NANOGEN INC
Form 10-K
March 31, 2003

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 year ended December 31, 2002

OR

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

For the transition period from to

Commission File Number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

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

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 $0.001 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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act),

YES o NO ý

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 June 28, 2002 (the last day of the registrant s most recently completed second fiscal quarter), as reported on the Nasdaq National Market was approximately $20,142,311. 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 22,058,579 as of March 24, 2003.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its annual meeting of stockholders to be held in 2003 are incorporated by reference in Items 10, 11, 12 and 13 of Part III of this Form 10-K.

NANOGEN, INC.

FORM 10-K

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SIGNATURES

PART I

Item 1. Business

Forward Looking Statement

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, would, expect, envision, potentially, variations of such words and similar expres to identify such forward-looking statements. The forward-looking statements contained in this Form 10-K include, but are not limited to, statements about matters including the following: (i) the development of the markets and demand for our products and services; (ii) our product development plans, including the introduction of new products, and anticipated activities designed to pursue these plans, including collaborations and other corporate partnering arrangements; (iii) our ability to generate substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements; (iv) the ability of our product platform to affect the market and become an industry standard; (v) our ability to generate license and other fee revenue in the future; (vi) the amounts we invest in research and development activities in the future; (vii) future levels of operating expenses associated with our business; (viii) future levels of interest income; (ix) any amounts we may be able to realize from the liquidation of our investments, including our investments in short-term securities; (x) operating results of joint ventures and other corporate partnering arrangements; (xi) the amounts and timing of our contractual obligations and capital commitments and (xii) our future capital needs and our ability to fund those needs. 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.

Our internet address (presented as a textual reference only) is www.nanogen.com. We make available through our website, free of charge, an annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed with or furnished to the SEC under Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we file them with, or furnish them to, the SEC.

Overview

Molecular Diagnostics Market

Increased awareness of the role of genes in regulating the functions of living organisms has generated a worldwide effort to identify and sequence genes and genomes of many organisms, including the estimated three billion nucleotide pairs of the human genome. In June 2000, the effort led by the Human Genome Project (sponsored by the Department of Energy and the National Institutes of Health) resulted in a first complete draft of the human genome sequence. While it is anticipated that many years of additional research will be required to understand the specific functions and roles in disease of each of these genes and their patterns of interaction, this research, commonly referred to as genomics, is leading to a new healthcare paradigm where disease is understood at the molecular level. It is believed that the use of genomics will lead to the introduction of new therapies, the development of targeted therapeutics and an abundance of new screening tests that will, in turn, shift the focus of medicine to proactive from reactive. Molecular diagnostic tools are integral to rendering genetic information accessible to researchers and

clinicians.

The market for molecular diagnostics tools, assays and other products has been estimated by an independent study conducted by industry experts Frost & Sullivan to be approximately $1.9 billion in 2002 and is predicted to grow to

$3.1 billion by 2005. Of the $1.9 billion spent in 2002, the Company believes that approximately seventy-five percent (75%) was spent on infectious disease testing products for such diseases as Human Immune Deficiency Virus (HIV) and Hepatitis C Virus (HCV) and the remaining twenty-five percent (25%) was spent for other products such as those used in genetic testing. As the molecular diagnostics market grows, we expect human genetic testing to represent an increasingly larger percentage of this annual amount.

The molecular diagnostics market currently primarily consists of customers in (1) research institutions such as universities, research hospitals, private companies and government institutions, (2) high complexity CLIA (Clinical Laboratory Improvements Act)-certified clinical diagnostics laboratories and (3) clinical diagnostics laboratories in hospitals, private companies and government clinics. Such customers are developing tests and assays to screen, predict, diagnose, treat or monitor individuals who have certain single nucleotide polymorphisms (SNP), short tandem repeats (STRs), insertions, deletions or other genetic mutations that are correlated with various disease states. Research customers normally develop and perform assays that are designed to correlate various SNPs or other mutations with certain disease states. High complexity CLIA-certified laboratories, which are regulated under the federal CLIA rules, normally develop and validate their own home brew tests or they may run assays purchased from platform manufacturers or others. In the development and validation of a home brew test, a laboratory may utilize Analyte Specific Reagents (ASRs). ASRs are reagents manufactured under the good manufacturing practices regulations and are subject to Food and Drug Administration (FDA) ASR regulations. As such, ASRs do not require the filing of a 510(k) or PreMarket Approval (PMA) application. Clinical diagnostic laboratories normally run clinical assays to help physicians diagnose and treat various diseases and typically such assays require a 510(k) or PMA application prior to being offered for sale or distribution.

Molecular diagnostics customers are seeking a versatile, accurate, simple and cost-effective platform technology on which to develop, validate and run simple and complex research and diagnostics tests and assays. While there are a number of platform technologies currently available to such molecular diagnostics customers, including those utilizing gel-based techniques such as Restriction Fragment Length Polymorphisms (RFLP), sequencing using capillary and gel-based techniques, dot-blot and glass slide based arrays, real-time PCR (polymerase chain reaction) methods and enzyme-based micro-well assays, it is our understanding that these technologies do not consistently meet their basic customer requirements. These platforms lack the versatility to perform both simple and complex assays customers are seeking a platform capable of developing, validating and running a broad menu of research, ASRs and clinical diagnostic tests. The molecular diagnostics customers also demand a technology platform that consistently provides results at a level approaching 100% accuracy. They also insist on operational simplicity, so that the laboratory technicians of any skill level may be used for its operation. Finally, they are seeking a cost-effective technology platform that will assist in optimizing its capital and labor costs.

We believe that the technology used to develop human genetic testing could also be applied in the future to other markets such as food, water and animal testing among other fields.

The Company

Nanogen develops and commercializes molecular diagnostics products and tests for the gene-based testing market for sale primarily in the United States, Europe and the Pacific Rim. By integrating microelectronics and molecular biology into a core proprietary technology platform, the Company seeks to establish the unique, open-architecture design of its primary products, the NanoChip® Molecular Biology Workstation and the NanoChip® Cartridge (collectively, the NanoChip® System) as the standard platform for molecular identification and analysis. Nanogen also seeks to become a leading supplier of molecular diagnostics testing products by developing ASRs and other commercial applications for the NanoChip® System. The Company continually conducts research and development by itself and with its subsidiary and third parties, to improve the NanoChip® System and to extend its technology to other applications such as biodefense, forensics and drug discovery (protein kinases).

Nanogen believes that its technology platform provides a key advantage over conventional manual and mechanical platforms in that it provides an accurate, simple, versatile and cost-effective integrated microelectronic system that is capable of improving the quality of molecular diagnostic testing while reducing the overall cost of such testing. At the heart of Nanogen s technology is a silicon chip called the NanoChip® Electronic Microarray. Each Electronic Microarray has 100 mircrolocations or test sites upon which genetic tests can be conducted. DNA or RNA is moved and concentrated by controlling the electric current at each test site, improving accuracy, speed

and flexibility. This electronic concentration of molecules greatly accelerates molecular binding at each test site. In addition, our technology allows the simultaneous analysis of multiple test results, or multiplexing, from a single sample. Current applications of the NanoChip® Electronic Microarray include SNPs, STRs, insertions, deletions and other mutation analyses.

Nanogen s mission is to deliver high quality, innovative molecular diagnostics products and services. The Company s current commercially available products include (1) the NanoChip® Molecular Biology Workstation, an automated, multi-purpose instrument primarily used for DNA-based analyses, (2) the NanoChip® Cartridge, which incorporates the NanoChip® Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules, (3) various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis and hereditary hemochromotosis and (4) Nanogen s Assay Toolbox™, that is designed to help customers develop tests on the NanoChip® System. The Company also has several other ASRs and applications of its proprietary technology under development. The Company provides technical support and field applications assistance to service and support its customers.

Nanogen is a Delaware corporation and its stock is listed on the Nasdaq National Market under the symbol NGEN . Its corporate offices are located at 10398 Pacific Center Court, San Diego, California 92121. Our main telephone number is 858-410-4600.

Our Technology and Relevant Markets

Limitations of Current Molecular Diagnostic Assay Technologies

The initial technique for the analysis of genetic variations was hybridization, which was first developed in the 1970s. Hybridization relies on the principle that a unique piece of DNA will bind, or hybridize, most strongly to its exact complement. In hybridization, short, synthetic segments of DNA, also known as probes, are used to locate and bind to their counterparts within a mixture of sample DNA or RNA. Hybridization is often performed using instrumentation that incorporates a detection medium that provides a signal to indicate whether the probe has hybridized to the sample DNA or RNA. However, initial hybridization techniques had several limitations. Even minute changes in testing conditions, could dramatically affect the outcome of the hybridization reaction and, therefore, the reliability of test results.

Beginning in the 1980s, various techniques were invented with the objective of improving the reliability of hybridization. However, these methods did not generally provide a signal that was sufficient to be easily detectable. Therefore, in order to use these methods, it was necessary to first copy or amplify the segment of DNA or RNA to be analyzed using a technique known as polymerase chain reaction, or PCR. These initial techniques have significant limitations, including:

Highly Complex Product Development Process: Conventional methods frequently require trial and error testing to validate tests or product designs. Therefore, with conventional technologies, the process of developing a test, or product, for analyzing a specific genetic variation is highly complex and cannot be automated easily.

Inaccuracy: Accuracy is essential to adequately detect and quantify genetic variations, which may involve the analysis of thousands of genetic variations per individual. Conventional methods can result in one or more data points in 10 being incorrect. 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 challenging to automate.

Lack of Flexibility: Many of the conventional analysis methods use a passive array in which what is done to one site on the array, must be done 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 utilize every site on the array.

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

Lack of Menu: Many of the existing methods of analysis require customers to purchase different instruments or technologies for each analysis performed.

Beyond the limitations indicated above, in order to capture and expand the market for genetic analysis, one must provide cost-effective and highly reliable tests.

