NANOGEN INC
Form 10-K
April 01, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal period ended December 31, 2001

OR

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

For the transition period from _____ to _____

Commission File Number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

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

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 ý No o

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 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. o

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 25, 2002, as reported on the Nasdaq National Market was approximately $70,924,905. Shares of Common Stock held by each executive officer and director and by each person (including shares beneficially owned by Citigroup, Inc.) who own 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 21,805,368 as of March 25, 2002.

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PART I

Item 1. Business

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," "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 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 that speak only as of the date hereof. We disclaim any intent or obligation to update these forward-looking statements.

Overview

It is our goal to become a leading provider of molecular diagnostic tests. We integrate advanced microelectronics and molecular biology into a core technology platform with potentially broad and diverse commercial applications. Our primary areas of focus have been in genomics and biomedical research, medical diagnostics, forensics and drug discovery. The first application we have developed, the NanoChip® System, is an integrated bioassay system consisting of the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge. The NanoChip® Workstation is comprised of two automated instruments and the NanoChip® Cartridge, a consumable cartridge, which incorporates a proprietary microchip. The NanoChip® System provides a flexible tool for the rapid identification and precision analysis of biological test samples containing charged molecules. We launched the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge, our first commercial products, during the second quarter of the year 2000, beginning our transformation from a research and development company to a customer-oriented company. In 2001, we accelerated this shift to a commercial medical diagnostics company with the addition of Dr. Randy White as Chief Executive Officer to our Company. Dr. White came to us from one of the top five clinical laboratories in the United States, American Medical Laboratories. He has over 28 years of clinical laboratory experience. We believe he has relevant experience in clinical assay development and clinical markets to provide our Company with the leadership needed to make products available to the molecular diagnostics marketplace.

The NanoChip® Molecular Biology Workstation had initially 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. In 2001, we expanded our targeted customers to include more production-oriented customers such as high complexity Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified clinical reference laboratories.

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. 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 and medical diagnostics.

During the year 2001, we accomplished the following:

Validated the Company's first five DNA-based research protocols for use on the NanoChip® Molecular Biology Workstation;

Increased the installed base of our NanoChip® Molecular Biology Workstation to sixty-one (61) instruments;

Converted two of our existing Development Site customers into sales transactions;

Expanded our intellectual property position for our core technology by adding twenty U.S. patents and seven foreign patents;

Settled our outstanding litigation with Motorola, Genometrix and MIT;

Formed a company with Aventis, Nanogen Recognomics GmbH, to research and develop new products and applications for the NanoChip® System; and

Received an additional government grant that provides for a total of $1.5 million of continued funding for the development of our core technologies for use in biowarfare applications.

Year 2001 Accomplishments

First Five DNA-based Research Protocols

In the second half of 2001, our introduction of five DNA-based research protocols moved us closer towards entry into the molecular diagnostic marketplace. Four of the protocols internally validated are associated with cardiovascular disease and the pathology of thrombosis. They include Factor V Leiden, Factor II (Prothrombin), a multiplexed protocol (i.e. a compilation of complete detailed steps and procedures to correctly genotype a single nucleotide polymorphism from a sample of purified genomic DNA), for both of these mutations at a single location on our microarray, and MTHFR. The fifth protocol is for a mutation related to Hereditary Hemochromotosis, a disorder that causes excess iron to be stored in cells of the liver, heart, pancreas and other organs. We believe that high complexity Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified laboratories that adopt our technology may further validate these protocols for internal use under "home-brew" formats. Eventually We plan to develop analytic specific reagents ("ASRs") for use by such high complexity CLIA certified labs that can generate revenue without the Company having to file for Food and Drug Administration ("FDA") approval.

Increased the Installed Base of the NanoChip® Molecular Biology Workstation

We ended 2001 with an installed base of sixty-one instruments, thirty-eight of which were placed in 2001. The thirty-eight shipments include fifteen title transfer transactions representing sales, thirteen of which were recorded as product revenue and two of which were recorded as sponsored research revenue as they were funded by corporate alliances. An additional two placements occurred for which revenue was deferred due to the structure of the transactions. The remaining placements were strategic placements made pursuant to development site agreements under non-title transfer transactions. Non-title transfer transactions may include development site agreements, leases and reagent rentals. Title transfer transactions normally result in recording of full instrument revenue at the time of the transaction, while non-title transfer transactions may spread instrument revenue associated with the transaction, if any, over the life of the instrument or the agreement.

As of December 31, 2001, our placements were with customers and partners in ten countries, including the research and high complexity CLIA certified laboratories of hospitals, universities, government organizations and pharmaceutical companies.

Two Development Sites converted into sales transactions

We believe that the conversion of two of our Development Sites into sales transactions validates our previously stated belief that Development Site Agreements may lead to potential sales of our NanoChip® System. We also believe these Development Site Agreements may eventually assist in the

development of customer-generated content in the form of assays, intellectual property, know-how and other developments to be used on the NanoChip® System for clinical research and diagnostic protocol development. At year-end 2001, we have been informed that our customers evaluated approximately forty-seven assays on our platform, validating this belief. We have certain potential intellectual property rights to assays developed by our customers. We believe customer developed assays help demonstrate the value of having an open platform. We believe that we may benefit from increased consumables usage as a result of the assays being evaluated by our customers.

Expanded our intellectual property portfolio

During 2001, we expanded our intellectual property portfolio adding twenty additional U.S. patents and seven additional foreign patents. As of December 31, 2001, we had a total of forty U.S. patents and twenty foreign patents.

Settled our litigation with Motorola, Genometrix and the Massachusetts Institute of Technology

We resolved our litigation with Motorola, Genometrix and the Massachusetts Institute of Technology during 2001. As part of the settlement, we obtained a license to and freedom to operate under certain patent claims relating to electronic hybridization. We obtained this license without providing Motorola access to our own technology, a key component of our litigation strategy. We believe that we remain the only current provider of commercially available electronic addressing and hybridization products.

Formed Nanogen Recognomics, a company with Aventis Research and Technologies, an affiliate of Hoechst AG ("Aventis")

In July 2001 we formed a new company, Nanogen Recognomics GmbH, with Aventis. We believe Nanogen Recognomics may allow us to benefit from the development of new technological advances for our platform technology while still focusing on our primary near-term goal of entry into molecular diagnostics. Aventis has been a collaborator with us since December 1997. Nanogen Recognomics adds intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to our Company, and we believe this expertise will bear fruit in our future development efforts.

Received additional government grant

In October 2001, we were awarded a three-year, $1.5 million grant from the U.S. Army to develop a miniaturized electronic device for isolating and detecting biological warfare and infectious disease agents from human blood samples. The U.S. Army Medical Research Institute of Infectious Disease at Fort Detrick, Maryland will supervise the research. This is the second 'Dual Use Science and Technology' grant awarded to Nanogen by the US Army Medical Research Acquisition Activity, the first one coming in October 5, 2000. We believe that the actions we are taking to develop our product platform for use in molecular diagnostics are directly portable and complementary to what we are doing in the biowarfare arena for the U.S. Army. As a result, we believe that our government and commercial programs complement one another. We also believe that certain technology developed from the government programs are directly portable over to what we are doing to enter into the molecular diagnostic market, the main focus of Nanogen.

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 and in particular in the molecular diagnostics market, including:

Low Degree of Accuracy. A high degree of accuracy is essential to detect and quantify genetic variations, which may involve the analysis of thousands of genetic variations per individual. Some conventional methods can result in one or more tests in ten being inaccurate. These inaccuracies are magnified in tests for multiple variations. For example, in a test panel involving six genetic variations, the overall panel accuracy for a technology having a 95% accuracy per result would be only 74%. Accuracy is critical in molecular diagnostics.

Difficulty of Use. Many of the conventional analysis methods involve multiple technical steps requiring human intervention, which make the analysis difficult to perform and difficult to fully automate.

Lack of Specificity. Many of the conventional analysis methods use a passive array in which what you do to one site on the array, you do to all sites. This results in a lack of flexibility for the customer in using these technologies as they cannot mix different assays on a single array or may not fully use every site on the array.

Lack of Menu. Many of the conventional methods of analysis cannot be done on multiple instrument platforms and many require its own instrumentation, requiring customers to purchase different instruments for each analysis performed.

Limited Clinical Viability. Because of the low degree of accuracy and difficulties associated with product development and use, conventional methods have not been shown to be broadly applicable to clinical settings.

The Nanogen Solution

We believe that our initial product, the NanoChip® Molecular Biology Workstation, or the NanoChip® 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® System as the research and high complexity CLIA certified laboratory standard for molecular biologists, and eventually the industry standard for accurate, targeted genomics in both laboratory and non-laboratory settings. The NanoChip® System provides the following advantages:

Accuracy

Accuracy is critical in laboratory analysis. The NanoChip® Molecular Biology Workstation, with its precision electronic addressing and high degree of stringency, equaled or exceeded the accuracy of current "gold standard" techniques in the SNP studies conducted at multiple locations to date.

Flexibility

Nanogen's technology is highly flexible. The NanoChip® System is centered around an electronics microarray containing 100 individually controllable and programmable electronic test sites. Both of the major bioassay formats are conveniently handled by the NanoChip® 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. Additionally, our platform will allow multiple Loaders to be controlled by one Reader.

Versatility

Our NanoChip® System is designed to analyze virtually any charged molecule. It can analyze DNA for 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. We have chosen to focus on the most promising market for our platform first, and then plan to branch out into additional markets if we are successful in the molecular diagnostics market.

Fast Array Design

We believe that experimental design of arrays on the NanoChip® Cartridge is relatively straightforward. Our customers can program NanoChip® arrays in their own laboratories, allowing for faster turnaround times and higher levels of confidentiality. Additionally, we have created and validated protocols for research use for customers that do not wish to develop their own protocols.

Ease of use

We believe that assays are easy to perform on our system. Our fully automated Loader allows the simultaneous programming of up to four NanoChip® arrays. A loaded cartridge is inserted and then analyzed on the Nanogen Reader. The NanoChip® 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.

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 believe that we have designed the NanoChip® System to be a cost-effective solution for most molecular biology assays. Our system's custom features allow users to employ their own reagents in designing arrays for specific purposes. We also plan to begin selling Analytic Specific Reagents ("ASR's") in 2002 so that customers may purchase reagents from our Company. Since the NanoChip® System consumes small quantities of reagents, generally at low concentration, bioassay reagent costs (such as DNA) per result may be 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 consumables, independently and in conjunction with highly regarded corporate and government partners, to facilitate breakthrough genetic analyses. Our NanoChip® System is designed to eventually 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 with a plan to migrate into the molecular diagnostic market. The capabilities that are incorporated into this system are the core technology platform that will serve as the basis for expanding the menu of protocols available on our platform and eventually 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. Our initial strategy to drive consumable revenues for our system is three-fold. First, increase the installed base of the instrument second, increase the menu of protocols that may be performed on our platform, and third broaden our product line to include consumable reagents such as ASR's and FDA approved kits.

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 accurate and targeted technology. We seek to position the NanoChip® System as such a technology. We intend to further 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

We intend to use substantially the same core hardware and consumable cartridge platform across a spectrum of applications (menu of protocols.) 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 per unit costs and improve margins over time. For our initial commercial markets, the biomedical research market and high complexity CLIA certified lab market, we do not anticipate the need for Food and Drug Administration ("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 the sale of consumables such as cartridges, ASR's and eventually kits. We believe that widespread market penetration of our instruments and the open architecture of the system will promote sustained demand for our consumables.

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 other 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 approval.

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® 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 platform may be applicable to a number of other types of 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 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® 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® 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 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 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, we revised our relationship with Becton Dickinson. 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. We believe that SDA may potentially provide our customers with both operational benefits as well cost benefits due to the high cost of the most common amplification method.

The NanoChip® System's Components

The NanoChip® 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® 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 (the "NanoChip® Electronic Microarray") utilizes advances in the semiconductor industry and is designed and constructed using microlithography and fabrication techniques. The NanoChip® Electronic Microarray 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 current production of consumable cartridges employs 100 different test sites on a single NanoChip® Electronic Microarray's.

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 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. This format 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® 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 referred to as, 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® Analysis Process

Cartridge

An active microelectronic chip is mounted within a plastic molded cartridge. The bar-coded cartridge is delivered in a ready-to-address format with no genetic sequences pre-attached at this time.

Electronic addressing

Users design and create their own genetic arrays on the microelectronic chip with our 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 may add 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.

Revenue Producing Transactions

We currently have two main types of revenue generating programs: title transfer transactions and non-title transfer transactions. Under title transfer transactions, we are involved in direct sales of our NanoChip® System to customers or distributors, leasing transactions either utilizing an outside leasing company or conducting the transaction internally whereby our customers can lease the system over a number of years and make monthly payments to either a leasing company or to us, and reagent rental transactions whereby the customers pay to either a financing company or directly to us, higher prices for our consumable cartridges over a number of years to cover the cost of the system. We may also generate revenue from such sales through the sale of consumable cartridges, extended warranties, certain Field Application Service assistance and eventually through the sale of ASR's and kit-based assay products. We require customers to assign system improvements created by them using the NanoChip® System to us.

