a platform technology with broad commercial applications in the fields of biomedical research, genomics, medical diagnostics, genetic testing and drug discovery. The Company operates in one business and operating segment.

NANOGEN EUROPE B.V.

In August 2000, Nanogen Europe B.V. was incorporated as a company with limited liability in The Netherlands. In conjunction with the incorporation, the Company was issued all of the outstanding shares of Nanogen Europe B.V. This wholly-owned subsidiary operates as the primary European sales and marketing office for the Company. The Company's consolidated financial statements at December 31, 2000 include \$718,000 in net tangible assets, excluding intercompany balances, and an operating loss of \$402,000 for the period from incorporation through December 31, 2000 related to Nanogen Europe B.V.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

BASIS OF CONSOLIDATION

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Nanogen Europe B.V. All significant intercompany transactions have been eliminated in consolidation.

CASH AND CASH EQUIVALENTS

Cash and cash equivalents consist of cash and highly liquid investments which include debt securities with remaining maturities of three months or less when acquired.

Edgar Filing: NANOGEN INC - Form 10-K

SHORT-TERM INVESTMENTS

Financial Accounting Standards Board ("FASB") Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, requires that investments in equity securities that have readily determinable fair values and investments in debt securities be classified in three categories: held-to-maturity, trading and available-for-sale. Based on the nature of the assets held by the Company and management's investment strategy, the Company's investments have been classified as available-for-sale. Management determines the appropriate classification of debt securities at the time of purchase. Securities classified as available-for-sale are carried at estimated fair value, as determined by quoted market prices, with unrealized gains and losses, net of tax, reported in a separate component of comprehensive loss. At December 31, 2000, the Company had no investments that were classified as trading or held-to-maturity as defined by the Statement. The amortized cost of debt securities classified as available-for-sale is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. Realized gains and losses are included in interest income. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in interest income.

CONCENTRATION OF CREDIT RISK

The Company invests its excess cash primarily in U.S. government securities and marketable debt securities of financial institutions and corporations with strong credit ratings. The Company has established guidelines relative to

F-7

diversification and maturities to maintain safety and liquidity. These guidelines are reviewed periodically and modified to take advantage of trends in yields and interest rates. The Company has not experienced any significant realized losses on its investments.

RESTRICTED CASH

During 1994, the Company obtained an irrevocable standby letter of credit in the amount of approximately \$464,000 to secure its building lease. The letter of credit is secured by a certificate of deposit, which is shown as restricted cash in the accompanying balance sheet. The letter of credit is reduced by approximately \$50,000 annually, and had a balance of approximately \$164,000 at December 31, 2000.

INVENTORY

Inventory is carried at the lower of cost or market, using the first-in, first-out method.

PROPERTY AND EQUIPMENT

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets, generally three to five years, using the straight-line method. Leasehold improvements are stated at cost and amortized over the shorter of the estimated useful lives of the assets or the lease term.

ACQUIRED TECHNOLOGY RIGHTS

Acquired technology rights are recorded at cost and amortized on a straight-line basis over their estimated useful lives of five years.

Edgar Filing: NANOGEN INC - Form 10-K

IMPAIRMENT OF LONG-LIVED ASSETS

In accordance with Statement of Financial Accounting Standards ("SFAS") No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of, if indicators of impairment exist, the Company assesses the recoverability of the affected long-lived assets by determining whether the carrying value of such assets can be recovered through undiscounted future operating cash flows. If impairment is indicated, the Company will value the asset at fair value. While the Company's current and historical operating and cash flow losses are indicators of impairment, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets' carrying value, and accordingly the Company has not recognized any impairment losses through December 31, 2000.

REVENUE RECOGNITION

Product revenues include sales of the NanoChip(TM) Molecular Biology Workstation and NanoChip(TM) Cartridges. Product revenues are recognized generally upon shipment and transfer of title to the customer.

Sponsored research, contract and grant revenues are recorded as the costs and expenses to perform the research are incurred. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Continuation of certain research agreements, contracts and grants are dependent upon the Company achieving specific contractual milestones.

Contract and grant revenue from one customer amounted to approximately 10%, 13% and 1% of total revenues in 2000, 1999 and 1998, respectively. Contract and grant revenue from a second customer amounted to approximately none, 8% and 10% of total revenues in 2000, 1999 and 1998, respectively. Additionally, revenues from sponsored research (see Note 9) represented 75%, 70% and 72% of total revenue in 2000, 1999 and 1998, respectively.