Despite recent advances in technology, many bioassays are too specialized or inflexible to be used throughout the various departments of a diagnostics or research laboratory. Current bioassay tools were designed for large scale data generation and the automation of repetitious tasks such as very high throughput discovery. In addition, many of these systems are not useful in molecular, protein, enzyme, cell biology, and forensics laboratories. These technologies 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.

The Nanogen Microelectronic Solution

Today, clinical and research laboratories use a number of different platforms to perform a wide-range of different molecular tests. We are marketing the NanoChip® System based on our proprietary microelectronic technology. The Company believes that the NanoChip® System provides the following eight major advantages:

Accuracy: Accuracy is critical in laboratory analysis. To date, the NanoChip® System has been shown to be exceptionally accurate. Additionally, the NanoChip® System embodies the technology that allows multiplexing capability. This means that it allows two or more tests to be performed simultaneously, speeding results to the laboratory technician. This capability has been critical in developing the ASRs for use in detecting the 25 mutations associated with the diagnosis of cystic fibrosis.

Simplicity. The NanoChip® System is fully automated and once programmed and validated by the customer, has simple point and click software. It allows the laboratory technician to load samples and easily modify parameters to facilitate minimal hands on time.

Versatility: One of the key attributes that positions the NanoChip® System as the platform for molecular diagnostics is its unique, open architecture. The flexible, addressable nature of the NanoChip® Cartridge enables assay development from a variety of sources. We believe this is particularly important to customers in an emerging and

rapidly growing market like molecular diagnostics, where new markers are constantly being introduced. The ability of a molecular laboratory to respond quickly to customers who request a test for a new marker without having to procure a new platform is key to their success.

Profit Incentive: Nanogen s focus is to offer a compelling value proposition to end users by providing laboratories an alternative to sending out their tests to third party laboratories. With Nanogen products, these smaller laboratories should have the potential to earn additional profits by handling tests within their own facilities.

Fast Assay Design: Experimental design of tests and assays on the NanoChip® System is relatively straightforward. Our customers can develop, program and validate assays in their own laboratories, allowing for faster turnaround times (i.e., days versus weeks) for solutions to complex analyses.

Ease of use: Assays are easy to develop, validate and perform on our NanoChip® System. Our fully automated Loader allows the simultaneous programming and testing on up to four NanoChip® Cartridges. A loaded Cartridge is inserted and then analyzed on the Nanogen Reader. The NanoChip® System also includes proprietary software to automate testing operation. All test design and development must be validated by the end user prior to reporting any results. Data interpretation that is user defined is clear-cut and presented in a user-friendly format.

Throughput: The NanoChip® System s ability to program as many as 100 test sites per Cartridge (and up to four Cartridges per run) allows for higher throughput than is achievable with many competitive technologies. As testing volumes in molecular laboratories continue to grow, throughput is becoming increasingly important. This throughput capacity permits highly efficient workflow for many biomedical applications in a variety of laboratory settings. We believe that the NanoChip® System is scalable to eventually utilize a Cartridge with 400 test sites at a time.

Cost effectiveness: The NanoChip® System has been designed to be a cost-effective solution for most molecular testing. The NanoChip® System s custom features allow users to employ their own reagents or Nanogen s ASRs in designing and validating assays for their specific purposes. Moreover, much of 2002 was dedicated to developing a menu of ASRs that many laboratories perform routinely. Consumables such as ASRs represent a significant revenue stream for companies providing successful platforms. 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.

Nanogen s Core Technology

Nanogen s patented microelectronics-based technology uses the natural positive or negative charge of most biological molecules. Applying an electric current to individual test sites on the NanoChip® System enables rapid movement and concentration of the molecules. Nanogen s technology involves electronically addressing biotinylated DNA samples, hybridizing complementary DNA and applying stringency to remove nonspecifically bound DNA after hybridization. The NanoChip® System technology provides an open platform that allows customers to effectively develop, validate and run common assays as well as customize their own tests.

The NanoChip® System can integrate in a single platform the following electronic operational features:

Electronic addressing

Electronic addressing involves placing charged molecules at specific test sites on a NanoChip® microarray. When a biotinylated sample solution is introduced onto the array, the negatively charged sample rapidly moves to the selected positively charged sites, where it is concentrated and bound to the streptavidin in the permeation layer. The array is then washed and another sample can be added. Site by site, row by row, an array of samples are assembled on the array. Such user-definable microchip arrays allow the customer to respond quickly to the ever evolving list of genes to be tested.

Electronic concentration and hybridization

In a standard SNP assay, following electronic addressing, red and green fluorescently-labeled reporter probes are used to discriminate between wildtype, heterozygote and mutant DNA. The ability of the NanoChip® technology to very specifically control binding of samples to reporters is a key feature of the platform.

Stringency control

Stringency control enables removal of unbound and nonspecifically-bound DNA quickly and easily after hybridization, providing quality control and ensuring that any bound pairs of DNA are truly complimentary. Nanogen s technology allows the customer to select electronic, thermal or chemical techniques, depending on the application, for precise, accurate stringency control. This provides extremely high discrimination and confidence in results.

Electronic multiplexing

The multiplexing feature is an extension of the open platform of the NanoChip® System. The customer may analyze multiple genes from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site.

The ability to control individual test sites permits biochemically unrelated molecules to be used simultaneously on the same microchip array. Conventional DNA arrays do not have this feature all process steps must be performed on an entire array. Nanogen s microelectronic array technology delivers increased versatility over 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. Nanogen was 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 also believe that SDA may potentially provide our customers with operational benefits such as being easier to use as well as cost advantages due to the high cost of the most common amplification method. Although the current NanoChip® System does not utilize SDA, we expect our next generation instrument to support SDA applications.

Commercialization Strategy: Platformation™

What is happening today in molecular diagnostics closely mirrors the activities that occurred in clinical chemistry laboratories thirty years ago. The first clinical chemistry tests were done by hand they were time intensive and required great skill not unlike some of today s molecular diagnostic assays. Then single assay systems were developed that reduced hands-on time and hastened the reporting of results to physicians. When multiple assay systems were introduced, a series of assays could be performed simultaneously. And finally clinical chemistry platforms were developed that enabled all chemistry assays to be performed on one system, further streamlining the laboratory. The bottom line: a transformation from manual assays to automated accurate systems that could perform multiple assays simultaneously, increasing the reporting efficiency and reducing the time to a reportable result.

Nanogen has focused on capturing the market right from the start by creating an open molecular diagnostics platform that we believe has the potential to become the gold standard of the industry. The process of consolidating a number of various molecular tests onto one platform is what we have termed Platformation . Nanogen s business strategy utilizes Platformation along with a razor/razorblade approach to sales and distribution of our products. The Company continually seeks to increase the installed base of the NanoChip® Systems and to establish our platform as a standard for the molecular diagnostics industry in order to reap the benefits of the higher margin profits on consumables such as the NanoChip® Cartridges, ASRs and other products. The NanoChip® System s open architecture facilitates development of molecular tests from multiple sources, driving the growth in assay development far beyond where Nanogen could take it on its own. From customers to development partners and licensing agreements, all act as an inspired research arm for NanoChip® assay development.

The NanoChip® System could transform molecular diagnostics, bringing to it the speed, efficiency and accuracy of a robust platform. As this market area grows and Nanogen s market share increases, the NanoChip® System could generate multiple revenue sources that will fuel next generation systems and the growth of the Company. Thus,

Platformation is not only the framework for tomorrow s molecular diagnostics laboratory; it is the foundation of Nanogen.

Nanogen s strategy to establish the NanoChip® System as the leading molecular diagnostics platform is five-fold. First, the Company seeks to increase the installed base for the NanoChip® System for use in high complexity CLIA certified and research laboratories through direct sales, reagent rental and cost per test agreements as well as development site agreements. Second, Nanogen seeks to continue to increase the breadth of its ASR menu on its NanoChip® System. We will determine on a case by case basis whether or not to file with the FDA for approval or clearance to market its first FDA-cleared product for sale to clinical diagnostics laboratories. Third, Nanogen intends to develop other products on its platform to facilitate customers development of their own home brew

tests on the System. Fourth, the Company plans to make improvements to the NanoChip® System and to increase the depth of other applications of the NanoChip® Electronic Microarray technology for other uses. And fifth, Nanogen intends to continually seek out strategic collaborations in order to strengthen our product menu, penetrate new markets, obtain new intellectual property and seek to enter the molecular diagnostics provider services market when appropriate.

Increase Installed Base of NanoChip® Systems

Nanogen seeks to increase the installed base of its NanoChip® Molecular Biology Workstation and to establish the NanoChip® System as the standard platform for the molecular diagnostics industry, in order to reap the benefits of the higher margin profits on consumables, such as the NanoChip® Cartridges, ASRs and other products. The Company has provided its customers with three main types of commercial transactions to obtain the NanoChip® System: outright sales, reagent rental agreements and/or cost per test agreements (collectively, reagent rentals) and development site agreements.

Nanogen typically sells its NanoChip® Systems directly to its customers through the Company s sales representatives in the U.S. or Europe or through distributors in other countries throughout the world. As of December 31, 2002, the Company had sold 45 NanoChip® Systems.