Our main non-title transfer transactions involve our Development Site Program. Pursuant to the program, We permit our customers to utilize the NanoChip® Workstation for a limited period to evaluate their SNP-based assays on our system. Under this program, we may provide a limited number of NanoChip® Cartridges and certain Field Application Services to assist the customer in optimizing their assays on our system and thereafter require additional cartridges and service to be purchased from us. We normally require that all improvements to the NanoChip® technology be assigned to us and that certain intellectual property rights to such assays that are, owned by or licensed to the customer, be made available to us for the purposes of eventually commercializing such assays. We also seek to assist our Development Site customers to publish papers on the progress of the NanoChip® Workstation and to eventually convert such Development Sites into sales. In 2001, we assisted in the drafting of twelve papers and converted two Development Sites to sales.

Products and Applications Under Development

Genomics and biomedical research applications

We began commercialization of the NanoChip® 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 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 Frost and Sullivan, published in February 2002, estimates that the molecular diagnostics market for U.S. clinical labs will grow from $1.9 billion in 2002 to $3.1 billion by 2005.

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 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 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 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. Initially, to stimulate demand for the NanoChip® Workstation and for NanoChip® Cartridges, we have and will continue to internally validate a number of different protocols for use on our NanoChip® Workstation. Protocols are instructions that describe how research and high complexity CLIA certified laboratories may run certain SNP based assays on our system and such protocols are

provided by us to our non-ASR customers on a request basis free of charge. We believe CLIA certified laboratories that adopt our technology may further validate these protocols in their own laboratories for use in a "home-brew" format. Under this model, our potential consumable revenues would result from the sale of NanoChip® Cartridges.

Next we expect to launch ASR's once we are Quality System Regulations ("QSR") compliant. ASR's are the specific reagents that permit our research and high complexity CLIA certified laboratory customers to run certain SNP assays on our system and on other systems and will be sold by us either directly or through our distributors. Under the ASR model, we expect to sell not only NanoChip® Cartridges, but also ASR sets that can be used to perform DNA- based tests capturing a larger percentage of the potential revenue from each analysis performed. We expect to further increase the potential revenue from each analysis performed with the launch of the SDA method of amplification. We also believe that with the launch of ASR's we will then be in a position to begin data collection on a protocol-by-protocol basis for a potential FDA submission for certain kit-based assays. Such kit-based assays normally include a protocol, ASR, other reagents and performance claims and can be used by a wider variety of customers to provide clinicians with results that they can provide to their patients.

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. Pharmacogenomics is the science of individualizing therapy based on genetic differences among patients.

Our NanoChip® 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, in conjunction with our manufacturing development partner Hitachi, to develop a more compact and inexpensive version of our NanoChip® 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. In the meantime, a patient requiring immediate therapy, must often 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 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, we are focused on developing and validating a protocol for cystic fibrosis, because it is the first molecular based test recommended for nationwide screening of healthy individuals. Cystic fibrosis is an autosomal recessive genetic disorder. To express the disease, a child must inherit two copies of the defective gene, one from each parent. Many people carry a single cystic fibrosis gene, and they do not experience any

significant health problems as a result. In the general population, approximately 1 in 31 Americans carries the gene. This is the reason the American College of Obstetrics and Gynecology ("ACOG") announced on July 17th of 2001 that the Standard of Medical Care includes screening women contemplating pregnancy for cystic fibrosis. To meet the standard of medical care, a physician must at least offer screening to each woman contemplating pregnancy. However, the disease can only occur in babies with two carrier parents. If initial screening of the prospective mother is positive for the cystic fribrosis gene, then further testing of the prospective father is warranted. When both parents are carriers, they have a 25 percent chance with every pregnancy of passing two copies of the defective gene to their child. The current recommendation from ACOG is for a 25-mutation screen. We are working towards validating a cystic fibrosis protocol for the ACOG recommended 25-mutations in 2002. We believe that the ACOG recommendations may drive a significant increase in genetic testing for cystic fibrosis. 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 that 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 pre-clinical drug discovery process takes an average of six and one-half years. Consequently, we believe there is a significant demand for improved tools that 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. Our electronic, fluorescent assays are free of antibodies and have the potential of improving the cost and quality of the screening process.

Forensic applications

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. Currently, we have four overseas Development Sites working on forensic applications. We believe our NanoChip® System may be useful in human identity testing.

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. In July 2001, we formed a company with Aventis named Nanogen Recognomics GmbH. 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 are directly involved with marketing our first product line to the biomedical research and genomics market. Additionally, we may distribute products in Japan and select Asian markets through the distribution arm of Hitachi, Nissei Sangyo Co., Ltd.

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 immunodiagnostics 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 term of this original collaboration agreement expired at the end of 2000. In September 1999 we entered into an additional collaboration agreement with Aventis that involved two new research and development programs focused on gene expression arrays and on an electronics-based high throughput screening system. We retained 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. The September 1999 agreement expired at the end of 2001. We do not expect to receive additional funding for these projects.

In July 2001, we formed a company with Aventis named Nanogen Recognomics GmbH. This company may allow us to benefit from the development of new technological advances for our platform while still focusing on our near-term goal of entry into molecular diagnostics. Nanogen Recognomics adds intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to

Nanogen.

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® Molecular Biology Workstation in specified research markets. Hitachi, Ltd.'s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip® Molecular Biology Workstation's components.

Under this agreement, Hitachi, Ltd. has the right to be the sole distributor of Hitachi, Ltd. produced NanoChip® Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip® Cartridges in Japan. We retained the right to distribute, directly or through others, Hitachi, Ltd. produced NanoChip® Molecular Biology Workstations outside of Japan. In addition, we currently develop and manufacture the NanoChip® Cartridges for distribution worldwide. 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. The agreement expands on the existing 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.

Becton Dickinson

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

In September 2000, both companies 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 us to commercialize products in the field of infectious diseases. Becton Dickinson also agreed to non-exclusively license SDA technology to us 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.

Research and Product Development

We seek to further develop the NanoChip® System, integrating new features and broadening the applications of the currently marketed system, including enhancing chip design and capabilities to simplify instrument design. Our scientists will investigate new opportunities and develop and validate new protocols and analytic specific reagents and other products for use on the NanoChip® System, 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® System may be designed to provide analysis of other charged molecules and antigen-antibody, enzyme substrate, cell-receptor, and cell-separation techniques. The NanoChip® System eventually may also become a portable lab on a chip for use in the field, away from the laboratory bench.

We 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 through the government grant system. In 2001, our scientists were awarded a three-year, $1.5 million grant from the U.S. Army to continue development of a miniaturized electronic device for isolating and detecting

biological warfare and infectious disease agents from human blood samples. The U.S. Army Medical Research Institute of Infectious Disease at Fort Detrick, Maryland will supervise the research. The development of these new technologies represent important elements in our long-term platform development strategy.

Proprietary Technology and Patents

As of December 31, 2001, we have forty issued U.S. patents, twenty 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 have and may enter into other license arrangements to obtain rights to third-party intellectual property where appropriate.

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 commercially 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 European patents and patent applications owned by Isis Innovations Ltd. (E.M. Southern). We have opposed one allowed European Patent which has broad claims to array technology for analyzing a predetermined polynucleotide sequence. Isis Innovation's position with respect to the opposed patent is that the claims relate to what it terms the "diagnostic mode." Those claims have now been narrowed before the Opposition Division to the point that, if these claims remain final before the European Patent Office, we believe they would not be infringed by our technology. In the Oral Proceedings before the Opposition Division on November 13, 14, and 15, 2001, the Division determined that the claims' language must be limited to arrays with "smooth, impermeable' surfaces. If the decision of the Opposition Division is successfully appealed by Isis Innovations and the original claims are reinstated, or if an application relating to arrays issued in another country with claims as broad as the original European patent, we would be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

In addition to the patent litigation 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.

Manufacturing

In January 2000, we formed a collaboration with Hitachi for the manufacture of our NanoChip® 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® 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® Molecular Biology Workstation during the second quarter of 2000. We have built a commercial structure that 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 States, Canada, Mexico and several European countries. 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 additional 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 is 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. The molecular diagnostic test market, in particular, is highly competitive, and we expect the intensity of competition to increase. We anticipate that our competitors in all the areas we expect to compete 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 both in the United States and abroad.

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 and the high complexity CLIA certified laboratory market, we do not anticipate the need for FDA or other regulatory approval for our NanoChip® System and certain ASR products prior to marketing. 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 will not be able to commence marketing or commercial sales in the U.S. of our 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 new devices 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 legally marketed devices). Before a 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 labeled for research, genomics, drug discovery and industrial applications will not require regulatory approvals or clearance. Some *in vitro* 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 three to six months or more from submission to obtain 510(k) premarket clearance, but the process may take longer if FDA requests more data or research.

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 non significant risk *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. We believe our diagnostics are non significant risk devices because 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 and due diligence controls must be established by the company 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.

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, as well as conduct a preapproval inspection of the manufacturing facility. If we are not in compliance with Quality System Regulations (QSRs) applicable to manufacturing, we will not receive PMA approval. 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.

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 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 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.

There can be no assurance that new legislation will not impose additional costs or lengthen review times for our products.

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, 2001, we had 194 full-time employees, of whom 42 hold Ph.D. degrees and 24 hold other advanced degrees. Approximately 92 are involved in research and development, 36 in operations, manufacturing and quality assurance, 37 in sales and marketing, and 29 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 are covered by a collective bargaining agreement.

Factors That May Affect Results

Our products may not be successfully developed or commercialized, which would harm us and force us to curtail or cease operations.

We are at an early stage of development. We currently have only two products for sale, our NanoChip® Molecular Biology Workstation and our NanoChip® Cartridge. All of our other potential products, such as our Analytic Specific Reagents ("ASR's"), are under development. Our NanoChip® System or our other products may not be successfully developed or commercialized on a timely basis, or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of our new products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

We introduced our first two products into the marketplace in 2000. For the years ending December 31, 2001 and 2000, we recognized sales revenue from the sale of thirteen and eight NanoChip® Systems, respectively. In addition, we sold two NanoChip® Systems in 2001 and two systems in 2000 under sponsored research programs. We also place instruments at various customer sites under Development Site Agreements whereby title of the NanoChip® Molecular Biology Workstation does not pass to the customer and therefore no revenue is recognized. As of December 31, 2001, we had a total installed base of 61 instruments.

Our success will depend upon our ability to overcome significant technological challenges and successfully introduce our products into the marketplace. A number of applications envisioned by us

will require significant enhancements to our basic technology platform. There can be no assurance that we can successfully develop such enhancements.

Lack of market acceptance of our technology would harm us.

We may not be able to develop commercially viable products. Even if we develop a product it may not be accepted in the marketplace. If we are unable to achieve market acceptance, we will not be able to generate sufficient product revenue to become profitable. We may also be forced to carry greater inventories of our products for longer periods than we may have anticipated. If we are unable to sell our inventory of our products in a timely fashion and at anticipated price levels, we may not become profitable. In addition, we may have to take accounting charges and reduce the value of our product inventory to its net realizable value. Market acceptance will depend on many factors, including our ability to:

convince prospective strategic partners and customers that our technology is an attractive alternative to other technologies;

manufacture products in sufficient quantities with acceptable quality and at an acceptable cost; and

sell, place and service sufficient quantities of our products.

In addition, our technology platform could be harmed by limited funding available for product and technology acquisitions by our customers, internal obstacles to customer approvals of purchases of our products and market conditions in general.

Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to find collaborators in the future, we may not be able to develop these products.

Our strategy for the research, development and commercialization of some of our products requires us to enter into contractual arrangements with corporate collaborators, joint venture partners, licensors, licensees and others. Our success depends in part upon the performance by these collaboration partners and potential collaboration partners of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect or we may not derive any revenue or other benefits from these arrangements.

We have collaborative agreements with a developer and manufacturer of instrumentation products and we formed a new company with the research and development subsidiary of a pharmaceutical company. We do not know whether these collaborations will successfully develop and market any products under our respective agreements. Moreover, some of our collaborators are also researching competing technologies targeted by our collaborative programs. We may be unsuccessful in entering into other collaborative arrangements to develop and commercialize our products. In addition, disputes may arise over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

We currently have agreements with Hitachi that contemplate the commercialization of products resulting from the agreements between the parties. In addition, we have a manufacturing and distribution agreement with Hitachi. In June 2001 we formed a company, Nanogen Recognomics GmbH, with Aventis Research and Technologies & Co. KG, in which we own 60% of the stock of Nanogen Recognomics and Aventis R&T owns the remaining 40%. Nanogen Recognomics seeks to combine our NanoChip® technology and Aventis R & T's intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to develop new products and applications for the NanoChip® System. These collaborations may not be successful.

We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

We began selling our first two products in the second quarter of 2000, but we did not sell significant quantities of our first products during fiscal 2000 or during the year ended December 31, 2001. From our inception to December 31, 2001, we have incurred cumulative net losses totaling approximately $123.4 million. Moreover, our negative cash flow and losses from operations will continue to increase for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, some of which could be significant. The amount and timing of product revenue recognition may depend on whether potential customers for the NanoChip® System choose to enter into title transfer or non-title transfer transactions.