F-8

COMPREHENSIVE INCOME (LOSS)

SFAS No. 130, Reporting Comprehensive Income ("SFAS 130") requires reporting and displaying comprehensive income (loss) and its components which, for the Company, includes unrealized gains and losses on investments. In accordance with SFAS 130, the accumulated balance of other comprehensive income (loss) is disclosed as a separate component of stockholders' equity.

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 per share is computed by dividing the net income 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. Due to the losses incurred by the Company during the years ended December 31, 2000, 1999, and 1998, 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.

Edgar Filing: NANOGEN INC - Form 10-K

STOCK-BASED COMPENSATION

As permitted by SFAS No. 123, the Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, and related Interpretations ("APB 25"), in accounting for its employee stock options. Under APB 25, when the exercise price of the Company's employee stock options is equal to or exceeds the fair value of the underlying stock on the date of grant, no compensation expense is recognized.

USE OF ESTIMATES

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

FOREIGN CURRENCY

The functional currency of our Netherlands subsidiary is the U.S. dollar. The monetary assets and liabilities are translated into U.S. dollars at the exchange rate in effect at the balance sheet date. Revenues, expenses, gains and losses associated with the monetary assets and liabilities are translated at the rates of exchange that approximate the rates in effect at the transaction date. Non-monetary assets and liabilities and related elements of expense, gains and losses are translated at historical rates. Resulting remeasurement gains or losses of our Netherlands subsidiary are recognized in the statement of operations. During fiscal 2000, foreign currency transaction losses were not material.

SEGMENT INFORMATION

SFAS No. 131, "Segment Information," amends the requirements for public enterprises to report financial and descriptive information about its reportable operating segments. Operating segments, as defined in SFAS No. 131, are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company in deciding how to allocate resources and in assessing performance. The financial information is required to be reported on the basis that is used internally for evaluating this segment performance. The Company operates in one business and operating segment only, and therefore adoption of this standard had no impact on the Company's consolidated financial position or results of operations.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the FASB issued SFAS No. 133, Accounting for Derivative Instruments and Hedging Activities. In July 2000, the FASB issued SFAS No. 137, which defers the adoption requirement to the first quarter of 2001. This statement establishes a new model for accounting for derivatives and hedging activities. Under SFAS No. 133,

F-9

all derivatives must be recognized as assets and liabilities and measured at fair value. Management does not believe the adoption of SFAS No. 133 will impact the financial statements as the Company currently does not invest in derivative instruments or engage in hedging activities.

In December 1999, the Securities and Exchange Commission (SEC) issued Staff

Edgar Filing: NANOGEN INC - Form 10-K

Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101") which provides guidance related to revenue recognition based on interpretations and practices followed by the SEC. In June 2000, the SEC staff amended SAB 101 to provide registrants with additional time to implement SAB 101. The Company adopted SAB 101 in the fourth quarter of fiscal 2000. The adoption of SAB 101 did not have a material effect on the Company's consolidated financial position or results of operations.

In March 2000, the FASB issued FASB Interpretation No. 44 ("FIN 44"), Accounting for Certain Transactions Involving Stock Compensation, which addresses practice issues related to the application of APB 25. The Company adopted FIN 44 effective July 1, 2000. The adoption of FIN 44 had no impact on the Company's consolidated financial position or results of operations.

3. FINANCIAL STATEMENT DETAILS

SHORT-TERM INVESTMENTS

As of December 31, 2000, short-term investments consisted of the following (in thousands):

	AMORTIZED COST	MARKET VALUE	UNREALIZED GAIN
	-----	-----	-----
Obligations of U.S. government agencies	\$ 12,504	\$ 12,583	\$ 79
Corporate debt securities	26,985	27,176	191
	-----	-----	-----
	\$ 39,489	\$ 39,759	\$ 270
	=====	=====	=====

Approximately 17% and 83% of these securities mature within one and two years of December 31, 2000, respectively.