The sale of NanoChip® Systems is only one piece of the revenue stream. As is common with clinical instruments, the consumables form a substantial revenue segment. NanoChip® Cartridges and those Cartridges and ASRs that are a part of each customer developed and validated assay will normally be ordered by customers to meet their testing demand. Nanogen anticipates demand to grow rapidly for certain ASRs, such as those for the detection of mutations in the CFTR gene that are associated with cystic fibrosis and the detection of mutations in the ApoE gene that are associated with Alzheimer s disease. While there may always be customers who wish to purchase the NanoChip® System outright, it is our belief that there will be many more within the high complexity CLIA-certified clinical laboratory market that will want to amortize the cost of the instrument over several years. These arrangements, called reagent rentals, have been the standard for the clinical instruments industry for the past 40 years, fueling the growth of industry leaders such as Beckman-Coulter, Abbott and Roche. Such agreements can span from three to five years and involve establishing a minimum monthly consumables ordering level. Based on that level and the term of the agreement, a premium is added to the cost of the consumables so that the total capital equipment cost of the NanoChip® System is recouped by the end of the agreement. The advantage of reagent rental agreements for Nanogen is that it locks in a minimum revenue flow over the term of each agreement after a normally brief validation period that normally varies from 30 to 90 days. Nanogen believes that many of its customers will increase their consumable ordering levels as new ASRs and ultimately FDA-cleared assays are made available. Because the customer s set premium level will be incorporated into each of these additional orders, Nanogen has the opportunity to obtain revenue over and above the cost of the original system during the life of the agreement. As of December 31, 2002, the Company had entered into 12 reagent rental agreements with customers, all of which were signed in 2002 and all of which were contingent upon the acceptance of the Company s ASR for the CFTR gene.

The increased use of reagent rental agreements is an indication of the Company s strategy to target more commercial transactions with high volume high complexity CLIA-certified laboratories. High complexity CLIA-certified clinical reference laboratories are traditionally the early adopters of new, innovative systems that bring efficiency to labor intensive assays. The Company s success in reaching beyond this core group into research hospitals and leading medical centers is a testament to the desire of these groups to enter into this testing segment.

The final type of agreement whereby a customer may use and eventually purchase a NanoChip® System, is a development site agreement. These development sites are normally with leading research organizations and laboratories or companies that will provide us with certain rights to commercialize the discoveries made using the our platform. These relationships have been focused on the discovery of the associations of specific genetic variations with major disease states, including cancer, hypertension, inflammation and cardiovascular disease. Our strategy is to offer our research collaborators early access in exchange for the rights to commercialize the discoveries they make using it. These rights may enable us to offer new genetic products for clinical research and clinical diagnostic applications if any are developed from the collaboration. Pursuant to development site

agreements, Nanogen installs a NanoChip® System at a customer site for a period ranging typically from six to nine months during which time the customer can test the System by developing, validating and running certain assays on the System. For the use of the System during this period, the Customer assigns to Nanogen rights to improvements to the System and Nanogen and the customer agree on certain Nanogen rights to any assays developed thereon. Once the development site period has terminated, the customer may then either return the System to the Company or purchase it through a sale or a reagent rental transaction. As of December 31, 2002, the Company had entered into 32 development site agreements with customers and converted 10 into commercial transactions that included 5 sales and 5 reagent rental transactions.

Increase the Breadth of the ASR Menu on the NanoChip® System to further Penetrate the Clinical Diagnostics Market

The second of Nanogen s five strategic goals is to increase the breadth of the NanoChip® System s ASR menu for commercial applications. Each Nanogen ASR includes specific reagents that enable the customer to develop, validate and perform a molecular test that determines the presence or absence of certain gene mutations associated with certain disease states. As part of Nanogen s Platformation strategy, the Company seeks to increase the number of commercially available ASRs that it provides its customers so as to both increase the attractiveness of the NanoChip® System to seek to gain some of the higher profit margins normally associated with the sale of such consumables.

During 2002, Nanogen introduced its first commercially available ASRs, that for Factor V Leiden, a gene mutation associated with the detection of thrombosis. The Company also undertook great efforts to develop a number of other ASRs. The Company internally developed and tested ASRs for mutations in the CFTR gene associated with the diagnosis of cystic fibrosis, for the mutations in the HFE gene associated with hereditary hemochromotosis and for a multiplexed Factor II/Factor V ASRs, all of which the Company introduced commercially in the first quarter of 2003.

Also, during 2002, Nanogen entered into license agreements and began development work on either ASRs or research reagents involving the following: ASPA gene mutations related to the diagnosis of Canavan disease (with the assistance of Nanogen Recognomics), the ApoE gene mutations associated with the diagnosis of Alzheimer s disease and for mutations in genes associated with the detection of beta thalasemia. Nanogen has also acquired rights from a third party to certain content potentially related to the diagnosis of epilepsy. The Company plans to introduce ASRs for detection of mutations in the ASPA gene associated with the diagnosis of Canavan disease, ASRs for ApoE and research reagents for the detection of mutations associated with beta thalasemia in the second quarter of 2003.

In addition, we expect to enter into more licensing and other collaborative agreements relating to securing rights to mutations to genes necessary to develop other ASRs.

In the future, we presently intend to file with the FDA for clearance to market both the NanoChip® System and certain of our products for clinical diagnostics. Nanogen is currently putting in place the internal procedures and groundwork necessary to submit such products for clearance in the near future. This may be a costly and time consuming process.

Development and Introduction of Research Products

Nanogen s third strategic goal is to develop products on its platform that facilitate customers development and validation of their own home brew tests on the NanoChip® System. In 2002, taking advantage of our open architecture system, we internally developed our Assay Toolbox™ product that provides research customers with the necessary tools and most of the reagents to develop and validate their own home brew tests on our System and take advantage of our open architecture system. We commercially launched the Assay Toolbox™ product in the first quarter of 2003 and believe that this product will help us further our Platformation goal. We also intend to develop and commercialize other valuable products for customers. 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 develop and validate diagnostic tests to meet their individual research needs and help drive development of novel applications.

Improve the NanoChip® System and increase the depth of other applications of the NanoChip® Electronic Microarray technology.

Nanogen s fourth strategic goal is to develop improvements to the NanoChip® System over time through our engineering and advanced technology groups along with the manufacturer of the NanoChip® System, Hitachi High Technologies. Initially, improvements will be focused on cost reduction and throughput. In the long term, we would like to develop sample-to-answer systems which integrate otherwise time-consuming and labor-intensive sample preparation procedures on the disposable cartridge. The availability of this lab-on-a-chip technology would fulfill a substantial unmet need in both academic research and commercial sectors.

We also intend to continue the development of other technologies that may complement and improve the NanoChip® System, utilize the NanoChip® Electronic Microarray technology or are designed and developed by our employees, subsidiaries or collaborators. Such products include those currently developed by Nanogen in the forensics, biodefense, and protein kinase as well as those developed by Nanogen Recognomics in the fields of synthetic oligonucleotide chemistry and advanced molecular biology.

Continue to establish strategic collaborations in order to strengthen our product menu, penetrate new markets, obtain new intellectual property and enter the service market when appropriate.

Our fifth strategic goal is to continue to enter into collaborations to expand applications of our technology platform and to accelerate the commercialization of products in order to strengthen our product menu, penetrate new markets, obtain new intellectual property and enter the molecular diagnostics service provider market when appropriate. We will pursue additional collaborations in various forms, including research and development agreements, licensing agreements and joint ventures. These collaborations permit integration of the technology and resources of our partners with our technology, while allowing Nanogen to pursue diagnostics and genomics opportunities outside the scope of these collaborations.

Nanogen s Current Products

NanoChip® System s Components

The Company is seeking to establish the NanoChip® System as the standard platform for the detection of genetic mutations and to develop applications for future clinical use. Nanogen markets its NanoChip® Molecular Biology Workstation to scientists and molecular diagnostics laboratories. The heart of Nanogen s offering is based on three different components: the Workstation, Cartridges and software.

The NanoChip® System consists of a consumable Cartridge containing a proprietary semiconductor microchip, the NanoChip® Electronic Microarray, a fully automated instrument and imbedded software that can be programmed by the end-user to control all aspects of microchip operations, processing, detection and reporting. The System has been designed so that once programmed, the end-user need only insert of a consumable Cartridge containing a test sample into the instrument and all subsequent steps may be handled automatically under computer control.

The NanoChip® 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. 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. We are additionally developing a cartridge that employees 400 different test sites on a single NanoChip® Electronic Microarray for our next generation instrument.

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 electrochemical environment near the electrode surface and provides the chemistry necessary for attachment of the samples.

Samples

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 samples can be addressed on the same microchip, allowing multiple tests to be processed on the same Cartridge. Our open architecture approach allows the customer to address their specific samples onto a microchip to perform individualized analyses.

The NanoChip® Molecular Biology Workstation

Our fully integrated NanoChip® 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 develop, validate and select protocols from a graphical user menu which controls all microchip operations, tabulates test results and prints test reports based upon user-defined inputs.

Microchip Loader

Our System includes a Cartridge/microchip Loader that will allow users to electronically address their own samples to selected 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 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

Within the fluorescent array scanner component of the System, the fluidics function 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 test selection, test operation, fluorescent signal detection and signal processing, calculation of assay results and report generation. The end-user must develop and validate the protocols used by the software as well as define the parameters used to calculate results and generate reports. Each of the individual array locations is separately controlled by the microprocessor. Fluorescent signals emanating from positive test sites are scanned, monitored and quantified.

NanoChip® Analysis Process

Cartridge

The electronic microchip 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.

Electronic addressing

Users design, create and validate their own genetic tests on the microelectronic chip with our automated System. A 96 well or 384 well microtiter plate containing genetic sequences is placed in the Loader. The System then automatically electronically addresses the microchip with user-defined tests.

Hybridization and stringency

Users may add test samples to the Cartridge and insert the Cartridge into the Reader. The customer may then select to have the instrument automatically perform hybridization and the appropriate stringency control is selected by the user, chemical, thermal or electronic. 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 easy-to-interpret output is available based upon user-defined inputs. 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 tests based on previous experimental results.

Applications Manager Software (AMS)

Nanogen plans to offer by mid 2003 a separately priced software package designed to streamline routine or frequent testing for the same genetic markers. AMS enables users to run protocols they ve written and validated for the NanoChip® System in a simplified, menu driven, point-and-click fashion. This supplemental software offers the ease of use required of those laboratories that run the same set of tests on a regular basis. It was designed in response to high complexity CLIA certified clinical

laboratories that are frustrated by research orientation of the currently available software. We believe that this software will provide a significant competitive advantage for the NanoChip® System.