To develop and sell our products successfully, we will need to increase our spending levels in research and development, as well as in selling, marketing and administration. We will have to incur these increased spending levels before knowing whether our products can be sold successfully.

We may need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.

We may need to raise more money to continue the research and development necessary to bring our products to market and to establish manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. If we cannot raise more money we will have to reduce our capital expenditures, scale back our development of new products, reduce our workforce and license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we will need will depend on many factors, including among others:

- the progress of our research and development programs;
- the commercial arrangements we may establish;
- the time and costs involved in:
  - scaling up our manufacturing capabilities;
  - meeting regulatory requirements, including meeting necessary Quality System Regulations or QSR regulations, obtaining necessary regulatory clearances or approvals;
  - filing, prosecuting, defending and enforcing patent claims and litigation; and
- the scope and results of our future preclinical studies and clinical trials, if any.

Additional capital may not be available on terms acceptable to us, or at all. Any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

Competing technologies may adversely affect us.

We expect to encounter intense competition from a number of companies that offer products in our targeted application areas. We anticipate that our competitors in these areas will include:

- health care and other companies that manufacture laboratory-based tests and analyzers;
- diagnostic and pharmaceutical companies;
- companies developing drug discovery technologies; and
- companies developing molecular diagnostic tests.

If we are successful in developing products in these areas, we will face competition from established companies and numerous development-stage companies that continually enter these markets. In many instances, our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Moreover, these competitors may offer broader product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Our competitors may succeed in developing, obtaining FDA approval or marketing technologies or products that are more effective or commercially attractive than our potential products, or that render our technologies and potential products obsolete.

As these companies develop their technologies, they may develop proprietary positions that may prevent us from successfully commercializing products.

Also, we may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future.

The uncertainty of patent and proprietary technology protection may adversely affect us.

Our success will depend in part on obtaining and maintaining meaningful patent protection on our inventions, technologies and discoveries. Our ability to compete effectively will depend on our ability to develop and maintain proprietary aspects of our technology, and to operate without infringing the proprietary rights of others, or to obtain rights to third-party proprietary rights, if necessary. Our pending patent applications may not result in the issuance of patents. Our patent applications may not have priority over others' applications, and even if issued, our patents may not offer protection against competitors with similar technologies. Any patents issued to us may be challenged, invalidated or circumvented and the rights created thereunder may not afford us a competitive advantage.

We also rely upon trade secrets, technical know-how and continuing inventions to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology and we may not be able to meaningfully protect our trade secrets, or be capable of protecting our rights to our trade secrets. We seek to protect our technology and patents, in part, by confidentiality agreements with our employees and contractors. Our employees may breach their existing Proprietary Information, Inventions, and Dispute Resolution Agreements and these agreements may not protect our intellectual property. This could have a material adverse effect on us.

Our products could infringe on the intellectual property rights of others, which may subject us to future litigation and cause us to be unable to license technology from third parties.

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in an action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

There are many U.S. and foreign patents and patent applications held by third parties in our areas of interest, and we believe that, besides our current litigation with CombiMatrix and Dr. Montgomery described below, there may be significant other litigation in the industry regarding patent and other intellectual property rights. Additional litigation could result in substantial costs and the diversion of management's efforts regardless of the result of the litigation. Additionally, the defense and prosecution of interference proceedings before the U.S. Patent and Trademark Office, or USPTO, and related administrative proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may in the future become subject to USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.

We are aware of U.S. and European patents and patent applications owned by Isis Innovations Ltd. (E.M. Southern). We have opposed one allowed European Patent which has broad claims to array technology for analyzing a predetermined polynucleotide sequence. Isis Innovation's position with respect to the opposed patent is that the claims relate to what it terms the "diagnostic mode." Those claims have now been

narrowed before the Opposition Division to the point that, if these claims remain final before the European Patent Office, we believe they would not be infringed by our technology. In the Oral Proceedings before the Opposition Division on November 13, 14, and 15, 2001, the Division determined that the claims' language must be limited to arrays with "smooth, impermeable' surfaces. If the decision of the Opposition Division is successfully appealed by Isis Innovations and the original claims are reinstated, or if an application relating to arrays issued in another country with claims as broad as the original European patent, we would be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

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

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

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

In December 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss Nanogen's complaint. In January 2001, the motion was denied as to all claims except a claim for conversion, as to which the motion was granted without prejudice. We elected not to amend our complaint as to the

conversion claim. On March 9, 2001, CombiMatrix and Dr. Montgomery answered Nanogen's complaint, asserted various affirmative defenses and filed a counterclaim for breach of contract against Nanogen for unspecified damages allegedly arising from the filing of the complaint at a time when CombiMatrix had announced its intent to make an initial public offering of its shares. The counterclaim asserts that Nanogen, by filing its complaint, breached a settlement agreement entered into between Nanogen and Dr. Montgomery in 1995. On May 14, 2001, Nanogen filed a motion to dismiss CombiMatrix's counterclaim, which was denied on July 27, 2001. Discovery is currently ongoing.

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

The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining required approvals for the commercialization of our products.

We anticipate that the manufacturing, labeling, distribution and marketing of any potential diagnostic products we may develop will be subject to regulation in the U.S. and other countries. These regulations could subject us to several problems such as:

failure to obtain necessary regulatory approvals or clearances for our products on a timely basis, or at all;

delays in receipt of or failure to receive approvals or clearances;

the loss of previously received approvals or clearances;

limitations on intended uses imposed as a condition of approvals or clearances; or

failure to comply with existing or future regulatory requirements.

In the U.S., the Food and Drug Administration, or FDA, regulates as medical devices most test systems, kits, and reagents that are marketed for human *in vitro* diagnostic use. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, safety, effectiveness, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of these products until we receive clearance or approval from the FDA, which can be a lengthy, expensive and uncertain process. We have not applied for FDA or other regulatory approvals with respect to any of our products under development. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of proposed products. Regulatory clearance or approval of any proposed products may not be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Noncompliance with applicable FDA requirements can result in:

criminal prosecution, civil penalties, other administrative sanctions, or judicially imposed sanctions such as injunctions;

recall or seizure of products;

total or partial suspension of production; and

failure of the government to grant premarket clearance or premarket approval for devices or withdrawal of marketing clearances or approvals once granted.

The FDA also has the authority to request the recall, repair, replacement or refund of the cost of any regulated device that may eventually be manufactured or distributed by us. Any devices manufactured or distributed by us pursuant to FDA clearance or approvals are subject to thorough and

continuing regulation by the FDA and certain state agencies, including the California Department of Health Services.

We depend on suppliers for materials that could impair our ability to manufacture our products.

Outside vendors provide key components and raw materials used by us and Hitachi in the manufacture of our products. Although we believe that alternative sources for these components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our and Hitachi's ability to manufacture our products until a new source of supply is identified and qualified. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or Hitachi or incompatible with our or Hitachi's manufacturing processes, could harm our or Hitachi's ability to manufacture products. We or Hitachi may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we or Hitachi fail to obtain a supplier for the manufacture of components of our potential products, we may be forced to curtail or cease operations.

We may not be able to manufacture products on a commercial scale.

Hitachi manufactures our NanoChip® System and we manufacture our NanoChip® Cartridges. We and Hitachi rely on subcontractors to manufacture the limited quantities of microchips and other components we require for use by and sale to our customers, as well as for internal and collaborative purposes. Manufacturing, supply and quality control problems may arise as we or Hitachi either alone, together or with subcontractors, attempt to scale up manufacturing procedures. We or Hitachi may not be able to scale-up in a timely manner or at a commercially reasonable cost. Problems could lead to delays or pose a threat to the ultimate commercialization of our products and cause us to fail.

We or Hitachi or any of our contract manufacturers could encounter manufacturing difficulties, including:

the ability to scale up manufacturing capacity;

production yields;

quality control and assurance; or

shortages of components or qualified personnel.

Our manufacturing facilities and those of Hitachi and any other of our contract manufacturers are or will be subject to periodic regulatory inspections by the FDA and other federal, state and international regulatory agencies and these facilities are or may become subject to Quality System Regulation, or QSR, requirements of the FDA. If we, Hitachi or our third-party manufacturers, fail to maintain facilities in accordance with QSR regulations, other international quality standards or other regulatory requirements then the manufacture process could be suspended or terminated which would harm us.

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

We anticipate that our products will be manufactured based on forecasted demand and will seek to purchase components and materials in anticipation of the actual receipt of purchase orders for our products from customers. Lead times for materials, components and our products vary significantly and depend on factors such as the business practices of each specific supplier and the terms of the particular contracts, as well as the overall market demand for such materials, components and products at any given time. If the forecasts are inaccurate, we could experience fluctuations in excess inventory

of our products, or shortages of critical components or products, either of which could cause our business to suffer.

We currently rely on one manufacturer of our Workstation, and only we manufacture our NanoChip® Cartridges, which may delay the manufacture and shipment of our products to customers.

We have signed an exclusive manufacturing agreement with Hitachi to manufacture our NanoChip® Workstation and a collaboration agreement to exclusively manufacture certain of our other products to be developed, subject to certain terms and conditions in each agreement. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreement and the collaboration agreement, each party is obligated to provide the other with certain notice periods if such party determines to curtail or terminate the manufacturing relationship. Nevertheless, while alternative manufacturers of our Workstation and other products currently exist, a lengthy process would be required to negotiate and begin work under a manufacturing agreement with a new manufacturer which could disrupt our manufacturing process and harm our business.

Energy shortages may adversely impact our operations.

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

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

At December 31, 2001, we had 37 employees in our sales and marketing group. In addition, in July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At December 31, 2001, this office employed 9 European-based sales executives and support personnel in the United Kingdom, Germany, The Netherlands and Denmark.

Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by Nanogen and certain of its employees. The size of our sales and marketing force may not result in corresponding numbers of sales or placements of the NanoChip® System nor increased product revenues associated with such sales or placements. Nanogen may be required to increase or decrease the size of this sales and marketing force as deemed necessary and such increases or decreases in staff will require additional capital and time expenditures by Nanogen and its employees.

Failure to expand our international sales as we intend would reduce our ability to become profitable.

We expect that a portion of our sales will be made outside the United States. A successful international effort will require us to develop relationships with international customers and partners. We may not be able to identify, attract or retain suitable international customers and distribution partners. As a result, we may be unsuccessful in our international expansion efforts. Furthermore, expansion into international markets will require us to continue to establish and expand foreign sales and marketing efforts, hire additional sales and marketing personnel and maintain good relations with our foreign customers and distribution partners.

International operations involve a number of risks not typically present in domestic operations, including:

currency fluctuation risks;

changes in regulatory requirements;

costs and risks of deploying the NanoChip® System in foreign countries;

licenses, tariffs and other trade barriers;

political and economic instability;

difficulties in staffing and managing foreign offices;

costs and difficulties in establishing and maintaining foreign distribution partnerships;

potentially adverse tax consequences; and

the burden of complying with a wide variety of complex foreign laws and treaties.

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

We may lose money when we exchange foreign currency received from international sales into US dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the US dollar and the currencies in which we do business will cause foreign currency transaction gains and losses. We cannot predict the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We currently do not engage in foreign exchange hedging transactions to manage our foreign currency exposure.

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. We may not be able to obtain insurance for such potential liability on acceptable terms with adequate coverage, or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance, once obtained, may not be renewed at a cost and level of coverage comparable to that then in effect.

If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.

We are highly dependent on the principal members of our scientific, manufacturing, marketing, administrative, management and executive personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. For the years ended December 31, 1999, 2000 and 2001 the rates of turnover at all levels of the Company were 17%, 19% and 31%, respectively. Turnover at these rates may, and if they continue, adversely affect the Company.

Health care reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

government health administration authorities;

private health coverage insurers;

managed care organizations; and

other organizations.

If appropriate reimbursement cannot be obtained, we could be prevented from successfully commercializing our potential products.

There are efforts by governmental and third party payors to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

Additionally, third party payors are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and whether adequate third party coverage will be available.

If ethical and other concerns surrounding the use of genetic information become widespread, we may have less demand for our products.

Genetic testing has raised ethical issues regarding confidentiality and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulation of the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Any of these scenarios could reduce the potential markets for our products, which could seriously harm our business, financial condition and results of operations.

We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes involve the controlled storage, use and disposal of hazardous materials including, but not limited to, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use,

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

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

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

- the results of our premarket studies and clinical trials or those of our collaborators or competitors or for DNA testing in general;
- evidence of the safety or efficacy of our potential products or the products of our competitors;
- the announcement by us or our competitors of technological innovations or new products;
- the announcement by us of acquisitions by customers of our NanoChip® System or our other products;
- announcements by us of government grants or contracts;
- announcements or developments relating to our litigation against Combimatrix and Dr. Montgomery;
- developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;
- loss of key personnel or the increase or decrease in size of our sales and marketing staff;
- governmental regulatory actions or the failure to gain necessary clearances or approvals;
- the ability to obtain necessary licenses;
- changes or announcements in reimbursement policies;
- developments with our subsidiaries and collaborators;
- changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;
- period-to-period fluctuations in sales, inventories and our operating results;

market conditions for life science stocks in general; and

changes in estimates of our performance by securities analysts.

Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in November 1998, as amended, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved by our board of directors and may have the effect of deterring hostile takeover attempts.

If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.

If appropriate opportunities become available, we may attempt to acquire businesses, technologies, services or products that we believe are a strategic fit with our business. We currently have no commitments or agreements with respect to any material acquisitions. If we do undertake any

transaction of this sort, the process of integrating an acquired business, technology, service or product may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to certain intangible assets, which could adversely affect our results of operations and financial condition.

Item 2. Properties

At December 31, 2001, we occupied the indicated square footage in the leased facilities described below:

Number of Buildings	Location	Total Square Footage	Primary Use
2	San Diego, California	50,800	Administrative offices, research and development, sales and marketing and manufacturing.
1	Helmond, Netherlands	2,600	Administrative offices and sales and marketing.
1	Frankfurt, Germany	9,500	Administrative offices and research and development.

Our leases expire at varying dates through 2010 not including renewals that would be at our option. We believe that our facilities will be suitable and adequate for the present purposes, and that the productive capacity in such facilities is substantially being utilized. In the future, we may need to purchase, build or lease additional facilities to meet the requirements projected in our long-term business plan.

Item 3. Legal Proceedings

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

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

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

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

Item 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, 2001.

PART II

Item 5. Market for the Registrant's Common Equity and Related Stockholder Matters

(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:

	High	Low
Year ended December 31, 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
Year ended December 31, 2001:		
1st Quarter	$ 13.44	$ 5.13
2nd Quarter	$ 10.60	$ 5.40
3rd Quarter	$ 7.50	$ 3.00
4th Quarter	$ 10.13	$ 4.54

As of March 25, 2002 there were approximately 225 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 herein:

	Years Ended December 31,				
	2001	2000	1999	1998	1997
	(In Thousands, Except Per Share Amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Sales	$ 2,245	$ 919	$	$	$
Sponsored research	7,457	8,457	5,688	5,461	1,243
Contract and grant	1,467	1,856	2,431	2,172	2,123
Total revenues	11,169	11,232	8,119	7,633	3,366
Operating expenses:					
Cost of sales	1,606	599			
Research and development	17,563	18,905	25,284	23,002	11,769
Selling, general and administrative	22,610	15,267	9,097	6,420	3,910
Litigation and settlement of patent matter	6,322				
Acquired in-process technology				1,193	
Total operating expenses	48,101	34,771	34,381	30,615	15,679
Loss from operations	(36,932)	(23,539)	(26,262)	(22,982)	(12,313)
Interest income, net	4,294	5,257	2,059	2,650	975
Other income (loss)	137		(996)	(610)	
Net loss	$ (32,501)	$ (18,282)	$ (25,199)	$ (20,942)	$ (11,338)
Net loss per share basic and diluted	$ (1.54)	$ (.92)	$ (1.39)	$ (1.60)	$ (8.42)
Number of shares used in computing net loss per share basic and diluted	21,091	19,944	18,069	13,097	1,347
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 67,524	$ 95,089	$ 41,021	$ 62,245	$ 19,498
Working capital	71,516	92,700	33,508	57,701	16,775
Total assets	90,091	111,168	50,785	72,704	23,215
Other long term liabilities and capital lease obligations, less current portion	3,430	2,065	2,831	4,176	1,193

	Years Ended December 31,				
Accumulated deficit	(123,413)	(90,912)	(72,630)	(47,431)	(26,489)
Total stockholders' equity	74,929	101,414	38,121	61,051	18,599

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," "potentially," "eventually," 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

It is our goal to become a leading provider of molecular diagnostic tests. We integrate advanced microelectronics and molecular biology into a core technology platform with potentially broad and diverse commercial applications. Our primary areas of focus have been in genomics and biomedical research, medical diagnostics, forensics and drug discovery. The first application we have developed, the NanoChip® System, is an integrated bioassay system consisting of the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge. The NanoChip® Workstation is comprised of two automated instruments and the NanoChip® Cartridge, a consumable cartridge, which incorporates a proprietary microchip (the "NanoChip® Electronic Microarray"). The NanoChip® System provides a flexible tool for the rapid identification and precision analysis of biological test samples containing charged molecules.

Since commencing operations in 1993, we have applied substantially all of our resources to our research and development programs. We have incurred losses since inception and, as of December 31, 2001, had an accumulated deficit of $123.4 million. We expect to continue to incur significant losses over at least the next few years as we attempt to further commercialize our products as well as expand the menu of applications for our current products.

We introduced our first two products into the marketplace in 2000. While we recognized revenue from product sales during the years ended December 31, 2001 and 2000, our main sources of revenues during these fiscal years and in 1999 were payments under our sponsored research agreements, contracts and grants. We believe that in future periods, however, our revenue base will shift to being more product driven as certain research collaboration agreements expire and new products are introduced to the marketplace. We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, market acceptance of the NanoChip® System and potential products under development, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements with Hitachi and various government agencies. The recognition of revenue under contracts, grants and sponsored research agreements will be subject to significant fluctuations in both timing and amount and therefore our results of operations for any period may not be comparable to the results of operations for any other period. The terms of our contracts and grants and sponsored research arrangements vary, but can generally be categorized as follows:

Aventis Development Program 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 immunodiagnostics 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. All project milestones were completed and the term of this collaboration agreement expired at the end of 2000. In September 1999, we entered into a collaboration agreement with Aventis that involved two

research and development programs focused on gene expression tools utilizing electronic bioarrays and on the development of high throughput screening tools for protein kinase development. We retained full commercialization rights for any products resulting from these new projects, while Aventis retained the right to use the technology for internal research and development. All project milestones established under these arrangements were completed as of fiscal year end 2001 at which time the agreements have expired. Under these programs, we demonstrated

quantitative, multiplexed and reliable gene expression monitoring on our electronic microarray system. Additionally, we delivered an electronic hybridization-based gene expression prototype detection system as well as a prototype system for analyzing protein kinases. The protein kinase prototype system was sold during the fourth quarter of 2001 to an affiliate of Aventis. As of December 31, 2001, we had incurred an aggregate of $14.2 million in direct and indirect research and development costs under these collaboration efforts. We do not expect to receive additional funding for these projects.

Hitachi Development Program In July 2000, we entered into a ten-year agreement with 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 arrangement provides that the parties will jointly determine which projects to prioritize over the term of the 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. Either party, subject to certain restrictions, may terminate the agreement before its expiration. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute up to $28.5 million in cash over the ten-year period. At a minimum the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. The Company received $2.25 million ($104,000 of which is a prepayment for 2002 research and development activities) and $1.0 million from Hitachi during the years ended December 31, 2001 and 2000, respectively. In addition, the Company is liable to repay fifty percent of all funding provided by Hitachi over an indefinite period of time. Payment amounts are determined as a percentage of the Company's gross NanoChip® Cartridge sales until the liability is paid in full. The Company has completed the identification of requirements phase of the project as of December 31, 2001 and anticipates completion of a prototype by the end of fiscal 2002. As of December 31, 2001, we have incurred an aggregate of $3.2 million in research and development costs since the beginning of this project in July 2000. Our failure to achieve established milestones under this collaboration could have a material adverse effect on funding available under this agreement, relations with Hitachi and our business, financial condition or results of operations.

DARPA Grants In September 1998, 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 ("DARPA") in an amount totaling approximately $2.4 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. The contract was completed in January 2001 and all milestones have been achieved. In August 2000, a second DARPA contract was granted to Nanogen in an amount totaling approximately $1.6 million over a two-year period. The contract is focused on developing an electronic sample preparation chip for the detection of biowarfare agents from blood samples. The project is on schedule to meet all contractual milestones and is expected to be completed mid-2002. As of December 31, 2001, we have incurred an aggregate of $2.9 million in direct and indirect research and development costs since the beginning of these contracts.

USAMRAA Cooperative Agreements The Company received funding from two cooperative research agreements with the U.S. Army Medical Research Acquisition Activity. The first agreement, entered into in October 2000, is focused on developing technology to identify biological warfare

compounds if used in combat against U.S. troops. The second cooperative agreement, entered into in October 2001, is to continue the development of miniaturized electronic devices for isolation and detection of biological warfare and infectious disease agents. In conjunction with the agreements, funding provided by the agency is matched dollar-for-dollar with Nanogen funds. As of December 31, 2001, we have incurred an aggregate of $693,000 in direct and indirect research and development costs since the beginning of these collaboration efforts.

NIJ Grant The National Institute of Justice, U.S. Department of Justice, provides funding for the development of a chip based genetic detector for rapid DNA-based identification of individuals. All milestones contemplated under Phase IV, the penultimate phase of this multi-year grant, are expected to be complete in mid-2002. As of December 31, 2001, we have incurred an aggregate of $2.3 million in direct research and development costs since the beginning of this multi-year grant. An application has been submitted for funding of final Phase V. If awarded, Phase V efforts could result in protocols and reagents suitable for beta-testing in crime labs.

While the majority of the Company's total revenues during fiscal 2001, 2000 and 1999 consisted of sponsored research and contract and grant funding, there was an increase in product revenues for the year ended December 31, 2001 when compared to the same period in 2000, the year we launched our first products. The makeup of our revenues is shifting from primarily sponsored research funding to product revenues as sales and marketing efforts increase the installed base of our NanoChip® Molecular Biology Workstation and as programs from research and development collaborations expire. We offer our products to customers under several different types of acquisition programs, some of which pass title of the instrument to the customer and some of which do not pass title to the customer. One of these acquisition programs is through Development Site Agreements, where title does not pass to the customer, however, these agreements may provide for the potential development of content for use on the NanoChip® System. As internal and external content development expand the capabilities of the NanoChip® System, the Company believes that consumable sales, including NanoChip® Cartridge sales and eventually analytic specific reagents ("ASR's") and

Food and Drug Administration ("FDA") cleared or approved kits will account for an increasing portion of our product revenues.

During the 2001 fiscal year, the Company internally and externally validated its first five DNA-based research protocols for use on the NanoChip® Molecular Biology Workstation. Four of these protocols are associated with cardiovascular disease and the pathology of thrombosis. They include Factor V Leiden, Factor II (Prothrombin), a multiplexed protocol for both of these mutations at a single location on our microarray, and MTHFR. The fifth protocol is for a mutation associated with hereditary hemochromotosis, a disorder that causes excess iron to be stored in cells of the liver, heart, pancreas and other organs. We believe high complexity CLIA certified laboratories that adopt our technology may further validate these protocols in their own laboratories for use in a "home-brew" format. During 2002, we plan to convert certain of these protocols into ASR's. Under the ASR model we will continue to sell blank cartridges in addition to the reagents necessary to perform these tests on the NanoChip® System.

Critical Accounting Policies and Estimates

This Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates and judgements, including those related to bad debts, inventories, investments, intangible assets, service obligations, contingencies and litigation. We base our estimates and judgements on

historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

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

Revenue recognition

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

Sponsored research and contract and grant revenue are generally recorded as the costs and expenses to perform the research are incurred. Under certain arrangements revenue is recorded ratably over the term of the arrangement as funding is provided for contractually on a scheduled basis. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Continuation of certain sponsored research and contracts and grants are dependent upon our achieving specific contractual milestones.

Bad debt

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

Inventory

We reduce the carrying value of our inventory, including NanoChip® Molecular Biology Workstations placed under Development Site arrangements, for estimated obsolescence or non-marketability based upon assumptions about future demand and market conditions. If actual

future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

Intangible Assets

We have intangible assets related to acquired technology rights. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances.

Results of Operations

Years ended December 31, 2001, 2000 and 1999

Revenues

For the year ended December 31, 2001, sales revenue totaled $2.2 million compared to $919,000 for the year ended December 31, 2000. Sales revenue primarily consists of revenue recognized from the sale of our NanoChip® Molecular Biology Workstations and NanoChip® Cartridges. We sold fifteen, and recognized revenue for thirteen, NanoChip® Systems during 2001 compared to eight NanoChip® Systems in 2000. In addition, we sold two NanoChip® Systems in both 2001 and 2000 under sponsored research programs. All revenue recorded related to sales of our NanoChip® Molecular Biology Workstation resulted from outright sales transactions where title of the instrument passed to the customer. We offer our products to customers under several different types of acquisition programs, some of which pass title of the instrument to the customer and some of which do not pass title to the customer. As of December 31, 2001, we had an installed base of 61 instruments, which consist of twenty-seven outright sales and thirty-four placements under non-title transfer transactions. 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, 2001, revenue from sponsored research totaled $7.5 million compared to $8.5 million and $5.7 million for the years ended December 31, 2000 and 1999, respectively. Sponsored research revenue in 2001 included the following:

- Revenue earned in connection with our research and development agreement entered into in January 1998 and September 1999 with Aventis totaling $6.4 million, which includes the sale of two NanoChip® Molecular Biology Workstations.