RECEIVABLES

Receivables are comprised of the following (in thousands):

	DECEMBER 31,	
	2000	1999
	-----	-----
Accounts receivables	\$ 510	\$ -
Sponsored research	490	747
Contract and grant	322	590
Interest	612	-
Other	442	304
	-----	-----
	\$ 2,376	\$ 1,641
	=====	=====

Edgar Filing: NANOGEN INC - Form 10-K

INVENTORY

Inventory consists of the following at December 31, 2000 (in thousands):

Raw materials	\$	288
Work in process		491
Finished goods		1,510
		=====
	\$	2,289

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

F-10

PROPERTY AND EQUIPMENT

Property and equipment consist of the following (in thousands):

	DECEMBER 31,	
	2000	1999
	-----	-----
Scientific equipment	\$ 4,049	\$ 3,738
Manufacturing equipment	86	42
Office furniture and equipment	2,793	2,156
Leasehold improvements	4,211	4,200
	-----	-----
	11,139	10,136
Less accumulated depreciation and amortization	(5,766)	(3,982)
	-----	-----
	\$ 5,373	\$ 6,154
	=====	=====

ACQUIRED TECHNOLOGY RIGHTS

As of December 31, 2000 and 1999, acquired technology rights is presented net of accumulated amortization of \$826,000 and none, respectively.

ACCRUED LIABILITIES

Accrued liabilities are comprised of the following (in thousands):

DECEMBER 31,	
2000	1999
-----	-----

Edgar Filing: NANOGEN INC - Form 10-K

	-----	-----
Accrued compensation and benefits	\$ 1,840	\$ 2,034
Accrued legal fees	921	-
Accrued product development costs	-	944
Accrued development funding liability	500	-
Other	1,334	748
	-----	-----
	\$ 4,595	\$ 3,726
	=====	=====

4. COMMITMENTS AND CONTINGENCIES

LICENSING AND RESEARCH AGREEMENTS

The Company is a party to licensing and research agreements with various entities whereby the Company is obligated to pay certain license fees and research funding. None of these agreements individually are considered material. Under some of these agreements, the Company may be required to pay royalties on product sales in the event that the Company incorporates the licensed technology in one or more of its commercial products.

LEASES

The Company leases its facilities and certain equipment under operating lease agreements that expire at various dates through 2005. Rent expense was \$631,000, \$577,000, and \$532,000 in 2000, 1999 and 1998, respectively.

The Company leases certain equipment under capital lease obligations. Cost and accumulated amortization of equipment under capital lease were \$9,481,000 and \$4,153,000 at December 31, 2000 and \$9,953,000 and \$3,872,000 at December 31, 1999, respectively. Amortization of equipment under capital lease obligations is included in depreciation expense.

Annual future minimum obligations for operating and capital leases as of December 31, 2000 are as follows (in thousands):

	OPERATING LEASES	CAPITAL LEASE OBLIGATIONS
	-----	-----
2001	\$ 697	\$ 2,234
2002	689	890
2003	692	408
2004	719	310
2005	191	201
Thereafter	--	--
	-----	-----
Total minimum lease payments	\$ 2,988	4,043
	=====	=====

Edgar Filing: NANOGEN INC - Form 10-K

Less amount representing interest	467

Present value of future minimum capital lease obligations	3,576
Less amounts due in one year	2,011

Long term portion of capital lease obligations	\$ 1,565
	=====

As of December 31, 2000, the Company has \$3.8 million of available funding under equipment lease lines.

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

Edgar Filing: NANOGEN INC - Form 10-K

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

F-12

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.

5. RELATED PARTY TRANSACTIONS

The Company has advanced funds aggregating \$240,000 to certain officers in connection with various employment agreements. These agreements provide for forgiveness of the advances over four-year periods. If an individual terminates his or her relationship with the Company, the unforgiven portion of the advances and any accrued interest are due and payable upon termination. These advances are secured by second trust deeds on the personal residences of the respective officers. As of December 31, 2000, \$120,000 of these advances has been forgiven, \$100,000 has been repaid to the Company in conjunction with the termination of the relationship between the Company and the individual, and \$20,000 is included in other assets. In addition, there are full-recourse notes receivable from certain officers totaling approximately \$1.1 million related to stock purchase agreements.