Analyte Specific Reagent (ASRs)

ASRs are the specific reagents that permit either research or high complexity CLIA certified laboratory customers to develop, validate and run certain SNP assays. Under the ASRs model, we sell not only NanoChip® Cartridges, but also the specific reagents that can be used to develop, validate and perform DNA-based tests. We expect to further increase the potential revenue from each analysis performed with the launch of the SDA method of amplification for use on our next generation instrument. We also believe that by providing ASRs for tests that are in high demand, such as those developed for the CFTR gene mutation associated with the diagnosis of cystic fibrosis, we are in a better 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, ASRs, 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.

We currently have four ASRs that are commercially available for (1) Factor V Leiden launched in 2002, (2) Factor II/Factor V multiplex launched in the first quarter 2003, (3) CFTR launched in the first quarter 2003 and (4) HFE launched in the first quarter 2003. Below is a more detailed description of the ASRs:

Factor V Leiden ASRs

Nanogen s Factor V (Leiden) ASRs determine if the G1691A mutation on Factor V (Leiden) gene is present in a sample by detecting the presence of a certain characteristic gene polymorphism. The Factor V (Leiden) ASRs consists of active reagents that CLIA-certified high complexity laboratories can use developing and validating their tests to detect this mutation. Factor V is a gene mutation associated with thrombosis. Thrombosis is defined as the formation, development or presence of a blood clot (thrombosis) in a blood vessel or the heart. Blood clots are associated with heart attack, stroke, and other severe health complications. Complete blockage of the vessel can lead to an embolism. Mutations in the Factor V (Leiden) gene have been linked to thrombotic events.

Factor II/Factor V Multiplex ASRs

Nanogen offers ASRs for the detection of two genetic mutations associated with thrombosis: the G1691A mutation on the Factor V (Leiden) gene and the G20210A mutation on the Factor II (Prothrombin) gene. CLIA certified high complexity laboratories may use the reagents to create and validate laboratory developed tests for detection of these two mutations. Currently, Nanogen is the only provider of the Factor V (Leiden) and Factor II (Prothrombin) mutations in a multiplexed format.

Nanogen s Factor II/Factor V ASRs are multiplexed ASRs meaning that the customer can develop and validate multiple Factor II and Factor V gene mutations from a single test site (representing one sample) or from multiple test sites (representing different samples). The customer also has the ability to electronically address multiplexed amplicons to a single test site. The ability to control individual test sites permits biochemically unrelated molecules to be used simultaneously on the same microchip array. Conventional DNA arrays do not have this feature; all process steps must be performed on an entire array. Nanogen s Factor II/Factor V ASRs are a prime example of how our unique microelectronic array technology delivers increased versatility over conventional methods.

CFTR ASRs

Nanogen s CFTR ASRs offer the customer the ability to develop and validate a test for the detection of the **25 CFTR mutations recommended by American College of Medical Genetics ACMG)/**American College of Obstetrics and Gynecology (ACOG) as part of a high complexity CLIA-certified laboratory homebrew assay.

These mutations are associated with the diagnosis of cystic fibrosis. Our ASRs are based upon the first molecular based test recommended for nationwide screening of healthy individuals. In early 2003, we completed beta-site testing of our set of ASRs for use in developing and validating tests for the mutations in the CFTR gene, which are associated with the diagnosis of cystic fibrosis, and commenced a controlled release of the product to market. Many people carry a single cystic fibrosis gene mutation, and they do not experience any significant health problems. In the general population, approximately 1 in 31 Americans carries the gene mutations. This is the reason ACOG announced 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 CFTR mutation, then further testing of the prospective father is warranted. When both parents are carriers, they have a 25% 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 believe that the ACOG recommendations may drive a significant increase in genetic testing for gene mutations associated with cystic fibrosis.

HFE ASRs

Nanogen offers ASRs for the development and validation of a test to detect the three mutations associated with hereditary hemochromatosis (HH). Reagents include oligonucleotides for the detection of nucleotides corresponding to the C282Y, H63D, and S65C mutations of the HFE gene. CLIA-certified high complexity laboratories may use the reagents to create and validate laboratory developed tests (LDT) for HFE. Currently, Nanogen s HFE ASRs are the only ASRs for use in developing and validating a test for the three mutations in the HFE gene.

Hereditary hemochromatosis is an autosomal recessive disorder characterized by unusually high levels of iron in the blood due to polymorphisms in the HFE gene. Excess iron accumulates over a period of years in the patients major organ systems. Clinical indications of HH include type II diabetes (also known as bronze diabetes), heart disease, arthritis, and liver disease.

Other Current Products

Assay ToolBox ™

The Nanogen Assay ToolBox is a collection of general purpose reagents and accessories used to facilitate assay and protocol development and validation on the NanoChip® platform. The Assay ToolBox components, together with oligos available from third party vendors, may be used to facilitate development and validation of laboratory developed tests by CLIA-certified high complexity laboratories or research laboratories. The unique, open-architecture of the NanoChip® Electronic Microarray and instrumentation enables researchers to define, select and build their own test panels. Customers may be required to obtain third party licenses to the specific gene mutations for the assays that they seek to develop or validate.

Products and Applications in Research and 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, ASRs and products for use on the NanoChip® System, while customers may create and validate new home brew 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. For example, 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.

Below is a brief description of some of future products and application currently in research and development at either the Company or with one of its collaborators.

Next Generation NanoChip® System

As part of the Nanogen Hitachi collaboration, we have been working on improvements to the current NanoChip® System and the development of a next generation NanoChip® System. We believe our next generation NanoChip® System must be more compact and less costly to access smaller hospital laboratories and other customers for molecular-based testing.

Additional Potential ASRs and other Products

ASRs for mutations in the ASPA Gene related to Canavan disease

During 2002, Nanogen entered into a non-exclusive license agreement with a third party that provided it with rights to develop ASRs for certain mutations in the ASPA gene associated with Canavan disease, a disease that has highest prevalence in the Ashkenazi Jewish community. This community has historically been very proactive in the United States in advocating that its members undergo genetic testing prior to having children. The ASPA mutation detection test is a key member of a panel of multiple tests frequently used in an Ashkenazi Jewish genetic disease screening panel. Cystic fibrosis also is a key part of this panel and Nanogen offers the ASRs to enable customers to develop and validate an assay to test for the specific mutations associated with the diagnosis of cystic fibrosis. Strategically, the ASPA ASRs are important as they provide patent licensure to the end user which has historically been a challenge for individual laboratories to obtain. This will allow many labs who are currently sending out this test to bring it in-house. Moreover, those labs that currently test internally typically run a home brew assay which most report as highly cumbersome. These ASRs will simplify and streamline their testing for this important gene.

During 2002, Nanogen and its subsidiary, Recognomics, jointly worked on developing and validating the ASRs and Nanogen currently has transferred the ASRs to an alpha test site. Nanogen currently expects to release the ASRs in the second quarter of 2003.

ApoE ASRs

In 2002, Nanogen non-exclusively licensed rights to develop and commercialize ASRs relating to ApoE gene mutations linked to the detection of Alzheimer s disease. The ASRs are currently in beta site testing and Nanogen expects to release the ASRs in the second quarter of 2003. Like the ASPA ASRs, strategically, the ApoE ASRs are important as they provide patent licensure to the end user which has historically been a challenge for individual laboratories to obtain. This will allow many labs who are currently sending out this test to bring it in-house. Since those labs that currently test internally typically run a home brew assay that most report as highly cumbersome, the ApoE ASRs will simplify and streamline their testing for this important gene.

ASRs for Genes related to epilepsy

In 2002, Nanogen entered into a development site agreement with Bionomics, an Australian company that provides for an option to the exclusive commercial rights for certain gene mutations believed to relate to epilepsy. Bionomics is currently in the initial stage of validating its hypothesis and developing a test for these mutations. Since this research is in the early stage of development, no definitive time table has been set for the release of any of such ASRs.

Beta thalassema research reagents

Nanogen has been working with a company in Europe to jointly develop a product for the detection of certain genes associated with the diagnosis of beta thalassimia, a disease that is most prevalent in the Mediterranean regions of Europe. These research reagents will be initially marketed through the European company as an alternative method for testing beta thalassemia in newborns. Nanogen expects to release these research reagents in the second quarter of 2003.

Advanced Technology and Research and Development

Besides the continued development of the NanoChip® System, ASRs and other similar products, we are currently conducting research and development into a number of other applications of our technology.

*Developing Advanced Technologies and Point-of-Care Applications***.**

In the long term, we plan to develop sample-to-answer systems which integrate otherwise time-consuming and labor-intensive sample preparation procedures on the disposable cartridge through the use of active microelectronics. The availability of this lab-on-a-chip technology would fulfill a substantial unmet need in both academic research and commercial sectors.

Nanogen Recognomics

Nanogen Recognomics, a joint venture of Nanogen and Aventis Research & Technologies, combines the 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. Besides assisting us in the development of ASRs for the detection of genes associated with Canavan disease, their current research efforts include genetic-based in vitro human detection, diagnostics, screening and monitoring applications, including research into novel oligonucleotide chemistries.

Biodefense

Nanogen began work on biodefense-related technology for the United States Government in 1995. The work has expanded to include three current government grants to support biowarfare detection efforts (one ongoing DARPA grant and two DUST grants).

Specific development efforts include a prototype portable field-based detection device and an integrated micro-laboratory and assay protocol to analyze simulated biowarfare targets. Also under development are assays aimed at detection of specific biowarfare agents and infectious diseases and a self-contained portable system capable of performing on-chip non-PCR amplification and detection of potential biowarfare threats.

Forensics

STRs are the genetic sequences chosen by the U.S. government and various foreign governments to populate their national criminal identification databases. Some foreign researchers and governments are also beginning to examine certain SNPs to develop such 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.

Our research collaborations in the area of forensic applications include identity testing and have allowed us to further develop existing technology and explore new technology. Prior and current grants from the National Institute of Justice have involved sponsored research for forensic applications, such as the development of a portable system for human identification at the crime scene and the development of on-chip non-PCR amplification.