- Revenue earned in connection with our development program entered into in July 2000 with Hitachi totaling $1.1 million.

Sponsored research revenue for the same period in 2000 and 1999 included the following:

- Revenue earned in connection with our research and development agreements entered into in January 1998 and September 1999 with Aventis totaling $7.7 million in 2000, which includes the sale of two NanoChip® Molecular Biology Workstations, and $3.6 million in 1999.

- Revenue earned in connection with the joint venture agreement with Becton Dickinson, as amended in September 2000, totaling $300,000 in 2000 and $1.6 million in 1999.

- Revenue earned in connection with our development program entered into in July 2000 with Hitachi totaling $417,000 in 2000.

- Revenue earned in connection with our nonexclusive research and development agreement with Élan totaling $568,000 in 1999.

All project milestones established under the research and development agreement entered into in September 1999 with Aventis were completed as of fiscal year end 2001 at which time the agreements have expired. We do not expect to receive additional funding from Aventis,

Becton Dickinson and Élan under the projects mentioned above.

We fund some of our research and development efforts through contracts and grants awarded by various federal 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 and 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 and gross margins

Cost of sales totaled $1.6 million in 2001 compared to $599,000 in 2000. There were no product sales in 1999. Gross margins on sales revenue were 28% and 35% for the years ended December 31, 2001 and 2000, respectively. Cost of sales during the years ended December 31, 2001 and 2000 were adversely impacted by underabsorbed overhead costs due to underutilized capacity. The cost per unit of our products remained high, as our volume of production relative to the available capacity remained low. In 2001, cost of sales was further impacted by a reserve for obsolete inventory. Gross margins in 2001 were also unfavorably impacted by sales to some customers under various discount programs. In comparison, during the year ended December 31, 2000, a portion of sales revenue related to prototypes and therefore did not have the related cost of sales recorded in the period sold as these costs had been expensed as research and development costs in prior years. As we are still in the early stages of commercialization, we expect to continue to incur significant costs associated with excess production capacity within our manufacturing facility in 2002.

Research and development expenses

Research and development expenses decreased to $17.6 million during the year ended December 31, 2001 from $18.9 million and $25.3 million for the years ended December 31, 2000 and 1999, respectively. Research and development expenses included the following in 2001:

Costs of salaries and benefits for scientific, engineering and operations personnel, costs associated with improving and refining our current products as well as development of potential new products and protocols, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities.

The number of personnel directly working in research and development related activities, within our U.S. operations decreased by approximately 10% in 2001 from 2000, primarily as a result of a reallocation of personnel to operations.

The decrease in research and development expenses from fiscal 1999 to 2000 resulted primarily from the different development stages of our NanoChip® Molecular Biology Workstation from period to period. During the year ended December 31, 1999, our NanoChip® Molecular Biology Workstation was in an advanced stage of prototype design and development. 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 expenses during 2000 and 1999 included the following:

Costs of salaries and benefits for scientific, engineering and operations personnel, product design and prototype development costs, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities.

Expenditures incurred both internally and with outside vendors related to engineering prototypes, as well as other costs associated with testing and refining the product in 1999.

We anticipate that we will continue to invest in research and product development at approximately the same level as 2001 for the foreseeable future.

Selling, general and administrative expenses

Selling, general and administrative expenses totaled $22.6 million in 2001 compared to $15.3 million in 2000 and $9.1 million in 1999. The year-to-year increases from 1999 through 2001 are

primarily due to costs associated with the expansion and development of our sales and marketing organization, the expansion of activities related to marketing and selling our products, and increased legal fees associated with enhancing and maintaining our intellectual property portfolio. Selling, general and administrative expenses are expected to continue at the current level for the forseeable future as we continue to market and sell our current and potential future products.

Litigation and Settlement of Patent Matter

Litigation and settlement of a patent matter totaled $6.3 million for the year ended December 31, 2001. In July 2001, a settlement agreement was reached with Motorola, Inc., Genometrix, Inc. and the Massachusetts Institute of Technology concluding the declaratory judgment action by us against Motorola, Genometrix and MIT as well as Motorola's counterclaim against us. In connection with the settlement, we paid a total of $5.0 million to the parties in the form of $2.5 million in cash and 416,666 shares of our common stock (valued at approximately $2.5 million based upon a per share price of $6.00, the fair market value on the date of settlement). Costs incurred during the year primarily consist of the settlement fee of $5.0 million in addition to legal fees incurred related to the litigation process.

Interest income, net

We had net interest income of $4.3 million in 2001 compared to net interest income of $5.3 million and $2.1 million, in 2000 and 1999, respectively. The decrease in net interest income is a result of lower average cash balances as well as lower yields on outstanding cash balances during 2001 when compared to 2000. The significant increase in 2000 when compared to 1999 can be primarily attributed to higher average cash balances in 2000 resulting from net proceeds received in conjunction with our follow-on public offering of common stock in March 2000.

Other income

Other income totaled $137,000 for the year ended December 31, 2001. Other income primarily consists of a gain realized from the sale of short-term investments during the year.

Equity in loss of joint venture

We recognized a loss of $996,000 for the year ended December 31, 1999, from the joint venture formed in 1997 with Becton Dickinson, based on the loss allocation described in the Partnership Agreement which requires losses to be allocated in proportion to and not to exceed required cash contributions. There was no loss recognized during 2001 and 2000 as no cash contributions were required to be made by us to the joint venture during those periods. 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 any additional funding to the joint venture.

Liquidity and capital resources

At December 31, 2001, we had $67.5 million in cash, cash equivalents and short-term investments, compared to $95.1 million at December 31, 2000. This decrease is primarily due to cash used in operations of approximately $33.0 million offset by $4.8 million in proceeds provided by Aventis for the operations of our majority-owned subsidiary, Nanogen Recognomics GmbH.

Net cash used in operating activities was $33.0 million, $19.8 million and $18.6 million for 2001, 2000 and 1999, respectively. Cash used for operations during 2001 and 2000 was primarily related to costs associated with commercializing our products including the expansion, development and support of our sales and marketing organization, the procurement of inventory pursuant to our manufacturing

arrangement with Hitachi, Ltd., support of our continuing research and development efforts, legal fees relating to establishing, maintaining and defending our intellectual property portfolio, and the costs associated with patent litigation. Cash used for operations during 1999 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.

Net cash used in investing activities was $17.1 million, $44.5 million and $1.0 million for 2001, 2000 and 1999, respectively. Cash used for investing activities during 2001 and 2000 primarily related to the purchase of short-term securities in an effort to maximize our return while preserving our cash balance. 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.

Net cash provided by financing activities was $5.2 million and $78.6 million for 2001 and 2000, respectively. Cash provided by financing activities in 2001 primarily related to the funds totaling $4.8 million provided by Aventis for the operations of Nanogen Recognomics as well as funding provided by Hitachi under the July 2000 research and development agreement. Cash provided by financing activities in 2000 primarily related to proceeds received pursuant to our follow-on public offering of common stock in March 2000. Net cash used in financing activities was $1.6 million in 1999, primarily related to payments under our capital lease obligations.

We fund most of our equipment acquisitions and leasehold improvements through capital leasing facilities. During 2001, equipment and leasehold improvement financing funded $1.1 million, compared to $944,000 and $881,000 of equipment acquired during 2000 and 1999, respectively. 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, 2001, we had $1.4 million of available funding under our equipment lease lines.

The following illustrates, on a comprehensive basis, all recorded liabilities on the consolidated balance sheets as included herein and contractual commitments associated with operating leases, purchase commitments and funding commitments under research and development collaborations as of December 31, 2001 (in thousands):

	Payments Due by Period				
Contractual Obligations & Other Commitments	**Total**	**Less Than 1 year**	**1 - 2 years**	**3 - 5 years**	**Thereafter**
Capital lease obligations	$ 2,815	$ 1,118	$ 687	$ 1,010	$
Other long term liabilities(a)	1,675				1,675
Operating leases	9,140	1,037	891	3,230	3,982
Purchase commitments(b)	5,116	4,096	1,020		
Research and development funding commitments(c)	29,925	3,850	4,100	11,475	10,500
Standby letters of credit(d)	299				299
Total contractual obligations & other commitments	$ 48,970	$ 10,101	$ 6,698	$ 15,715	$ 16,456

(a) In connection with the agreement entered into with Hitachi in July 2000, we are required to repay fifty percent of the total contributions made by Hitachi. Payment amounts are determined as a percentage of our gross NanoChip® Cartridge sales until the liability is paid in full. This liability is non-interest bearing and will survive any termination of the agreement among the parties until it is paid. We have received a total of $3.2 million since July 2000 under this arrangement. Other long term liabilities also reflects our obligation under an employee pension plan established by our majority-owned subsidiary, Nanogen Recognomics.

(b) Our manufacturing agreement with Hitachi, Ltd. ("Hitachi") requires that we provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of December 31, 2001, we had commitments to purchase approximately $4.9 million in NanoChip® Workstations through March 31, 2003. The requirement of future purchase commitments will be determined based on product demand and inventory levels. In connection with the service agreement established with Hitachi in October 2000, as amended

in December 2001, we have committed to provide Hitachi with a minimum of $200,000 in payments for maintenance service provided in fiscal 2002.

(c)

We are required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi under the research and development agreement established in July 2000. Amounts included in the table above assume Hitachi will make all scheduled payments under this arrangement totaling $28.5 million since inception of the agreement in fiscal 2000. In connection with the formation of Nanogen Recognomics in fiscal 2001, we are required to spend an aggregate of $5.5 million, at a rate of $1.1 million per year beginning April 1, 2001, for its own general technology development which benefits the commercialization and development of potential Nanogen Recognomics' products.

(d)

Payments are not required under the standby letters of credit and expire at various dates and therefore the table above does not reflect payment information over the five year period.

The Company is a party to Development Site Agreements with various entities whereby the Company may be obligated to pay license fees or royalties for any customer owned or licensed intellectual property used to develop any Nanogen commercial products. None of these agreements individually are considered material.

We expect that our existing capital resources, combined with anticipated revenues from potential product sales, reagent rentals, leases or other types of acquisition programs for the NanoChip® System, sponsored research agreements, contracts and grants will be sufficient to support our planned operations through at least the next two years at our fiscal 2001 rate of expenditures. This estimate of the period for which we expect our available sources of liquidity to be sufficient to meet our capital requirements is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. Our future liquidity and capital funding requirements will depend on numerous factors including, but not limited to, commercial success of our products, or lack thereof, of our current products, the extent to which our products under development are successfully developed and gain market acceptance, the timing of regulatory actions regarding our potential products, the costs and timing of expansion of sales, marketing and manufacturing activities, prosecution and enforcement of patents important to our business and any litigation related thereto, the results of clinical trials, competitive developments, and our ability to maintain existing collaborations and to enter into additional collaborative arrangements. We have incurred negative cash flow from operations since inception and do not expect to generate positive cash flow to fund our operations for at least the next several years. We may need to raise additional capital to fund our research and development programs, to scale-up manufacturing activities and expand our sales and marketing efforts to support the commercialization of our products under development. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through entering into collaborative agreements or other arrangements on unfavorable terms. Our failure to raise capital on acceptable terms when needed could have a material adverse effect on our business, financial condition or results of operations.

Net operating loss carryforwards

As of December 31, 2001, we had federal and state net operating loss, or NOL, carryforwards of approximately $109.7 million and $18.6 million, respectively, and $4.4 million and $2.8 million of research and development, or R&D, tax credits available to offset future federal and state income

taxes, respectively. The federal and state 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 state tax loss carryforwards will begin to expire in 2002, unless previously utilized. The federal and state R&D tax credit carryforwards will begin expiring in 2007 unless previously utilized. Our initial public offering combined with the concurrent private placement, which occurred in April 1998, may be perceived as 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 typically 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. Recent downgrading of issuers of such securities we believe, have had no material impact on our investment portfolio.

The functional currency for our Netherlands and German subsidiaries is the U.S. dollar and euro, respectively. The German subsidiary's accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. The net tangible assets of our subsidiaries, excluding intercompany balances, is $1.3 million at December 31, 2001.

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.

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 14, 2002 (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 "Compensation of Executive Officers and Directors."

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."