In November 1998, the Company entered into a Standstill Agreement and Right of First Negotiation (the "Agreement") with Graviton, Inc. ("Graviton"), granting the Company an exclusive period of time to negotiate a license to certain technologies licensed to and/or developed by Graviton. In exchange for the Agreement, the Company advanced to Graviton through a secured loan the sum of \$500,000. In May 1999, the Company advanced to Graviton through a secured loan an additional \$500,000, the proceeds of which were to be used by Graviton in part to secure additional intellectual property rights which the Company could license. In December 1999, the Company entered into a Collaboration and License Agreement with Graviton. Pursuant to this agreement, the total loans of \$1.0 million, plus accrued interest, were exchanged for license fees which are reflected as "acquired technology rights" in the accompanying consolidated balance sheets.

Edgar Filing: NANOGEN INC - Form 10-K

Mr. Birndorf, Chairman of the Board, Chief Executive Officer, and a director of the Company, is also a director of and investor in Graviton. Mr. Birndorf holds a significant controlling ownership interest in Graviton. Given the interrelationship among the parties, the Company's Board appointed a committee of disinterested Board members to evaluate this opportunity. After full disclosure of the above-referenced interrelationships, the Committee determined that it was in the best interests of the Company to enter into the license agreement which was executed on December 15, 1999.

6. EMPLOYEE BENEFIT PLANS

401(k) PLAN

The Company has a 401(k) defined contribution savings and retirement plan (the "Plan"). The Plan is for the benefit of all qualifying employees and permits employees to make voluntary contributions up to a maximum of 20% of base salary (as defined), subject to annual limits. The Board of Directors may, at its sole discretion, approve Company contributions. On January 26, 2001, the Compensation Committee of the Board of Directors approved a Company match in the form of Company stock equal to 50% of the total employees' contributions for the year ended December 31, 2000.

RETIREMENT PLANS

The Company's foreign subsidiary maintains separate defined contribution retirement savings plans for each country in which its employees reside. Participants may contribute a portion of their annual salaries subject to statutory annual limitations in each country. The Company contributes to these plans as required by local statute and may make additional contributions at its discretion. For the year ended December 31, 2000, the Company contributed approximately \$10,000 to these plans.

STOCK OPTION PLANS

Under the Company's 1993 Stock Option Plan, as amended in April 1995, 654,671 shares of common stock were reserved for issuance upon exercise of stock options granted by the Company. In April 1995, the Board of Directors

F-13

adopted the 1995 Stock Option/Stock Issuance Plan under which 333,333 shares of common stock were reserved for issuance. In April 1996, an additional 650,000 shares of common stock were reserved for issuance under the 1995 Plan. The plans provide for the grant of stock options to officers, directors, employees and consultants to the Company.

In August 1997, the Board of Directors adopted the 1997 Stock Incentive Plan, under which 1,641,341 shares of common stock were reserved for issuance upon exercise of stock options granted by the Company. In November 1997, June 1999 and June 2000, an additional 600,000 shares, 925,000 shares and 1,000,000 shares, respectively, were reserved for issuance under the 1997 Plan.

The exercise price of incentive stock options to be granted under the stock option plans shall not be less than 100% of the fair value of such shares on the date of grant. The exercise price of nonqualified stock options to be granted under the plans shall not be less than 85% of the fair value of such shares on the date of grant. Options granted prior to April 13, 1998 (the date of the Company's initial public offering) are generally exercisable immediately; however, options granted subsequent to the initial public offering are generally

Edgar Filing: NANOGEN INC - Form 10-K

exercisable only as they vest. All shares granted under the Stock Option Plans generally vest at the rate of one fourth after one year and the remainder ratably over the remaining three years. Options granted have a term of up to ten years.

As of December 31, 2000, 765,961 shares are available for future grant under the stock option plans. The following table summarizes stock option activity through December 31, 2000:

	NUMBER OF SHARES	PRICE PER SHARE	WEIGHTED AVERAGE EXERCISE PRICE PER SHARE
	-----	-----	-----
Outstanding at December 31, 1997	416,716	\$.02 to \$.90	\$.60
Granted	1,344,874	\$3.00 to \$10.00	\$ 4.48
Exercised	(248,479)	\$.15 to \$ 3.00	\$ 1.98
Cancelled	(406,910)	\$.15 to \$10.00	\$ 6.23

Outstanding at December 31, 1998	1,106,201	\$.02 to \$ 5.00	\$ 2.94
Granted	849,326	\$.001 to \$21.88	\$ 5.23
Exercised	(314,870)	\$.001 to \$ 4.75	\$.49
Cancelled	(381,389)	\$.375 to \$ 9.63	\$ 3.75