Kinase

Working with Aventis, Nanogen has developed an electronic, fluorescent kinase assay and instrument for use in drug discovery. The assay is configured for 384-well microtiter plates and uses no antibodies or radioactivity. While particularly attractive for serine/threonine kinases, the electronic assay can also be applied to phosphatases and proteases.

The assay principle involves kinase phosphorylation to invert the charge of a fluorophore-labeled peptide substrate, followed by electrophoresis to separate the phosphorylated and unphosphorylated peptides. The intensity of the fluorescence is quantitatively read on a conventional plate reader and directly related to the effectiveness of the inhibitor.

Nanogen has placed ElectroCapture HTS workstations in beta-site locations. Direct comparisons with fluorescence polarization, homogeneous time-resolved fluorescence and radioactive filter binding assays have been presented by Eli Lilly & Company and Aventis at several drug discovery conferences. The primary advantages our electronic technology identified by our collaborators are assay simplicity and low fluorescence compound interference. We have developed a proprietary method to quickly identify specific fluorophore labeled proprietary substrates for kinase and orphan kinases that are assay-ready. By combining the substrate identification method with our electronic assay, we believe that high-quality screening results can be generated for a large fraction of the kinases and phosphatases in the human genome. We will be identifying the on-going business strategy for the optimum commercial impact of this technology. Nanogen does not plan to commercialize the kinase technology on its own, but will identify third party collaborators to commercialize it.

Other Potential Applications

As the Human Genome Project opportunity and other public and private genetic sequencing efforts yield increasing amounts of genetic information, we believe that 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. 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.

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 offer our customers the opportunity to lower their costs and improve productivity by automating all or a significant portion of their labor-intensive testing.

Drug discovery applications

We believe we have a powerful tool, the ElectroCapture workstation, which will help clarify appropriate pathways for therapeutic intervention, identify and evaluate lead compounds and simultaneously assess the efficacy and toxicology of these compounds in model systems. It is estimated that the 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 tests are free of antibodies and have the potential of improving the cost and quality of the screening process. We will be identifying the ongoing business strategy for the optimum commercialization of this technology.

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.

Collaborative Alliances

We intend to continue to enter into collaborations to expand applications of our technology platform and to accelerate the commercialization of products. We will pursue additional collaborations in various forms, including research and development agreements, licensing agreements and joint ventures. These collaborations permit integration of the technology and resources of our partners with our technology, while allowing Nanogen to pursue diagnostics, drug discovery and genomics opportunities outside the scope of these collaborations.

We are currently involved in two material corporate collaborations. 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 and clinical diagnostics labs. Additionally, we may distribute products in Japan and select Asian markets through the distribution arm of Hitachi High Technologies.

Aventis/Nanogen Recognomics

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 retain full commercialization rights for any products resulting from these new projects, while Aventis retains the right to use the technology for internal research and development. 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.

As described earlier herein, Nanogen Recognomics combines the 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 current research efforts include genetic-based in vitro human detection, diagnostics, screening and monitoring applications, including research into novel oligonucleotide chemistries.

Hitachi

In January 2000, we executed an agreement with Hitachi, Ltd. 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 after July 26, 2003, subject to certain conditions. 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.

Government Grants

In 2002, we continued work under a number of biodefense-related technology grants for the United States Government. The work has expanded to include three current government grants to support biowarfare detection efforts (one ongoing DARPA grant and two DUST grants) In the latter part of 2002, we received an additional $1.7 million grant from the National Institute of Justice (NIJ) to continue an earlier NIJ grant for the development of a forensics detection system for the identification of certain relevant SNPs and STRs and we received a grant from the National Institute of Health for $162,000 for the development of a sample preparation system for the detection of certain biological agents.

Specific development efforts include a prototype portable field-based detection device and an integrated micro-laboratory and assay protocol to analyze simulated biowarfare targets. Also under development are assays aimed at detection of specific biowarfare agents and infectious diseases and a self-contained portable system capable of performing on-chip non-PCR amplification and detection of potential biowarfare threats.

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.

Proprietary Technology and Patents

As of December 31, 2002, we have forty-seven issued U.S. patents and thirty-six foreign 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 Oxford Gene Technology (OGT). We have opposed one allowed European Patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. OGT 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. The case is currently on appeal. If the decision of the Opposition Division is successfully appealed by OGT 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 could 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 Oxford Gene Technologies 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.

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 latter part of 2000. Since then, we have built a commercial structure that allows us to sell directly in certain markets, while selling through distributors and partners in other markets. We began selling our first ASRs for Factor V Leiden in Spring of 2002.

Our commercial organization includes direct sales representatives and sales management, customer support personnel, field support personnel and marketing. We began selling our product to customers in the United States, Canada, Mexico and several European countries. Hitachi s distribution company, Hitachi High Technologies, began distributing our product in Japan during the latter part of 2000 as well. 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 system and applications 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 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

Currently our NanoChip® System is registered for general purpose use in the U.S. and distributed for research use in Europe. The ASRs under development and commercially available are manufactured and distributed in the U.S. pursuant to 21CFR 864.4020. Future short term plans include distribution of these reagents for research use in Europe with eventual CE marking of test systems under the European IVDMDD regulations.

For our initial commercial markets, the biomedical research market and the high complexity CLIA certified laboratory market, we do not anticipate the need for FDA or other regulatory clearances for our NanoChip® System and certain ASRs prior to marketing. We have not applied for FDA or other regulatory clearances 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, Medical Device Reporting and adherence to Quality System Regulation, or QSR). Class II devices are subject to general and special controls (e.g., performance standards, premarket notification, 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 Premarket Approval (PMA) application 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..

After a PMA is accepted for filing, the FDA begins its review of the submitted information, which generally takes between one and two years. 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, 2002, we had 195 full-time employees, of whom 37 hold Ph.D. degrees and 17 hold other advanced degrees. Approximately 81 are involved in research and development, 40 in operations, manufacturing and quality assurance, 40 in sales and marketing, and 34 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. As of March 2003, we had only a limited product offering that includes our NanoChip® System, NanoChip® Cartridge, four ASRs and one other product. All of our other platforms and ASRs and other potential products are under development. Our NanoChip® System, ASRs 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.

As of December 31, 2002 we have sold a total of 45 NanoChip® Systems. We also placed instruments at various customer sites under development site agreements whereby title of the NanoChip® Molecular Biology Workstation did not pass to the customer and therefore no revenue was recognized.

We are also party to transactions known as reagent rentals and cost-per-test agreements. As of December 31, 2002, we entered into three reagent rental agreements and nine cost-per-test agreements for 2002. Under these types of transactions, we place a Workstation at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. The nine cost-per-test transactions entered into in 2002 require customer acceptance of our CFTR

ASRs as a pre-condition to this commitment which we released in the first quarter of 2003. These reagent rentals and cost per test agreements might have an adverse impact on our short-term instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer. Our success will depend upon our ability to continue to overcome significant technological challenges and successfully introduce our products into the marketplace. A number of applications envisioned by us may require significant enhancements to our basic technology platform. There can be no assurance that we can successfully develop such enhancements.

As of December 31, 2002, we have received approximately $388,000 in revenue from the sale of our NanoChip® Cartridges. Also, as of December 31, 2002, we have not yet recognized any revenue from the sale of our ASRs.

Lack of market acceptance of our technology would harm us.

Although we have developed a number of products as discussed above, we may not be able to further develop these products or to develop other 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 the 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, and 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.

From our inception to December 31, 2002, we have incurred cumulative net losses totaling approximately $145.7 million. Moreover, our negative cash flow and losses from operations will continue 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, which fluctuations could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the NanoChip® System choose to enter into sales, reagent rentals, cost-per-test or development site transactions.

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

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

We will need to raise more money to continue the research and development necessary to further develop our current products to bring our products to market and to further our 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 seek to 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 QSRs and obtaining necessary regulatory clearances or approvals;

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

the scope and results of our future clinical trials, if any.

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

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 current or potential products, or that render our technologies and current or 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, 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 Oxford Gene Technology (OGT). We have opposed one allowed European Patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. OGT 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. The case is currently on appeal. If the decision of the Opposition Division is successfully appealed by OGT 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 could be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

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

In December 2002, Oxford Gene Technologies (OGT) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that Nanogen infringes U.S. Patent No. 6,054,270 (the 270 Patent) entitled Analytical Polynucleotide Sequences . Nanogen denies that it infringes the 270 Patent. Although it is Nanogen s position that OGT s assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees can yet be assessed. No assurances can be given that the Company will prevail in the lawsuit or that it can successfully defend itself against the claim and the Company may not prevail in the action, which could have a material adverse effect on the Company.

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

The manufacturing, labeling, distribution and marketing of any 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 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 an exemption, 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 current products or 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.

Our dependence on suppliers for materials 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, including qualification under applicable FDA regulations. 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, our ASRs and most of our other products. 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 further scale up manufacturing procedures or to manufacture new products. 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 those relating to:

- 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 obtaining materials and components for our products and the manufacturing and introduction of our products may vary significantly which could lead to excess inventory levels as well as shortages of critical components and products if our supply and demand forecasts are inaccurate.

We anticipate that our products, including our ASRs and most of our other products will be manufactured and introduced by us and third parties, if any, based on forecasted demand and will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and components to be included in our products vary significantly and may 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 and components at any given time. Also, we often rely on our own and third party forecasted

demand for various products and the accuracy of such forecasts may depend on a number of factors, including but not limited to, government reports and recommendations for certain genetic testing, regulatory burdens, competitive products, the nature and effectiveness of our products, the timing and extent of the introduction of our products into the marketplace and other factors. 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 for certain future generations of the Workstation and other hardware products, and only we manufacture our NanoChip® Cartridges, and our ASRs and most of our other products, 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 second generation Workstations and other hardware 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.

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

At December 31, 2002, we had 40 total employees in our worldwide sales and marketing group. In July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. At December 31, 2002, this office employed 11 European-based sales executives and support personnel in the United Kingdom, Germany and The Netherlands..