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

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
3.(i)1(3)	Restated Certificate of Incorporation. (3.(i)1)
3.(i)2(3)	Certificate of Designations, as filed with the Delaware Secretary of State on November 23, 1998. (3.(ii)2)
3.(ii)(13)	Amended and Restated Bylaws of Registrant. (3.(ii)1).
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
4.3(8)	Amendment No. 1 to Rights Agreement, dated as of December 11, 2000 between Registrant and FleetBoston, N.A.
10.1(13)(A)	1997 Stock Incentive Plan of Nanogen, Inc. ("1997 Plan"), as amended. (10.7)
10.2(6)(A)	Form of Incentive Stock Option Agreement under the 1997 Plan, as amended. (10.2)
10.3(6)(A)	Form of Nonqualified Stock Option Agreement under the 1997 Plan, as amended. (10.3)
10.4(12)(A)	Nanogen, Inc. Employee Stock Purchase Plan, as amended.
10.5(1)(A)	Form of Indemnification Agreement between Registrant and its directors and executive officers. (10.7)
10.6(7)	Warrant to Purchase Common Stock between Registrant and Aventis Research and Technologies Verwaltungs, GmbH, dated September 22, 2000. (10.9)
10.7(5)(+)	Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement by and between Registrant and Hitachi, Ltd. dated as of December 15, 1999.
10.8(7)(+)	First Amendment to Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement between Registrant and Hitachi, Ltd., dated July 26, 2000. (10.7)
10.9(7)(+)	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)
10.10(7)	Common Stock Purchase Agreement between Registrant and the Hitachi Parties, dated July 26, 2000. (10.8)
10.11(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)

10.12(1)	Master Lease Agreement between Registrant and Mellon US Leasing, dated September 11, 1997. (10.19)

10.13(1)	Master Lease Agreement between Registrant and LMP Properties, Ltd., dated June 29, 1994. (10.20)
10.14(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)
10.15(1)(A)	Form of Promissory Note between Registrant and certain of its executive officers, dated August 22, 1996. (10.23)
10.16(1)(A)	Form of Promissory Note between Registrant and certain of its executive officers, dated June 30, 1995. (10.24)
10.17(1)(A)	Form of Performance Stock Option Agreement. (10.26)
10.18(10)(A)	Agreement between Registrant and Kieran T. Gallahue, dated January 26, 2001.
10.19(13)(A)	Amended and Restated Employment Agreement between Registrant and Howard C. Birndorf, dated as of June 3, 2001. (10.2)
10.20(9)(A)	Secured Promissory Note between Registrant and Kieran T. Gallahue, dated April 23, 1998.
10.21(13)(A)	Amended and Restated Employment Agreement between Registrant and Vera P. Pardee, Esq., dated as of April 27, 2001. (10.4)
10.22(13)(A)	Amended and Restated Employment Agreement between Registrant and Gerard A. Wills, dated as of April 27, 2001. (10.5)
10.23(11)(A)	Employment Agreement between Registrant and V. Randy White, dated June 4, 2001. (10.2)
10.24(11)(A(+)	Cooperation and Shareholders' Agreement among Aventis Research & Technologies GmbH & Co. KG ("Aventis R&T"), Registrant and Nanogen Recognomics GmbH ("Nanogen Recognomics"), dated June 29, 2001 (10.3).
10.25(11)(A)(+)	Contribution Agreement among Aventis R&T, Registrant and Nanogen Recognomics, dated June 27, 2001 (10.4).
10.26(13)(+)	Settlement Agreement between Motorola, Inc., Genometrix, Inc., the Massachusetts Institute of Technology and Registrant, dated July 20, 2001. (10.6)
10.25(4)	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 Exhibit 4.2 to the Registrant's Registration Statement on Form 8-A, filed on November 24, 1998.

(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.

(4) 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

(5) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.

(6) 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.

(7) 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.

(8)

Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on December 12, 2000.

(9)

Incorporated by reference to Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2001.

(11)

Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 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 the Registrant's Form S-8 filed on June 20, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed

(13)

Incorporated by reference to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.

(A)

Indicates management compensatory plan or arrangement.

(+)

Confidential treatment has been requested for certain portions of these agreements.

(b)

Reports on Form 8-K

We have filed no reports on Form 8-K during the quarter ended December 31, 2001.

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 29, 2002 By: /s/ HOWARD C. BIRNDORF

Howard C. Birndorf
Chairman of the Board and
Executive Chairman

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.

Name	Title	Date

Name	Title	Date
/s/ HOWARD C. BIRNDORF Howard C. Birndorf	Chairman of the Board and Executive Chairman (Principal Executive Officer)	March 29, 2002
/s/ GERARD A. WILLS Gerard A. Wills	Vice President, Chief Financial Officer, and Treasurer (Principal Financial and Accounting Officer)	March 29, 2002
/s/ VANCE R. WHITE Vance R. White	Chief Executive Officer and Director	March 29, 2002
/s/ VAL BUONAIUTO Val Buonaiuto	Director	March 29, 2002
/s/ CAM L. GARNER Cam L. Garner	Director	March 29, 2002
/s/ REGINA E. HERZLINGER Regina E. Herzlinger	Director	March 29, 2002
/s/ DAVID G. LUDVIGSON David G. Ludvigson	Director	March 29, 2002
/s/ STELIOS B. PAPADOPOULOS Stelios B. Papadopoulos	Director	March 29, 2002

NANOGEN, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. 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 all material respects, the consolidated financial position of Nanogen, Inc. at December 31, 2001 and 2000 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

San Diego, California
January 22, 2002

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

	December 31,	
	2001	**2000**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,455	$ 55,330
Short-term investments	57,069	39,759
Receivables, net	4,380	1,322
Inventories, net	4,688	2,289
Other current assets	2,473	1,689
Total current assets	79,065	100,389
Property and equipment, net	5,386	5,373
Acquired technology rights, net	4,183	5,179
Other assets, net	1,158	63
Restricted cash	299	164
	$ 90,091	$ 111,168
LIABILITIES AND STOCKHOLDERS' EQUITY		

	December 31,	
Current liabilities:		
Accounts payable	$ 1,051	$ 1,223
Accrued liabilities	4,916	4,095
Deferred revenue	522	360
Current portion of capital lease obligations	1,060	2,011
Total current liabilities	7,549	7,689
Capital lease obligations, less current portion	1,755	1,565
Other long-term liabilities	1,675	500
Total long-term liabilities	3,430	2,065
Minority interest in consolidated subsidiary	4,183	
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, $.001 par value, 5,000,000 shares authorized at December 31, 2001 and 2000; no shares issued and outstanding at December 31, 2001 and 2000		
Common stock, $.001 par value, 50,000,000 shares authorized at December 31, 2001 and 2000; 21,616,172 and 20,913,151 shares issued and outstanding at December 31, 2001 and 2000, respectively	22	21
Additional paid-in capital	198,387	193,459
Accumulated other comprehensive income	1,253	270
Deferred compensation	(336)	(325)
Notes receivable from officers	(984)	(1,099)
Accumulated deficit	(123,413)	(90,912)
Total stockholders' equity	74,929	101,414
	$ 90,091	$ 111,168

See accompanying notes.

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

	Years Ended December 31,		
	2001	2000	1999
Revenues:			
Sales	$ 2,245	$ 919	$
Sponsored research	7,457	8,457	5,688
Contract and grant	1,467	1,856	2,431
Total revenues	11,169	11,232	8,119
Operating expenses:			
Cost of sales	1,606	599	
Research and development	17,563	18,905	25,284

	Years Ended December 31,		
Selling, general and administrative	22,610	15,267	9,097
Litigation and settlement of patent matter	6,322		
Total operating expenses	48,101	34,771	34,381
Loss from operations	(36,932)	(23,539)	(26,262)
Interest income, net	4,294	5,257	2,059
Other income	137		
Equity in loss of joint venture			(996)
Net loss	$ (32,501)	$ (18,282)	$ (25,199)
Net loss per share basic and diluted	$ (1.54)	$ (0.92)	$ (1.39)
Number of shares used in computing net loss per share basic and diluted	21,091	19,944	18,069

See accompanying notes.

NANOGEN, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Deferred Compensation	Notes Receivable From Officers	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount						
Balance at December 31, 1998	18,835	$ 19	$ 111,489	$	$ (1,512)	$ (1,514)	$ (47,431)	$ 61,051
Issuance of common stock	94		246					246
Repurchase of common stock	(73)		(114)		86			(28)
Cancellation of notes receivable related to unvested restricted stock	(116)		(104)			104		
Restricted stock awards	251		1,820		(1,820)			
Stock based compensation expense			237		1,773			2,010
Payments received and accrued interest on notes receivable from officers						41		41
Net loss							(25,199)	(25,199)
Balance at December 31, 1999	18,991	19	113,574		(1,473)	(1,369)	(72,630)	38,121
Components of comprehensive loss:								
Net loss							(18,282)	(18,282)

	Common Stock			Accumulated Other Comprehensive Income	Notes Receivable From Officers		Total Stockholders' Equity (Deficit)
Unrealized gain on short-term investments				270			270
Total comprehensive loss							(18,012)
Issuance of common stock	462		1,835				1,835
Repurchase of common stock	(58)		(437)		201		(236)
Sale of common stock under secondary public offering, net of expenses	1,500	2	76,538				76,540
Sale of common stock in private placement	75		2,000				2,000
Cancellation of notes receivable related to unvested restricted stock	(57)		(51)			56	5
Stock based compensation expense					947		947
Payments received and accrued interest on notes receivable from officers						214	214
Balance at December 31, 2000	20,913	21	193,459	270	(325)	(1,099)	(90,912)	101,414
Components of comprehensive loss:							
Net loss							(32,501)	(32,501)
Unrealized gain on short-term investments				892				892
Cumulative currency translation adjustment				91				91
Total comprehensive loss								(31,518)
Issuance of common stock	330		1,248					1,248
Repurchase of common stock	(47)		(282)		11			(271)
Issuance of common stock in settlement of litigation and patent matter	417	1	2,500					2,501
Issuance of warrant to development partner			1,200					1,200
Issuance of common stock in connection with defined benefit plan, net of forfeitures	25		297		(284)			13
Stock based compensation expense					367			367
Options issued to consultants			105		(105)			
Payments received and accrued interest on notes receivable from officers	(22)		(140)			115		(25)
Balance at December 31, 2001	21,616	$ 22	$ 198,387	$ 1,253	$ (336)	$ (984)	$ (123,413)	$ 74,929

See accompanying notes.

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

	Years Ended December 31,		
	2001	**2000**	**1999**
Operating activities:			
Net loss	$ (32,501)	$ (18,282)	$ (25,199)
Adjustments to reconcile net loss to net cash used in operating activities:			
Issuance of common stock pursuant to litigation settlement	2,500		
Minority interest in loss of consolidated subsidiary	(907)		
Depreciation and amortization	3,475	2,553	1,709
Amortization (accretion) related to short-term investments	(53)	29	
Stock-based compensation expense	367	947	2,010
Interest capitalized on notes receivable from officers	(63)	(57)	(74)
Gain on sale of short-term investments	(116)		
Net loss from sale of property and equipment			24
Cumulative currency translation adjustment	91		
Equity in loss of joint venture			996
Changes in operating assets and liabilities:			
Receivables	(3,058)	(735)	(94)
Inventories	(2,398)	(2,289)	
Other assets	(919)	47	(88)
Accounts payable	(172)	625	(468)
Accrued liabilities	610	369	2,293
Deferred revenue	162	(3,013)	308
Net cash used in operating activities	(32,982)	(19,806)	(18,583)
Investing activities:			
Purchase of short-term investments	(26,941)	(39,461)	
Proceeds from sale of short-term investments	10,692		
Purchase of technology rights	(150)	(5,000)	
Purchase of equipment	(652)	(59)	(32)
Investment in joint venture			(996)
Proceeds from sale of assets			6
Net cash used in investing activities	(17,051)	(44,520)	(1,022)
Financing activities:			
Proceeds from minority interest shareholder	4,794		
Proceeds from development partner	1,125	500	
Proceeds (payments) from restricted cash balances	(135)	55	51
Principal payments on capital lease obligations	(1,818)	(2,335)	(2,003)
Issuance of common stock, net	1,149	80,139	218
Note receivable payments from officers	38	276	115

	Years Ended December 31,		
Net cash provided by (used in) financing activities	5,153	78,635	(1,619)
Effect of exchange rate changes	5		
Net increase (decrease) in cash and cash equivalents	(44,875)	14,309	(21,224)
Cash and cash equivalents at beginning of year	55,330	41,021	62,245
Cash and cash equivalents at end of year	$ 10,455	$ 55,330	$ 41,021
Supplemental disclosure of cash flow information:			
Interest paid	$ 340	$ 461	$ 580
Supplemental schedule of noncash investing and financing activities:			
Equipment acquired under capital leases	$ 1,062	$ 944	$ 881
Common stock issued for settlement of patent matter	$ 2,500	$	$
Warrant issued for research and development collaboration	$ 1,200	$	$
Assets and liabilities contributed by minority shareholder	$ 307	$	$
Unrealized gain on short-term investments	$ 892	$ 270	$
Common stock issued in connection with employee benefit plan, net of forfeitures	$ 284	$	$
Cancellation of notes receivable related to unvested restricted stock, net of payments on notes receivable	$ 139	$ (56)	$ (104)
Options issued to non-employees for services	$ 105	$	$
Cancellation of unvested restricted stock	$ 11	$ 201	$ 86
Exchange of notes receivable for acquired technology rights	$	$	$ 1,005
Deferred compensation related to stock options and restricted stock awards, net	$	$	$ 1,734

See accompanying notes.

NANOGEN, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
December 31, 2001

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.

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, 2001 include $1.3 million in net tangible assets, excluding intercompany balances, and an operating loss of $1.8 million for the year ended December 31, 2001 related to Nanogen Europe B.V.