Outstanding at December 31, 1999	1,259,268	\$.02 to \$21.88	\$ 4.86
Granted	1,518,150	\$8.50 to \$45.81	\$33.17
Exercised	(247,734)	\$.15 to \$ 9.63	\$ 2.88
Cancelled	(237,260)	\$.15 to \$45.81	\$27.23

Outstanding at December 31, 2000	2,292,424	\$.02 to \$45.81	\$21.50
	=====		

The Company has the option to repurchase, at the original issue price, unvested shares issued pursuant to early exercise of options in the event of termination of employment or engagement. At December 31, 2000, 226,488 shares issued under the stock option plans were subject to repurchase by the Company.

On September 25, 1998, the Compensation Committee of the Board of Directors authorized a plan for certain option holders whereby each holder could have exchanged all of his or her current vested and unvested options on a one-for-one basis for new options priced at the market value as of September 25, 1998. An aggregate of 365,463 options at an average price of \$6.69 were exchanged for options with an exercise price of \$3.8125 per share. All of these replacement options vest based on the original grant date. Generally, the replacement options were not exercisable until September 26, 1999, or under certain circumstances at an earlier date.

All replacement options are included in grants and cancellations in the above summary of stock option activity.

The Company recognized an aggregate of \$6,124,000 through December 31, 2000 as deferred compensation for the excess of the fair value of the common stock issuable on exercise of such options over the exercise price. The deferred

Edgar Filing: NANOGEN INC - Form 10-K

compensation expense is being recognized over the vesting period of the options. Compensation expense related to these options was \$947,000, \$1,773,000, and \$2,181,000 for the years ended December 31, 2000, 1999, and 1998, respectively.

F-14

On January 26, 2001, the Compensation Committee of the Board of Directors authorized a plan for certain option holders whereby each holder could cancel certain of his or her vested and unvested options and receive a written promise 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 (excluding executive officers and directors) 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.

Following is a further breakdown of the options outstanding as of December 31, 2000:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING	WEIGHTED AVERAGE REMAINING LIFE IN YEARS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS EXERCISABLE	WEIGHTED AVERAGE EXERCISE PRICE OF OPTIONS EXERCISABLE
-----	-----	-----	-----	-----	-----
\$.02 - \$.90	81,686	5.87	\$.39	81,686	\$.39
\$3.00 - \$3.94	331,032	7.54	\$ 3.68	278,263	\$ 3.66
\$4.00 - \$4.75	137,265	8.03	\$ 4.35	69,901	\$ 4.36
\$5.00 - \$6.97	71,338	8.48	\$ 6.56	36,813	\$ 6.70
\$7.00 - \$8.50	180,267	8.69	\$ 7.32	59,465	\$ 7.35
\$9.63 - \$9.88	47,528	9.65	\$ 9.83	3,521	\$ 9.63
\$10.00 - \$14.75	171,850	9.41	\$11.90	28,686	\$10.07
\$15.81 - \$19.38	218,875	9.65	\$17.27	1,354	\$17.88
\$20.06 - \$29.31	251,675	9.52	\$23.69	16,931	\$24.98
\$32.00 - \$38.50	256,425	9.40	\$33.41	9,000	\$34.14
\$40.13 - \$45.81	544,483	9.11	\$45.62	121,352	\$45.81
\$.02 - \$45.81	2,292,424	8.81	\$21.50	706,972	\$12.27
	=====			=====	

RESTRICTED STOCK AWARDS

On July 27, 1999, the Board of Directors authorized the issuance of an aggregate of 251,000 shares of the Company's common stock to certain officers and key employees at a price per share of par value (\$.001). All of these shares were purchased by the respective officers and key employees and are subject to repurchase if the officer or key employee leaves the Company prior to July 26, 2001. Repurchase rights as to certain of the shares lapse upon the attainment of certain performance milestones or upon a change in control. Deferred compensation aggregating \$1,820,000 has been recorded for the excess of the fair market value of the stock on the date of the award over the purchase price per share and is being amortized over the restricted period.

Edgar Filing: NANOGEN INC - Form 10-K

These restricted shares have been included in the summary of stock option activity under the caption STOCK OPTION PLANS above.