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

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

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

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

currency fluctuation risks;

changes in regulatory requirements;

costs and risks of deploying the NanoChip® System, ASRs and other products in foreign countries;

licenses, tariffs and other trade barriers;

political and economic instability, including the war on terrorism;

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 U.S. dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the 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. 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 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 year ended December 31, 2002, the rate of turnover at all levels of the Company was 39%. For the years ended December 31, 2001 and 2000 the turnover rates of the Company were 31% and 19%, respectively. Turnover at these rates may, and if they continue, will adversely affect the Company.

In October 2002, the Company reduced its workforce by approximately 10% and incurred severance charges of approximately $290,000 during the fourth quarter of fiscal 2002 related to this event. Continued layoffs could have an adverse effect on 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, ASRs or our other products;

announcements by us of government grants or contracts or of failure to obtain such government grants or contracts;

announcements by us of involvement in litigation;

developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;

loss of key board, executive, management or other 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 and other stocks in general;

purchases by the Company pursuant to the stock repurchase program;

changes in estimates of our performance by securities analysts and the loss of coverage by one or more securities analysts;

the announcement by us of any stock repurchase plan, any purchases made thereunder by us and any cessation of the program by us;

changes in the United States war on terrorism and other geopolitical and military situations in which the country is involved; and

changes in the price of petroleum, heating oil and any other raw materials that the Company uses at its facilities.

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 in advance by our board of directors and may have the effect of deterring unsolicited 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 and increased operating expenses, which could adversely affect our results of operations and financial condition.

Item 2. Properties

At December 31, 2002, we occupied the indicated square footage in the leased facilities described below:

Number of Buildings	Location	Total Square Footage	Primary Use
1	San Diego, California	44,000	Administrative offices, research and development, sales and marketing and manufacturing for a term ending on March 31, 2010 (with an option to extend).
1	Helmond, Netherlands	2,900	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 December, 2002, Oxford Gene Technologies (OGT) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that Nanogen infringes U.S. Patent No. 6,054,270 (the 270 Patent) entitled Analytical Polynucleotide Sequences . Nanogen denies that it infringes the 279 Patent. Although it is Nanogen s position that OGT s assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees can yet be assessed. No assurances can be given that the Company will prevail in the lawsuit or that it can successfully defend itself against the claim and 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, 2002.

PART II

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

Market Information

Our common stock trades on the National Association of Securities Dealers Automated Quotation (Nasdaq) National Market under the symbol NGEN. 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, 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
Year ended December 31, 2002:		
1st Quarter	$ 6.34	$ 3.95
2nd Quarter	$ 4.74	$ 2.49
3rd Quarter	$ 3.67	$ 1.50
4th Quarter	$ 2.23	$ 1.22

As of March 24, 2003 there were approximately 218 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,				
	2002	2001	2000	1999	1998
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales	$ 3,384	$ 2,245	$ 919	$	$
License fees	10,844				
Sponsored research	1,355	7,457	8,457	5,688	5,461
Contract and grant	1,596	1,467	1,856	2,431	2,172
Total revenues	17,179	11,169	11,232	8,119	7,633
Operating expenses:					
Cost of product sales	2,466	1,606	599		
Research and development	21,020	18,597	18,905	25,284	23,002
Selling, general and administrative	20,540	22,032	15,267	9,097	6,420
Litigation and settlement of patent matters	(165)	6,900			
Acquired in-process technology					1,193
Total operating expenses	43,861	49,135	34,771	34,381	30,615
Loss from operations	(26,682)	(37,966)	(23,539)	(26,262)	(22,982)
Interest income, net	2,119	4,390	5,257	2,059	2,650
Minority interest in loss of consolidated subsidiary	2,156	907			
Other income (loss)	161	168		(996)	(610)
Net loss	$ (22,246)	$ (32,501)	$ (18,282)	$ (25,199)	$ (20,942)
Net loss per share basic and diluted	$ (1.02)	$ (1.54)	$ (0.92)	$ (1.39)	$ (1.60)
Number of shares used in computing net Loss per share basic and diluted	21,722	21,091	19,944	18,069	13,097
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 52,729	$ 67,524	$ 95,089	$ 41,021	$ 62,245
Working capital	53,050	71,516	92,700	33,508	57,701
Total assets	71,360	90,091	111,168	50,785	72,704
Other long term liabilities and capital lease obligations, less current portion	4,219	3,430	2,065	2,831	4,176
Accumulated deficit	(145,659)	(123,413)	(90,912)	(72,630)	(47,431)
Total stockholders equity	57,393	74,929	101,414	38,121	61,051

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-K includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties that could cause our actual results to vary materially from those reflected in the forward-looking statements. Words such as believes, anticipates, plans, estimates, future, could, may, should, expect, envision, potentially, eventually, and variations of such words and simila intended to identify such forward-looking statements. The forward-looking statements contained in this Form 10-K include, but are not limited to, statements about matters including the following: (i) the development of the markets and demand for our products and services; (ii) our product development plans, including the introduction of new products, and anticipated activities designed to pursue these plans, including collaborations and other corporate partnering arrangements; (iii) our ability to generate substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements; (iv) the ability of our product platform to affect the market and become an industry standard; (v) our ability to generate license and other fee revenue in the future; (vi) the amounts we invest in research and development activities in the future; (vii) future levels of operating expenses associated with our business; (viii) future levels of interest income; (ix) any amounts we may be able to realize from the liquidation of our investments, including our investments in short-term securities;

(x) operating results of joint ventures and other corporate partnering arrangements; (xi) the amounts and timing of our contractual obligations and capital commitments and (xii) our future capital needs and our ability to fund those needs. 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 Company s current commercially available products include (1) the NanoChip® Molecular Biology Workstation, an automated, multi-purpose instrument primarily used for DNA-based analyses, (2) the NanoChip® Cartridge, which incorporates the NanoChip® Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules, (3) various ASRs for gene mutations associated with diseases such as cystic fibrosis and hereditary hemochromotosis and (4) Assay Toolbox™, a product designed to help customers develop their own assays on the NanoChip® System. The Company also has several other ASRs and applications of its proprietary technology under development. The Company provides technical support and field applications assistance to its customers.

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, 2002, had an accumulated deficit of $145.7 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, 2002, 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 and, in 2002, a license fee valued at $10.8 million received from a litigation settlement with CombiMatrix Corp. 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 had 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, 2002, we

had incurred an aggregate of $14.7 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 10-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 10-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 to the Company for that year. The Company received $2.8 million ($125,000 of which is a prepayment for 2003 research and development activities), $2.3 million, and $1.0 million from Hitachi during the years ended December 31, 2002, 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 middle of 2003. As of December 31, 2002, we had incurred an aggregate of $4.6 million in direct research and development costs in addition to other related general technology development costs that exceed $1.4 million 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 which was subsequently reduced to $1.4 million in 2002. The contract is focused on developing an electronic sample preparation chip for the detection of biowarfare agents from blood samples. The contract was completed in November 2002 and all milestones have been completed. As of December 31, 2002, we have incurred an aggregate of $3.6 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, 2002, we have incurred an aggregate of $2.1 million 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 final phase of this multi-year grant, were completed in 2002. In July 2002, the Company was awarded a Phase V grant of $1.7 million over a two-year period; efforts in Phase V could result in protocols and reagents suitable for beta-testing in crime labs. As of December 31, 2002, we have incurred an aggregate of $2.6 million in direct research and development costs since the beginning of this multi-year grant.

NIH Grant The National Institute of Health, U.S. Department of Health and Human Services, provides funding for the development of a compact centrifugal microfluidics-based analyzer. The Company received the award in July 2002 for approximately $162,000 extending over 14 months. As of December 31, 2002, we have incurred an aggregate of $25,000 in direct and indirect research and development cost since the beginning of the contract.

Combined sponsored research, contract and grant revenue has declined during the fiscal years ended 2002 from our experience in 2001 and 2000. Revenues for 2002 consisted of $1.6 million from government contracts and grant revenue funding and $1.4 million from sponsored research, all pertaining to the development program entered into in July 2000 with Hitachi. Revenues during years 2001 and 2000 were primarily derived from sponsored research and contract and grant funding. The decline in combined revenue associated with sponsored research, contract and grants between 2000 and 2002 is the result of the Company s strategic shift away from such sponsored research revenue and more towards product revenue. The Company 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 ASRs and FDA-cleared or approved kits will account for an increasing portion of our product revenues.

Fiscal year 2002 included a number of highlights. An important milestone for the Company was the release of the ASRs for the detection of the 25 mutations of the CFTR gene most commonly associated with cystic fibrosis, to our first customer site for evaluation. The Company announced a worldwide, non-exclusive licensing agreement with Bio-Rad Laboratories Inc. for the two most common gene mutations associated with the diagnosis of hereditary hemochromatosis (HH), a disorder resulting in excessive iron build-up in tissues and major organs of the body. The Company also announced in 2002 license agreements or collaboration agreements for rights to commercialize mutations in the ApoE gene from Athena Diagnostics that are associated with Alzheimers disease, for mutations in the ASPA gene associated with the diagnosis of Canavan disease and with Bionomics Limited, an Australian company, for mutations to certain genes associated with the diagnosis of epilepsy. During 2002, the Company introduced its first ASRs for Factor V Leiden. In the first quarter 2003, the Company introduced three additional ASRs for the CFTR gene associated with cystic fibrosis, for the HFE gene associated with hereditary hemochromotosis, and multiplexed ASRs for Factor II (Prothrombin) and Factor V (Leiden), genes associated with thrombosis. In March 2003, the Company also introduced a product the Assay ToolBox a product that is designed to assist research institutions conduct their own home brew assays on the System. Under the ASRs 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

We prepare our financial statements in conformity with United States generally accepted accounting principals. These accounting principals require management to make certain judgments 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 judgments, including those related to bad debts, inventories, investments, intangible assets, service obligations, contingencies and litigation. We base our estimates and judgments 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 judgments and estimates used in the preparation of our consolidated financial statements:

Revenue recognition

We generate product revenue by the sale of our commercial products and services under various sales programs to the end user or through distribution channels. We recognize revenue in accordance with Staff Accounting Bulletin 101 Revenue Recognition in Financial Statements and record revenues as follows:

We offer our NanoChip® Molecular Biology Workstations under various commercial programs such as: direct sale, reagent rental programs and cost-per-test agreements. We also offer our Workstations to customers under

development site programs that may result in one of the above commercial transactions. We sell our Workstations direct to the end user and to distributors. Revenue from the sale of consumables is recognized upon shipment (f.o.b. shipping point) as we do not sell consumables with a right of return.