Nanogen Recognomics GmbH

In June 2001, the Company entered into agreements with Aventis to create a new company, Nanogen Recognomics GmbH ("Nanogen Recognomics"). The company was established to develop new products and applications for the NanoChip® System. Nanogen Recognomics is sixty percent owned by the Company and forty percent owned by Aventis and is based in Frankfurt, Germany. Aventis provided $5.0 million of funding and other fixed assets for the operations of the new company and also contributed intellectual property in the form of eighteen patents. In conjunction with the agreement to form Nanogen Recognomics, the Company issued a warrant to Aventis to purchase 315,863 shares of the Company's common stock exercisable through July 17, 2006 at an agreed upon price of $9.828 per share. The value of this warrant, as determined by the Black-Scholes valuation model, is $1.2 million, and is included in other assets in the accompanying consolidated financial statements and is being amortized over a two and a one-half year period. The Company's consolidated financial statements at December 31, 2001 include $4.5 million in tangible assets, including intercompany balances, of which $4.2 million consists of cash and cash equivalents, related to Nanogen Recognomics. An operating loss of $907,000 for the period from inception through December 31, 2001 related to Nanogen Recognomics is reflected as an offset to "minority interest in consolidated subsidiary" as included in the consolidated balance sheets herein.

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. and its majority-owned subsidiary, Nanogen Recognomics. The consolidated financial statements include 100 percent of the assets and liabilities of Nanogen Recognomics and the ownership interest of minority participants is recorded as "Minority interest in consolidated subsidiary." In addition, 100 percent of the results of operations of Nanogen Recognomics is reflected as a reduction to the "Minority interest in consolidated subsidiary" account as the minority interest owner provided the first $5.0 million in funding for the operations of this

organization and which is being used to fund all of the operating costs up to the amounts advanced. 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.

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, 2001, 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 other 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 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

Since 1994, the Company obtained an irrevocable standby letter of credit to secure its building lease. The letter of credit is secured by a certificate of deposit, which is reflected as restricted cash in the accompanying consolidated balance sheet. The letter of credit is reduced by approximately $50,000 annually, and had a balance of approximately $114,000 at December 31, 2001.

In December 2001, the Company obtained a standby letter of credit in the amount of approximately $185,000 to secure the purchase of a NanoChip® System. The letter of credit is secured by a certificate of deposit, which is reflected as restricted cash, and as deferred revenue, in the accompanying consolidated balance sheet. The letter of credit may be revoked by its beneficiary within 175 days from the date it was established.

Inventories

Inventories are 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 over their estimated useful lives of five years.

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, 2001.

Revenue Recognition

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

due to the type of acquisition program our customers may choose.

Sponsored research, 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.

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 foreign

currency translation adjustments and unrealized gains and losses on short-term investments. The Company presents other comprehensive income (loss) in its consolidated statements 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 and shares issued under the Company's 401K benefit plan prior to vesting. Due to the losses incurred by the Company during the years ended December 31, 2001, 2000, and 1999, 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.

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 for our Netherlands and German subsidiaries is the U.S. dollar and euro, respectively. The German subsidiary's accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. During fiscal 2001, 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 July 2001, the Financial Accounting Standards Board (FASB) issued FASB Statements Nos. 141 and 142 (FAS 141 and FAS 142), "Business Combinations" and "Goodwill and Other Intangible Assets." FAS 141 replaces APB 16 and eliminates pooling-of-interests accounting prospectively. It also provides guidance on purchase accounting related to the recognition of intangible assets and accounting for negative goodwill. FAS 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Under FAS 142, goodwill will be tested annually and whenever events or circumstances occur indicating that goodwill might be impaired. FAS 141 and FAS 142 are effective for all business combinations completed after June 30, 2001. Upon adoption of FAS 142, amortization of goodwill recorded for business combinations consummated prior to July 1, 2001 will cease, and intangible assets acquired prior to July 1, 2001 that do not meet the criteria for recognition under FAS 141 will be reclassified to goodwill. Companies are required to adopt FAS 142 for fiscal years beginning after December 15, 2001. The adoption of these standards is not expected to have a material impact on the Company's results of operations and financial position.

In August 2001, the FASB issued FAS 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." FAS 144 replaces FAS 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of." The FASB issued FAS 144 to establish a single accounting model, based on the framework established in FAS 121, as FAS 121 did not address the accounting for a segment of a business accounted for as a discontinued operation under APB 30, "Reporting The Results of Operations Reporting The Effects of Disposal of a Segment of a Business, and Extraordinary Unusual and Infrequently Occurring Events and Transactions." FAS 144 also resolves significant implementation issues related to FAS 121. Companies are required to adopt FAS 144 for fiscal years beginning after December 15, 2001, but early adoption is permitted. The adoption of these standards is not expected to have a material impact on the Company's results of operations and financial position.

3. Financial Statement Details

Short-term Investments

Short-term investments consisted of the following at December 31 (in thousands):

	Amortized Cost Value	Market	Unrealized Gain
2001			
Obligations of U.S. government agencies	$ 21,592	$ 21,991	$ 399
Corporate debt securities	27,315	27,931	616
Asset backed securities	7,000	7,147	147
	$ 55,907	$ 57,069	$ 1,162
2000			
Obligations of U.S. government agencies	$ 12,504	$ 12,583	$ 79
Corporate debt securities	26,985	27,176	191
	$ 39,489	$ 39,759	$ 270

The estimated fair value of available for sale securities by contractual maturity at December 31, 2001 is as follows (in thousands):

	Amortized Cost	Market Value
Due in one year or less	$ 33,531	$ 34,257
Due after one year	22,376	22,812
	$ 55,907	$ 57,069

Realized gains from sale of securities were $116,000, for the year ended December 31, 2001. There were no gains or losses realized from the sale of securities for the years ended December 31, 2000 and 1999.

Receivables

Receivables are comprised of the following (in thousands):

	December 31,	
	2001	2000
Product	$ 1,569	$ 510
Sponsored research	2,714	490
Contract and grant	296	322
	4,579	1,322
Allowance for doubtful accounts	(199)	
	$ 4,380	$ 1,322

Inventories

Inventories consists of the following at December 31, 2001 (in thousands):

	December 31,	
	2001	2000
Raw materials	$ 796	$ 453
Work in process	1,436	493
Finished goods	3,956	1,543
	6,188	2,489
Reserve for obsolescence	(1,500)	(200)
	$ 4,688	$ 2,289

Finished goods includes $2.0 million and $1.5 million of NanoChip® Systems at December 31, 2001 and 2000, respectively, that are installed at customer sites where title has not transferred to the customer.

Property and Equipment

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

	December 31,	
	2001	2000
Scientific equipment	$ 5,356	$ 4,049
Office furniture and equipment	3,155	2,793
Manufacturing equipment	334	86
Leasehold improvements	4,336	4,211
	13,181	11,139
Less accumulated depreciation and amortization	(7,795)	(5,766)
	$ 5,386	$ 5,373

For the years ended December 31, 2001, 2000 and 1999, depreciation expense totaled $2.0 million, $1.8 million and $1.7 million, respectively.

Acquired Technology Rights

As of December 31, 2001 and 2000, acquired technology rights is presented net of accumulated amortization of $2,036,000 and $826,000, respectively.

Accrued Liabilities

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

	December 31,	
	2001	2000
Accrued compensation and benefits	$ 2,640	$ 1,840
Accrued legal fees	628	921
Other	1,648	1,334
	$ 4,916	$ 4,095

4. Commitments and Contingencies

Licensing and Research 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 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. 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. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute up to $28.5 million in cash over the ten-year period. At a minimum the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. The Company received $2.25 million and $1.0 million from Hitachi pursuant to this agreement during the years ended December 31, 2001 and 2000, respectively.

In June 2001, the Company entered into agreements with Aventis to create a new company, Nanogen Recognomics GmbH ("Nanogen Recognomics"). Nanogen Recognomics was established to develop new products and applications for the NanoChip® System. The Company is required to spend an aggregate of $5.5 million, at the rate of $1.1 million per year beginning April 1, 2001, for its own general technology development which benefits the commercialization and development of potential Nanogen Recognomics products.

The Company is a party to development site agreements with various entities whereby the Company may be obligated to pay license fees or royalties for any customer owned or licensed intellectual property is used to develop any Nanogen commercial products. None of these agreements individually are considered material.

Other Long-Term Debt and Purchase Commitments

The Company's manufacturing agreement with Hitachi, Ltd. ("Hitachi") requires that the Company provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of December 31, 2001, the Company had commitments to purchase approximately $4.9 million in NanoChip® Workstations through March 31, 2003. The requirement of future purchase commitments will be determined based on product demand and inventory levels.

In connection with the agreement entered into with Hitachi in July 2000, the Company is required to repay fifty percent of the total contributions made by Hitachi. Payment amounts are determined as a percentage to the Company's gross NanoChip® Cartridge sales until the liability is paid in full. This liability is non-interest bearing and will survive any termination of the agreement among the parties until it is paid. Amounts are reflected as "Other long-term liabilities" in the accompanying balance sheets and totaled approximately $1.6 million and $500,000 at December 31, 2001 and 2000, respectively.

In October 2000, the Company entered into an agreement with Hitachi for the service by Hitachi of the NanoChip® Molecular Biology Workstations after their sale or placement by the Company with the Company's customers. In December 2001, this agreement was amended to include, among other things, a commitment by the Company to provide Hitachi with a minimum of $200,000 in payments for maintenance service provided in fiscal 2002. This expense will be recorded during fiscal 2002 over the relative service periods.

Leases

The Company leases its facilities and certain equipment under operating lease agreements that expire at various dates through 2010. Rent expense was $783,000, $631,000, and $577,000 in 2001, 2000 and 1999, respectively.

The Company leases certain equipment under capital lease obligations. Cost and accumulated amortization of equipment under capital lease were $11,875,000 and $7,594,000 at December 31, 2001 and $9,481,000 and $4,153,000 at December 31, 2000, 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, 2001 are as follows (in thousands):

	Operating Leases	Capital Lease Obligations
2002	$ 1,037	$ 1,312
2003	891	798
2004	918	610
2005	1,173	345
2006	1,139	125
Thereafter	3,982	
Total minimum lease payments	$ 9,140	$ 3,190

	Operating Leases	Capital Lease Obligations
Less amount representing interest		375
Present value of future minimum capital lease obligations		2,815
Less amounts due in one year		1,060
Long term portion of capital lease obligations		$ 1,755

As of December 31, 2001, the Company has $1.4 million of available funding under equipment lease lines.

Litigation

In July 2001, the Company entered into a settlement agreement with Motorola, Genometrix, and MIT concluding the declaratory judgment action by the Company against Motorola, Genometrix and MIT and Motorola's counterclaim against the Company. In connection with the settlement, the Company has secured a license from Motorola to certain claims of the "939 Patent. In exchange, the Company made a one-time payment of $2.5 million in cash and issued 416,666 shares of the Company's common stock (valued at approximately $2.5 million based upon a per share price of $6.00, the fair market value on the date of settlement, as determined using the Black-Scholes valuation model) to the parties involved. The settlement does not include any cross-licensing provisions of the Company's technology to Motorola, Genometrix or MIT. The lawsuit and the counterclaim have now been dismissed.

For the years ended December 31, 2001, 2000 and 1999 costs associated with the litigation and settlement of the Motorola patent matter totaled $6.3 million, $0 and $0, respectively. Costs incurred during the year ended December 31, 2001, primarily consist of the settlement fee of $5.0 million in addition to legal fees incurred related to the litigation process.

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

In December 2000, CombiMatrix and Dr. Montgomery filed a motion to dismiss the Company's complaint. In January 2001, the motion was denied as to all claims except a claim for conversion, as to which the motion was granted without prejudice. The Company elected not to amend its complaint as

to the conversion claim. On March 9, 2001, CombiMatrix and Dr. Montgomery answered the Company's complaint, asserted various affirmative defenses and filed a counterclaim for breach of contract against the Company for unspecified damages allegedly arising from the filing of the complaint at a time when CombiMatrix had announced its intent to make an initial public offering of its shares. The counterclaim asserts that the Company, by filing its complaint, breached a settlement agreement entered into between the Company and Dr. Montgomery in 1995. On May 14, 2001, the Company filed a motion to dismiss CombiMatrix's counterclaim, which was denied on July 27, 2001. Discovery is currently ongoing.

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

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 advance over a four-year period. If the individual terminates his relationship with the Company, the unforgiven portion of the advances and any accrued interest are due and payable upon termination. As of December 31, 2001, $130,000 of these advances has been forgiven and $100,000 was repaid to the Company in 2000 in conjunction with the termination of the individuals relationship with the Company. Additionally, there is a full-recourse note receivable from Randy White, Chief Executive Officer, totaling approximately $150,000 accruing interest at a rate of 7%, compounded quarterly, and due in 2005 which is included in other assets. These advances and the note receivable are secured by second trust deeds on the personal residences of the respective officers. In addition, there are full-recourse notes receivable from certain officers totaling approximately $984,000 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, net", in the amount of approximately $603,000, in the accompanying consolidated balance sheets.