ACCOUNTING FOR STOCK-BASED COMPENSATION

Adjusted pro forma information regarding net loss is required by SFAS 123 and has been determined as if the Company had accounted for its employee stock options under the fair value method of SFAS 123. The fair value for these options was estimated at the date of grant using the Black-Scholes valuation model for option pricing with the following assumptions for 2000, 1999, and 1998: a risk-free interest rate of 6.0%, 6.0%, and 5.75%, respectively, a dividend yield of zero; volatility factors of the expected market price of the Company's common stock of 70%, 70%, and 65%, respectively, and a weighted average expected life of the option of five years.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

F-15

For purposes of adjusted pro forma disclosures, the estimated fair value of the options is amortized to expense over the vesting period. The Company's adjusted pro forma information is as follows (in thousands):

	YEARS ENDED DECEMBER 31,		
	2000	1999	1998
Adjusted pro forma net loss	\$ (26,197)	\$ (26,443)	\$ (21,379)
Adjusted pro forma net loss per share	\$ (1.31)	\$ (1.46)	\$ (1.63)

The weighted average fair value of options granted during 2000, 1999 and 1998 was \$20.83, \$5.40, and \$2.68 per share, respectively.

The pro forma effect on net loss for 2000, 1999 and 1998 is not necessarily indicative of potential pro forma effects on results for future years.

EMPLOYEE STOCK PURCHASE PLAN

In November 1997, the Board of Directors approved the Employee Stock Purchase Plan (the "Purchase Plan"). A total of 300,000 shares of common stock have been authorized for issuance under the Purchase Plan. The Purchase Plan permits eligible employees of the Company to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the participant's base salary subject to certain limitations, and the purchase price will not be less than 85% of the lower of

Edgar Filing: NANOGEN INC - Form 10-K

the fair market value of the stock at either the beginning of the applicable "offering period" or the last day of the accumulation period. Each offering period is 24 months long, with new offering periods commencing every six months, and an accumulation period is six months in duration. During the years ended December 31, 2000, 1999 and 1998, 75,773, 35,216 and 26,783 shares, respectively, were issued under the Purchase Plan.

SHARES RESERVED FOR FUTURE ISSUANCE

The following shares of common stock are reserved for future issuance at December 31, 2000:

Stock options	3,058,385
Employee stock purchase plan	162,228

	3,220,613
	=====

7. STOCKHOLDER RIGHTS PLAN

In November 1998, the Company's Board of Directors adopted a Stockholder Rights Plan which provides for a dividend of one Preferred Stock Purchase Right for each share of common stock to stockholders of record on November 30, 1998. Each Right will entitle stockholders to buy one one-thousandth of a share of Series A Participating Preferred Stock of the Company at an exercise price of \$50.00, subject to antidilution adjustments. The Rights will become exercisable only if a person or group becomes the beneficial owner of 15% or more of the common stock, or commences a tender or exchange offer which would result in the offeror beneficially owning 15% or more of common stock, which is not approved by the Company's Board of Directors. The Board of Directors is entitled to redeem the Rights at \$0.01 per Right at any time prior to the public announcement of the existence of a 15% holder. If not earlier terminated or redeemed, the Rights will expire on November 17, 2008.

On December 12, 2000, the Company's Board of Directors amended the Rights Plan to allow Citigroup Inc. and its affiliates and associates to acquire the beneficial ownership of up to 25% of the outstanding common stock of the Company without triggering the ability of the Company's stockholders to exercise the rights governed by the Rights Plan. The Board of Directors required Citigroup to maintain its status as a filer on Schedule 13G with respect to its beneficial ownership of the Company's common stock to take advantage of this exception.

F-16

8. INCOME TAXES

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2000 and 1999 are shown below. A valuation allowance of \$38,970,000 has been recognized to offset the deferred tax assets as realization of such assets is uncertain.