Revenue from the direct sale of NanoChip® Molecular Biology Workstations is recognized following receipt of a purchase order, shipment (f.o.b. shipping point) of product, and transfer of title when sold directly to the end user or to a distributor. 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 sold with a one year warranty contract. The fair value of the warranty is recorded as deferred revenue and recognized ratably over the warranty period included in the customer contract. The fair value of the warranty is based on the renewal price paid by the same customer. This renewal price for the maintenance contract is consistent for all customers. We provide for the estimated cost of product warranty at the time revenue is recognized.

We also recognize revenue from the sale of our NanoChip® System under reagent rental and cost-per-test transactions whereby customers pay a premium for our consumable products (NanoChip® Cartridges or ASRs) over a number of years that is intended to cover the sales price of the NanoChip® Workstation, consumables and warranty. Under a reagent rental transaction, the customer commits to purchasing a fixed number of consumable products on a periodic basis for a specified period of time (i.e. a certain number of cartridges for a certain number of years). Revenue for the Workstation, consumables and warranty under reagent rental transactions is recognized as consumable products are shipped, over a period of generally two to five years, depending on the specific customer arrangement as they may vary by customer. We reclassify the recorded value of the Workstation from inventory to fixed assets, recognizing the depreciation expense as cost of sales ratably over the period of the arrangement. Under a cost-per-reportable transaction, the customer agrees to purchase a certain number of consumable products on a periodic basis determined by the customer s volume of reported test results (to third parties) from the use of our consumable products. We recognize revenue under this type of transaction at the time we receive evidence of the customer s test results reported to third parties. Under these arrangements, we provide product warranty coverage for the Workstation over the period of the contract. Under both of these sale transactions, the fair value of the warranty is recognized ratably over the warranty period included in the customer contract. The cost of sales related to the consumables is recorded in line with the revenue (i.e. as consumables are shipped or consumed, depending on the terms of the contract).

We also place our NanoChip® Molecular Biology Workstations at customer sites under programs, such as development site arrangements, where title of the NanoChip® Workstation does not transfer to the customer. No revenues are recognized at the time of placement under these agreements. These arrangements are for a period normally between six and nine months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that we may license in the future. In addition, a primary intent of the program is for the customer to purchase the NanoChip® Workstation during the period of the arrangement or at its expiration. We provide a warranty for these NanoChip® Workstations as well as insure them during the development site period. Warranty expense is recorded ratably over the period of the arrangement within selling, general, and administrative (SG&A) expenses. Development site customers are normally required to purchase any consumables to be used on the instrument from us during the development site period. We classify this inventory as consignment inventory and include this within finished goods. We record a reserve for the refurbishment costs, recorded within SG&A, for each unit included in consignment inventory for the purpose of resale in the event the unit is returned

under this arrangement. In addition, we have recorded a reserve related to the older production units that may be deemed obsolete or sold to the customer at a discount due to the age of the unit during the development site period. Transactions under these types of programs do not result in the recognition of revenue, however, if the customer opts to purchase the NanoChip® Workstation at any time, sales revenue is recognized upon receipt of a purchase order. Cost of sales for the Workstation is provided for at the time revenue is recognized.

Workstations sold to distributors are sold outright with title transferring at point of shipment (i.e., f.o.b. shipping point) without a right of return. Workstations are sold at a discount to the standard sales price (but not below the cost of manufacturing the instrument) and without warranty coverage.

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.

License fees include nonrefundable fees generated from the licensing of the Company s technology. Revenue is recognized immediately when the Company has no further obligation to perform and collections are reasonably assured.

Bad debt

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We record additions to our reserve based on specific analysis of each customer s balance due us. 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 after considering future purchase commitments and 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, 2002, 2001 and 2000

Revenues

For the year ended December 31, 2002, product sales revenue totaled $3.4 million compared to $2.2 million for the year ended December 31, 2001. Product sales primarily consists of revenue recognized from the sale of our NanoChip® Molecular Biology Workstations and NanoChip® Cartridges. We sold twenty-four NanoChip® Systems in 2002 compared to thirteen and eight during 2001 and 2000, respectively. In addition, we sold two NanoChip® Systems in each of 2001 and 2000 under sponsored research programs. All revenue recorded in connection with sales of our NanoChip® Systems 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, 2002, we had an installed base of 85 instruments, which consists of 45 outright sales and 40 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, 2002, license fees contributed $10.8 million to revenue as the result of a litigation settlement with CombiMatrix (see Note 4 of Notes to Financial Statements). The amount recorded was based on the fair value of the CombiMatrix shares received in the settlement. These fees were non-recurring and we do not anticipate recognizing significant license fees in 2003. There were no license fee revenues earned for 2001 or 2000.

For the year ended December 31, 2002, revenue from sponsored research totaled $1.4 million compared to $7.5 million and $8.5 million for the years ended December 31, 2001 and 2000, respectively. Sponsored research revenue in 2002 consisted of revenue earned in connection with our development program entered into in July 2000 with Hitachi totaling $1.4 million in 2002. We expect the Hitachi funding to continue at approximately the same level in 2003.

Sponsored research revenue for 2001 and 2000 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 and $7.7 million for 2001 and 2000, respectively, which included the sale of 2 NanoChip® Molecular Biology Workstations in each year.
- Revenue earned in connection with the joint venture agreement with Becton Dickinson, as amended in September 2000, totaling $300,000 for 2000.
- Revenue earned in connection with our development program entered into in July 2000 with Hitachi totaling $1.1 million for 2001 and $417,000 for 2000.

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 or Becton Dickinson 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 $2.5 million in 2002 compared to $1.6 million and $599,000 in 2001 and 2000, respectively. Gross margins on product sales revenue were 27% in 2002 compared to 28% and 35% in 2001 and 2000, respectively. Cost of sales during the years ended December 31, 2002 and 2001 were adversely impacted by underabsorbed overhead costs due to underutilized capacity. The cost per unit of our products remained high, as our volume of production relative to the available capacity remained low. In 2002 and 2001, cost of sales was further impacted by a reserve for obsolete inventory. Gross margins in 2002 were also unfavorably impacted due to manufacturing scrap as a result of lower yields on new products released into production. 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 2003. In addition to underabsorbed overhead costs, cost of sales was further impacted by a reserve for obsolete inventory totaling $28,000, $109,000, and $176,000 for the years ended December 31, 2002, 2001, and 2000, respectively. This reserve relates primarily to excess instrument parts in our inventory that could potentially become obsolete prior to their consumption. If necessary, these parts will be used as replacement parts for Nanogen Systems located both internally and at customer sites. Gross margins during these periods were further impacted by sales of NanoChip® Workstations to certain customers

under various discount programs and by sales to distributors, which are generally at a discount. Gross margins in future periods may additionally be impaired by minimum product royalties or potential adjustments made to reflect the impairment of intangible assets related to products sold.

Research and development expenses

Research and development expenses totaled $21.0 million, $18.6 million and $18.9 million for the years ended December 31, 2002, 2001, and 2000, respectively. The increase in research and development expenses from 2001 to 2002 is primarily the result of costs incurred by our majority-owned subsidiary, Nanogen Recognomics GmbH, which began operations in the third quarter of 2001. The majority-owned subsidiary recorded losses of $2.2 million in 2002 compared to $907,000 in 2001. Additionally, research and development costs increased from the prior year, in part, as a result of the termination of a collaboration agreement resulting in a loss of $452,000 in 2002. The loss represented the remaining carrying value of acquired technology rights originally obtained in 1999. Research and development expenses included the following during the years 2002, 2001, and 2000: 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.

Research and development expenses decreased from 2000 to 2001 as the number of personnel working directly in research and development related activities within our U.S. operations decreased by approximately 10% as a result of a reallocation of personnel to operations. We anticipate that we will continue to invest in research and product development at approximately the same level as 2002 for the foreseeable future.

Selling, general and administrative expenses

Selling, general and administrative expenses totaled $20.5 million in 2002 compared to $22.0 million in 2001 and $15.3 million in 2000. The decline in expenses between 2001 and 2002 is primarily the result of curtailed spending associated with the launch of products and reduced personnel costs. The increase from 2000 to 2001 is 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 foreseeable future as we continue to market and sell our current and potential future products.

Litigation and Settlement of Patent Matter

The net benefit for litigation and settlement of a patent matter totaled $165,000 for the year ended December 31, 2002 and net expenses totaled $6.9 million for the year ended December 31, 2001. There were no litigation and settlement of patent matter expenses incurred during 2000 that were material.

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 disputed 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. Costs incurred during 2001 primarily consist of the settlement fee of $5.0 million in addition to legal fees incurred related to the litigation process. Costs associated with the litigation and settlement of this matter totaled approximately $6.3 million for the year ended December 31, 2001. There were no costs incurred during 2002 or 2000.