Mr. Birndorf, Chairman of the Board and an officer of the Company, is also a director of and investor in Graviton. Mr. Birndorf holds an approximate 10% 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. Mr. Garner, a director of Nanogen, is also a shareholder of Graviton, and holds less than a 1% interest.

Mr. Birndorf owns an aircraft which is leased by a local charter aircraft company. For the years ended December 31, 2001 and 2000, the Company paid approximately $420,000 and $137,000, respectively, to the local charter aircraft company for the Company's use of Mr. Birndorf's aircraft for business related travel. There were no payments related to Mr. Birndorf's aircraft made by the

Company in 1999. Mr. Birndorf receives $1,500 per hour of usage when his aircraft is leased to outside parties. Mr. Birndorf received approximately $207,000 and $59,000 for the years ended December 31, 2001 and 2000, respectively, as a result of the Company's use of Mr. Birndorf's aircraft. The Company believes that the terms of the charter arrangements are no less favorable to the Company than those that could be obtained from unrelated third parties, based on review of lease fees published by other charter aircraft companies.

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. The Compensation Committee of the Board of Directors approved a Company match in the form of Company stock equal to 25% or approximately $188,000 and 50% or approximately $335,000 of total employees' contributions for the years ended December 31, 2001 and 2000, respectively.

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. The Company contributed approximately $24,000 and $10,000 for the years ended December 31, 2001 and 2000, respectively, 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 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, June 2000 and June 2001, an additional 600,000 shares, 925,000 shares, 1,000,000 shares and 1,500,000 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 exercisable only as they vest. 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, 2001, 1,393,838 shares are available for future grant under the stock option plans. The following table summarizes stock option activity through December 31, 2001:

	Number of Shares	Price Per Share	Weighted Average Exercise Price Per Share
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
Granted	2,000,641	$ 3.70 to $12.09	$ 7.55
Exercised	(259,258)	$ .02 to $8.00	$ 3.34
Cancelled	(1,082,243)	$ .15 to $45.81	$ 24.36
Outstanding at December 31, 2001	2,951,564	$ .09 to $45.81	$ 12.61

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, 2001, 18,063 shares issued under the stock option plans were subject to repurchase by the Company.

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 on February 28, 2001 and receive a written promise from the Company to issue, on a one-for-one basis, new options which would be granted and priced at the fair market value on August 29, 2001. This plan applied only to options granted to employees of the Company (excluding executive officers and directors) between January 1, 2000 and February 27, 2001. These options are exercisable on August 29, 2001 or when they vest, whichever is later. The new options granted contain similar vesting schedules as the cancelled options. A total of 389,900 option shares were cancelled on February 28, 2001 and 281,600 option shares were subsequently granted on August 29, 2001 related to this plan.

Following is a further breakdown of the options outstanding as of December 31, 2001:

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
$.90 - $4.56	328,936	7.58	$ 3.72	198,734	$ 3.55
$4.74 - $6.15	404,500	9.50	$ 5.87	42,500	$ 5.82
$6.22 - $6.88	359,036	9.32	$ 6.32	135,765	$ 6.37
$6.88 - $7.47	363,405	8.80	$ 7.02	76,431	$ 7.06
$7.56 - $8.60	462,125	9.16	$ 8.26	26,184	$ 8.04
$8.75 - $11.94	388,078	9.19	$ 10.43	50,368	$ 11.45
$12.09 - $35.81	330,109	8.66	$ 19.68	137,962	$ 21.87
$41.13 - $45.81	315,375	8.10	$ 45.77	150,685	$ 45.78
$.90 - $45.81	2,951,564	8.84	$ 12.61	818,629	$ 15.96

Deferred compensation aggregating $4.3 million has been recorded for the excess of the fair value, as determined on the date of our initial public offering, of common stock issuable on exercise of options over the exercise price granted prior to April 11, 1998. The deferred compensation expense is being recognized over the vesting period of the options.

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 were subject to repurchase if the officer or key employee terminated employment with the Company prior to July 26, 2001. Deferred compensation aggregating $1.8 million 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 has been fully amortized as of December 31, 2001.

Compensation expense related to options granted prior to the effective date of our initial public offering, as mentioned above, and restricted stock awards, was $327,000, $947,000, and $1,773,000 for the years ended December 31, 2001, 2000, and 1999, respectively.

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 2001, 2000, and 1999: a risk-free interest rate of 5.0%, 6.0%, and 6.0%, respectively, a dividend yield of zero; volatility factors of the expected market price of the Company's common stock of 65%, 70%, and 70%, 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.

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,

	2001	2000	1999
Adjusted pro forma net loss	(38,438)	$ (26,197)	$ (26,443)
Adjusted pro forma net loss per share	(1.82)	$ (1.31)	$ (1.46)

The weighted average fair value of options granted during 2001, 2000 and 1999 was $4.05, $20.83, and $5.40 per share, respectively.

The pro forma effect on net loss for 2001, 2000 and 1999 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"), under which 300,000 shares of common stock were authorized for issuance under the Purchase Plan. In June 2001, an additional 150,000 shares were reserved 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 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, 2001, 2000 and 1999, 70,329, 75,773 and 35,216 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, 2001:

Stock options	4,345,402
Employee stock purchase plan	241,899
Warrants outstanding	315,863
	4,903,164

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.

8. Income Taxes

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2001 and 2000 are shown below. A valuation allowance of $51,662,000 has been established to offset the deferred tax assets as realization of such assets is uncertain.

	2001	2000
Deferred tax assets:		
Net operating loss carryforwards	$ 39,462	$ 29,862
Research and development credits	6,208	5,102
Capitalized research expenses	4,191	3,558
Accrued expenses	835	
Amortization	551	
Other, net	665	818
Total deferred tax assets	51,912	39,340
Valuation allowance for deferred tax assets	(51,662)	(38,970)
Net deferred tax assets	250	370
Deferred tax liabilities:		
Depreciation	(250)	(370)
Net deferred tax assets	$	$

At December 31, 2001, the Company has federal and state net operating loss carryforwards of approximately $109.7 million and $18.6 million, respectively. The difference between the federal and State tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for state tax purposes and the fifty-five percent limitation on state loss carryforwards. The federal tax loss carryforwards will begin expiring in 2006 unless previously utilized. The state tax loss carryforwards will begin to expire in 2002, unless previously utilized. The Company also has federal and state research and development tax credit carryforwards of approximately $4.4 million and $2.8 million, 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 $4,080,000. 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® Molecular Biology Workstation in specified research markets. Hitachi, Ltd.'s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip® Molecular Biology Workstation's components.

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

In July 2000, the Company executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, "Hitachi") to develop, manufacture and distribute additional potential products based on the parties' proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The

agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute up to $28.5 million in cash over the ten-year period. At a minimum the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. In addition, 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.

Revenue recognized under this agreement totaled $1.1 million and $417,000 for the years ended December 31, 2001 and 2000, respectively.

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.

In September 1999, the Company entered into two technology development programs with Aventis Research and Technologies, an affiliate of Hoechst AG ("Aventis"), which focus on the development of gene expression tools utilizing electronic bioarrays and the development of high throughput screening tools for kinase analyses. In total, the two programs provided $11.9 million in funding to the Company through December 31, 2001. Under these programs, the Company demonstrated quantitative, multiplexed and reliable gene expression monitoring on Nanogen electronic microarray system. Additionally, we delivered an electronic hybridization-based gene expression prototype detection system as well as a prototype system for analyzing protein kinases. This prototype system was sold during the fourth quarter of 2001 to an affiliate of Aventis. All project milestones established under these arrangements were completed as of fiscal year end 2001 at which time the agreements have expired. We do not expect to receive additional funding for these projects.

Revenue is primarily recognized under these agreements as expenses are incurred, and totaled $6.4 million, $7.7 million and $3.6 million for the years ended December 31, 2001, 2000 and 1999, respectively. Funding received in advance of incurred expenses is recorded as deferred revenue until the expenses are incurred, and totaled none and $123,000 at December 31, 2001 and 2000, respectively.

In June 2001, the Company entered into agreements with Aventis to create a new company, Nanogen Recognomics GmbH ("Nanogen Recognomics"). The company was established to develop new products and applications for the NanoChip® System. Nanogen Recognomics is sixty percent

owned by the Company and forty percent owned by Aventis and is based in Frankfurt, Germany. Aventis provided the first $5 million of funding for the operations of the new company and also contributed intellectual property in the form of eighteen patents. The Company is required to spend an aggregate of $5.5 million, at the rate of $1.1 million per year beginning April 1, 2001, for its own general technology development which benefits the commercialization and development of potential Nanogen Recognomics products. In addition, Nanogen Recognomics will own several patent applications filed jointly by the Company and Aventis. The Company has licensed certain aspects of its NanoChip® technology to the new company and will seek to commercialize new products and applications developed by Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics. In conjunction with the agreement to form Nanogen Recognomics, the Company issued a warrant to Aventis to purchase 315,863 shares of common stock exercisable through July 17, 2006 at an agreed upon price of $9.828 per share. The value of this warrant, as determined by the Black-Scholes valuation model, is equal to $1.2 million, is included in other assets in the accompanying consolidated financial statements and is being amortized over a two and a half year period.

The results of operations for Recognomics are fully consolidated in the financial statements included herein. The total operating loss of Recognomics is reflected as a reduction of the "minority interest in consolidated subsidiary" liability account and totaled $907,000 for the year ended December 31, 2001.

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"). 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 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 and $1.6 million for the years ended December 31, 2000 and 1999, respectively. No revenue was recognized under the agreement during the year ended December 31, 2001.

Élan Corporation, plc

In December 1997, the Company entered into an agreement with Élan Corporation, plc ("Élan") for a non-exclusive research and development agreement for the development of genomics and gene expression research tools. Pursuant to the agreement, Élan purchased Company common stock worth an aggregate of $5.0 million, at the initial public offering price, in the private placement in April 1998. Nanogen and Élan 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 Élan.

Revenue is recognized under the agreement as expenses are incurred, and totaled $568,000 for the year ended December 31, 1999. No revenue was recognized under the agreement during the years ended December 31, 2001 and 2000.

10. Contract and Grant Revenue

In September 1998, 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 ("DARPA") in an amount totaling approximately $2.4 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 August 2000, a second DARPA contract was granted to Nanogen in an amount totaling approximately $1.6 million over a two-year period. The contract is focused on developing an electronic sample preparation chip for the detection of biowarfare agents from blood samples. Revenue is recognized under these agreements as expenses are incurred and totaled $737,000, $1.1 million and $1.1 million for the years ended December 31, 2001, 2000 and 1999, respectively.

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 three-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. In October 2001, the Company entered into an additional cooperative agreement with USAMRAA in the amount totaling $1.5 million over a three-year period. The second cooperative agreement is to develop miniaturized electronic devices for isolation and detection of biological warfare and infectious disease agents. In conjunction with the agreements, funding provided by the agency is matched dollar-for-dollar with Nanogen funds. Revenue is recognized under these agreements as expenses are incurred and totaled $340,000, $6,000 and none for the years ended December 31, 2001, 2000 and 1999, respectively.

The National Institute of Justice, U.S. Department of Justice, provides funding for the development of a chip based genetic detector for rapid DNA-based identification of individuals. Revenue is recognized under these agreements as expenses are incurred and totaled $383,000, $599,000 and $432,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

11. Geographic Sales and Significant Customers

The Company has determined that, in accordance with Statement of Financial Accounting Standards No. 131, it operates in one segment as it only reports operating results on an aggregate basis

to chief operating decision makers of the Company. The Company had product sales by region as follows for the years ended December 31, 2001 and 2000 (in thousands):

	2001	2000	1999
Customer Location:			
United States	$ 1,097	$ 571	$
Europe	943	348	
Mexico	205		
Total	$ 2,245	$ 919	$

Revenue from customers representing 10% or more of total revenue during 2001, 2000 and 1999 is as follows:

	2001	2000	1999
Sponsored research:			
Customer A	57%	69%	44%
Customer B	10%	4%	

12. Quarterly Financial Data (unaudited)

Summarized quarterly financial data for fiscal 2001 and 2000 are as follows (in thousands, except per share data):

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Fiscal 2001				
Revenues	$ 2,939	$ 2,715	$ 3,219	$ 2,296
Operating expenses(2)(3)	10,538	15,561	11,383	10,619
Loss from operations(3)	7,599	12,846	8,164	8,323
Net loss	6,279	11,750	7,020	7,452
Net loss per share basic and diluted	$ (.30)	$ (.56)	$ (.33)	$ (.35)
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)

(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 expenses rather than cost of sales as required.

(3)

The amounts reflected as "minority interest in loss of consolidated subsidiary" in the Form 10-Q filed for the three and nine month period ended September 30, 2001 and amounts for the three and twelve month period ended December 31, 2001 have been reclassed to operating expenses as an offset to research and development expenses at year end. Amounts reclassed totaled $485,000 and $422,000 for the three month period ended September 30, and December 31, 2001, respectively.

NANOGEN, INC.
EXHIBIT INDEX

Exhibit No.	Description
23.1	Consent of Ernst & Young LLP, independent auditors.

QuickLinks