2000	1999
-----	-----

Edgar Filing: NANOGEN INC - Form 10-K

Deferred tax assets:		
Net operating loss carryforwards	\$ 29,862	\$ 22,945
Research and development credits	5,102	3,913
Capitalized research expenses	3,558	2,931
Other, net	818	522
	-----	-----
Total deferred tax assets	39,340	30,311
Valuation allowance for deferred tax	(38,970)	(29,928)
	-----	-----
assets		
Net deferred tax assets	370	383
Deferred tax liabilities:		
Depreciation	(370)	(383)
	-----	-----
Net deferred tax assets	\$ --	\$ --
	=====	=====

At December 31, 2000, the Company has federal and California net operating loss carryforwards of approximately \$83,550,000 and \$10,773,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California tax purposes and the fifty percent limitation on California loss carryforwards. The federal tax loss carryforwards will begin expiring in 2006 unless previously utilized. The California tax loss carryforwards will continue to expire in 2001, unless previously utilized (approximately \$1,557,000 expired in 2000). The Company also has federal and California research and development tax credit carryforwards of approximately \$3,706,000 and \$2,148,000, respectively, which will begin expiring in 2007 unless previously utilized.

Under Sections 382 and 383 of the Internal Revenue Code, the annual use of the Company's net operating loss and credit carryforwards may be limited because of cumulative changes in ownership of more than 50% which occurred during 1995, 1997 and 1998. However, the Company does not believe such limitations will have a material impact upon the ultimate utilization of these carryforwards.

The net operating loss carryforwards include stock option deductions of approximately \$1,601,000. The benefit of these net operating loss carryforwards will be credited to equity when realized.

9. 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(TM) 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(TM) Molecular Biology Workstation's components.

Hitachi, Ltd. has the right to be the sole distributor of Hitachi, Ltd. produced NanoChip(TM) Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip(TM) Cartridges in Japan. The Company retains the right to distribute, directly or through others, Hitachi, Ltd. produced NanoChip(TM) Molecular Biology Workstations outside of Japan. In addition, the Company seeks to develop and manufacture the NanoChip(TM) Cartridges for distribution worldwide. Except for Hitachi, Ltd.'s exclusive distribution rights of Hitachi, Ltd. produced Workstations

Edgar Filing: NANOGEN INC - Form 10-K

in Japan, the agreement is non-exclusive and excludes certain 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 certain restrictions. Pursuant to the terms of the

F-17

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 on 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 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, the two new 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 these agreements as expenses are incurred, and totaled \$7.7 million, \$3.6 million and \$2.1 million for the years ended December 31, 2000, 1999 and 1998, respectively. Funding received in

Edgar Filing: NANOGEN INC - Form 10-K

advance of incurred expenses is recorded as deferred revenue until the expenses are incurred, and totaled \$123,000 and \$3.4 million at December 31, 2000 and 1999, respectively.

BECTON, DICKINSON AND COMPANY

The Company entered into a Master Agreement with Becton, Dickinson and Company ("Becton Dickinson") in October 1997 to develop and commercialize products in the field of IN VITRO nucleic acid-based diagnostic and monitoring technologies in the field of infectious diseases. Pursuant to this Master Agreement, Becton Dickinson and the Company agreed to form The Nanogen/Becton Dickinson Partnership (the "Partnership"). Pursuant to a General Partnership Agreement, Becton Dickinson and the Company contributed to the Partnership their respective rights under a Collaborative Research and Development Agreement established in May 1997, certain Intellectual Property Licenses and cash of approximately \$8.6 million through December 31, 1999, of which approximately \$7.0 million was paid by Becton Dickinson and approximately \$1.6 million was paid by the Company. The amounts paid or due to the Partnership by the Company have been recorded as the Company 's share of the joint venture's loss in the period paid or accrued, and totaled \$996,000 and \$610,000 for the years ended December 31, 1999 and 1998, respectively. Concurrent with the execution of the joint venture agreement in 1997, the Company entered into a worldwide, royalty-bearing, nonexclusive license agreement with Becton Dickinson, relating to Becton Dickinson's proprietary SDA technology for use by the Company outside the Partnership in the fields of IN VITRO human genetic testing and IN VITRO cancer diagnostics.

In September 2000, the Company and Becton Dickinson modified the joint venture to permit the partners the opportunity to commercialize certain of the Partnership's technology and allow them to collaborate with third parties to develop and commercialize certain products in the field of infectious diseases. Pursuant to amendments to the Master Agreement, the General Partnership Agreement and the Collaborative Research and Development and

F-18

License Agreement, the Partnership exclusively licensed other Partnership technology developed up to that date to Becton Dickinson and Becton Dickinson exclusively sublicensed the Partnership technology to the Company to commercialize products in the field of infectious diseases. Becton Dickinson also agreed to non-exclusively license SDA technology to the Company for its use and for sublicensing purposes in the field of infectious diseases. Becton Dickinson also expanded the field of use for the Company's SDA license outside of the Partnership to not only include IN VITRO human genetic testing and IN VITRO cancer diagnostics, but also IN VITRO testing of environmental, agricultural and veterinary samples. Pursuant to the amendments, Becton Dickinson paid the Company \$300,000. The Company does not expect to receive any additional funding from Becton Dickinson.

Revenues are recognized under the agreements as expenses are incurred, and totaled \$300,000, \$1.6 million and \$2.5 million for the years ended December 31, 2000, 1999 and 1998, respectively.

ELAN CORPORATION, PLC

In December 1997, the Company entered into an agreement with Elan Corporation, plc ("Elan") for a non-exclusive research and development agreement for the development of genomics and gene expression research tools. Pursuant to the agreement, Elan purchased Company common stock worth an aggregate of \$5.0 million, at the initial public offering price, in the private placement in April

Edgar Filing: NANOGEN INC - Form 10-K

1998. Nanogen and Elan have not agreed upon specific program objectives with respect to the nonexclusive research and development program. The Company does not expect to receive any additional funding from Elan.

Revenue is recognized under the agreement as expenses are incurred, and totaled \$568,000 and \$929,000 for the years ended December 31, 1999 and 1998, respectively. No revenue was recognized under the agreement during the year ended December 31, 2000.

10. CONTRACT AND GRANT REVENUE

In August 2000, the Company was awarded a contract by the Space and Naval Warfare Systems Center San Diego ("SSC San Diego") for the Defense Advanced Research Projects Agency in an amount totaling approximately \$1.6 million over a two year period. The goal of the contract is to develop and refine electronically driven sample preparation protocols on specifically designed microelectronic chips. In October 2000, the Company entered into a cooperative agreement with the U.S. Army Medical Research Acquisition Activity ("USAMRAA") in an amount totaling approximately \$1.1 million over a two year period. The objective of the USAMRAA agreement is to develop an arrayable electronic system for the identification of biological warfare or infectious disease agents. Revenue is recognized under these agreements as expenses are incurred and totaled \$98,000 for the SSC San Diego contract and \$6,000 for the USAMRAA agreement for the year ended December 31, 2000.

11. QUARTERLY FINANCIAL DATA (UNAUDITED)

Summarized quarterly financial data for fiscal 2000 and 1999 are as follows (in thousands, except per share data):

	1ST QUARTER -----	2ND QUARTER -----	3RD QUARTER -----	4TH QUARTER -----
Fiscal 2000				
Revenues	\$ 2,312	\$ 2,340	\$ 3,546	\$ 3,034
Operating expenses (2)	6,524	7,859	9,908	10,480
Loss from operations	4,212	5,519	6,362	7,446
Net loss	3,678	4,113	4,579	5,912
Net loss per share-basic and diluted (1)	\$ (.20)	\$ (.20)	\$ (.22)	\$ (.29)
Fiscal 1999				
Revenues	\$ 1,930	\$ 2,205	\$ 1,946	\$ 2,038
Operating expenses (2)	8,697	8,936	7,567	9,181
Loss from operations	6,767	6,731	5,621	7,143
Net loss	6,859	6,533	5,219	6,588
Net loss per share-basic and diluted (1)	\$ (.38)	\$ (.36)	\$ (.29)	\$ (.36)

 (1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share will not necessarily equal the total for the year.

(2) Since the majority of the Company's revenues are derived from sponsored research and contracts and grants and the related costs are reported as research and development expense, the Company chose to disclose operating

Edgar Filing: NANOGEN INC - Form 10-K

expenses rather than cost of sales as required.

F-19

NANOGEN, INC. EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
10.38(A)	Secured Promissory Note between Registrant and Kieran T. Gallahue, dated April 23, 1998.
10.46(A)	Agreement between Registrant and Vera P. Pardee, dated as of November 1, 2000
10.47(A)	Agreement between Registrant and James P. O'Connell, dated as of October 4, 2000
10.48(A)	Agreement between Registrant and Harry J. Leonhardt, dated as of December 1, 2000
10.49(A)	First Amendment to Agreement between Registrant and Clare "Bud" Bromley, dated as of July 28, 2000
23.1	Consent of Ernst & Young LLP, independent auditors.

(A) Indicates management compensatory plan or arrangement.