In September 2002, the Company entered into a settlement agreement with CombiMatrix Corp. (CombiMatrix) and Dr. Donald Montgomery concluding pending litigation in the U.S. District Court for the Southern District of California. Pursuant to the settlement agreement, Nanogen agreed to drop its claims against CombiMatrix and Dr. Montgomery that include certain causes of action relating to U.S. patent Nos. 6,093,302 and 6,280,595 (the patented technology) that were assigned by Dr. Montgomery, an ex-Nanogen employee, to CombiMatrix in 1995 and assertions relating to other matters. In exchange, CombiMatrix agreed to pay $1.0 million as a reimbursement of legal costs; issue 4,016,346 shares of CombiMatrix tracking common stock that as of December 18, 2002 became publicly tradable on the Nasdaq National Market, which represents seventeen and one-half percent (17.5%) of its outstanding common stock; and make royalty payments of twelve and one-half percent (12.5%) on sales of products by either CombiMatrix or its affiliates that incorporate the patented technology. Also, as part of the settlement agreement, CombiMatrix and Dr. Montgomery agreed to drop their counterclaims against Nanogen and CombiMatrix retained sole ownership of the patented technology. The 4,016,346 shares of CombiMatrix tracking common stock were initially valued at $10.8 million based on the initial offering price and has been recorded as license fee revenue for the year ended December 31, 2002. The net benefit and costs associated with the litigation and settlement of the CombiMatrix and Dr. Montgomery litigation patent matter totaled approximately $165,000 and $578,000 for the years ended December 31, 2002 and 2001, respectively. The benefit of $165,000 for the year ended December 31, 2002 is net

of the settlement receivable of $1.0 million from CombiMatrix. There were no costs relating to this matter in 2000 that were material.

Interest income, net

We had net interest income of $2.1 million in 2002 compared to $4.4 million and $5.3 million, in 2001 and 2000, respectively. The year to year decrease in net interest income is a result of lower average cash and investment balances as well as lower yields on outstanding cash and investment balances during 2002 when compared to 2001 and 2000. Based on the continued consumption of cash and short-term investments to augment operating activities, we expect net interest income to decline during in 2003.

Other income

Other income totaled $161,000 for the year ended December 31, 2002 compared to $168,000 for the year ended December 31, 2001. For both years, other income primarily consists of gains realized from the sale of short-term investments during the respective years. We do not anticipate realizing significant gains from the sale of short-term securities in 2003. In February 2003, the Company sold 3,000,000 shares of CombiMatrix common stock for net proceeds totaling $4.5 million and recognized a realized loss of approximately $3.6 million.

Minority interest in loss of consolidated subsidiary

We had losses relating to our majority-owned subsidiary, Nanogen Recognomics GmbH, of $2.2 million in 2002 compared to $907,000 in 2001. The losses increased from 2001 to 2002 as operations for the subsidiary began in the third quarter of 2001. We expect to experience continued losses with the majority-owned subsidiary similar to levels incurred during 2002. These losses are funded by the investment from minority interest investors and are therefore offset against the minority interest balance in the respective balance sheet.

Liquidity and capital resources

At December 31, 2002, we had $52.7 million in cash, cash equivalents and short-term investments, compared to $67.5 million at December 31, 2001. This decrease is primarily due to cash used in operations of approximately $28.5 million offset by securities received from the CombiMatrix settlement during 2002 with a value of $14.6 million as of December 31, 2002. While the CombiMatrix securities are included in this category, there is significant risk associated with market value fluctuations in this investment and we expect to receive substantially less than $14.6 million from the sale of these securities. In February 2003, the Company sold 3,000,000 shares of CombiMatrix common stock for net proceeds totaling $4.5 million and recognized a realized loss of approximately $3.6 million.

Net cash used in operating activities was $28.5 million, $33.1 million, and $19.8 million for 2002, 2001, and 2000, respectively. The decline in cash used in operating activities from 2001 to 2002 was primarily due to payments received from receivables. Cash used for operations during 2002, 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.

Net cash provided by investing activities totaled $26.5 million in 2002 compared to cash used in investing activities of $17.1 million and $44.5 million for 2001 and 2000, respectively. Cash provided by investing activities in 2002 related to proceeds received from the sale of short-term investments. 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 $353,000, $5.2 million and $78.6 million for 2002, 2001 and 2000, respectively. Cash provided by financing activities in 2002 primarily related to proceeds received from a development partner totaling $1.4 million, release of restricted cash balances of approximately $235,000 and lease proceeds of $222,000 which were primarily offset by payments on capital lease obligations totaling $1.5 million. 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.

We fund much of our equipment acquisitions and leasehold improvements through capital leasing facilities. During 2002, equipment and leasehold improvement financing funded $400,000 compared to $1.1 million and

$944,000 during 2001 and 2000, respectively. We anticipate that we will continue to use capital equipment leasing or debt facilities to fund much of our equipment acquisitions and leasehold improvements. As of December 31, 2002, we had approximately $1.0 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, 2002 (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	$ 1,939	845	1,055	39	$
Other long term liabilities (a)	3,084				3,084
Operating leases	8,448	1,028	2,268	3,570	1,582
Purchase commitments (b)	2,600	2,600			
Research and development funding commitments (c)	26,075	4,100	4,100	10,375	7,500
Standby letters of credit (d)	63				63
Total contractual obligations & other commitments	$ 42,209	$ 8,573	$ 7,423	$ 13,984	$ 12,229

(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 $6 million since July 2000 under this arrangement.

(b) Our manufacturing agreement with Hitachi, Ltd. (Hitachi) requires that we provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of December 31, 2002, we had commitments to purchase approximately $2.4 million in NanoChip® Workstations through June 30, 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 2003.

(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 our 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 eighteen months. 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, 2002, we had federal and state net operating loss, or NOL, carryforwards of approximately $127.0 million and $24.1 million, respectively, and $4.8 million and $3.4 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 2004, 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 9 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 foreign subsidiaries, excluding intercompany balances, was $5.1 million at December 31, 2002.

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 12, 2003 (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. In January 2003, the Board of Directors of the Company approved an Ethics Policy for all employees of the Company including the Company s senior executives and financial management.

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 and Related Stockholder Matters

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 and Equity Compensation Plan Information .

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.

Item 14. Controls and Procedures

Within 90 days prior to the date of this report, an evaluation was carried out under the supervision and with the participation of Nanogen s management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of Nanogen s disclosure controls and procedures (as defined in Rule 13a-14(c) under the Securities Exchange Act of 1934, as amended (the Exchange Act)). Based on that evaluation, the Chief Executive Office and Chief Financial Officer have concluded that Nanogen s disclosure controls and procedures are effective to ensure that information required to be disclosed by Nanogen in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. A control system, however, no matter how well designed and operated, cannot provide absolute assurances that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurances that all control issues and instances of fraud, if any, within any company have been detected. Subsequent to the date of that evaluation, there were no significant changes to Nanogen s internal controls or in other factors that could significantly affect these controls, including any corrective actions with regard to significant deficiencies or material weaknesses.

PART IV

Item 15. 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)***(11)***	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***(11)(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***(10)(A)***	Nanogen, Inc. Employee Stock Purchase Plan, as amended.
10.5***(13)(A)***	Nanogen, Inc. 2002 Stock Bonus Plan
10.6***(1)(A)***	Form of Indemnification Agreement between Registrant and its directors and executive officers. (10.7)
10.7***(7)***	Warrant to Purchase Common Stock between Registrant and Aventis Research and Technologies Verwaltungs, GmbH, dated September 22, 2000. (10.9)
10.8***(12)***	Warrant to Purchase Common Stock between Registrant and Genetic Technologies Limited, dated June 3, 2002 (10.9)
10.9***(5)(+)***	Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement by and between Registrant and Hitachi, Ltd. dated as of December 15, 1999.
10.10***(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)

10.11*(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)
10.12*(7)*	Common Stock Purchase Agreement between Registrant and the Hitachi Parties, dated July 26, 2000. (10.8)

10.13***(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)
10.14***(1)***	Master Lease Agreement between Registrant and Mellon US Leasing, dated September 11, 1997. (10.19)
10.153***(1)***	Master Lease Agreement between Registrant and LMP Properties, Ltd., dated June 29, 1994 as amended on March 14, 2001. (10.20)
10.16***(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)
10.17***(1)(A)***	Form of Promissory Note between Registrant and certain of its executive officers, dated August 22, 1996. (10.23)
10.18***(1)(A)***	Form of Promissory Note between Registrant and certain of its executive officers, dated June 30, 1995. (10.24)
10.19***(1)(A)***	Form of Performance Stock Option Agreement. (10.26)
10.20***(11)(A)***	Amended and Restated Employment Agreement between Registrant and Howard C. Birndorf, dated as of June 3, 2001. (10.2)
10.21***(A)***	Separation Agreement between Registrant and Kieran T. Gallahue, dated as of January 2, 2003
10.22***(A)***	Separation Agreement between Registrant and Dr. Vance R. White, dated as of December 11, 2002
10.23***(A)***	Employment Agreement between Registrant and Ira Marks, dated January 24, 2003
10.24***(A)***	Employment Agreement between Registrant and Bruce A. Huebner, dated December 1, 2002
10.25***(A)***	Employment Agreement between Registrant and William Franzblau, dated January 24, 2003
10.26***(A)***	Employment Agreement between Registrant and David Macdonald, dated January 24, 2003
10.27***(A)***	Employment Agreement between Registrant and Graham Lidgard, dated January 24, 2003
10.28***(11)(A)***	Amended and Restated Employment Agreement between Registrant and Gerard A. Wills, dated as of April 27, 2001. (10.5)
10.29***(12)(A)***	Severance Agreement between Registrant and Joseph Turgeon, dated May 21, 2002 (10.4)
10.30***(A)***	Indemnification Agreement between Registrant and Bruce A. Huebner, dated effective as of December 1, 2002
10.31***(A)***	Indemnification Agreement between Registrant and Graham Lidgard, dated effective as of January 24, 2003
10.32(9)(+)	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).
10.33**(9)(A)(+)**	Contribution Agreement among Aventis R&T, Registrant and Nanogen Recognomics, dated June 27, 2001 (10.4).
10.34**(11)(+)**	Settlement Agreement between Motorola, Inc., Genometrix, Inc., the Massachusetts Institute of Technology and Registrant, dated July 20, 2001. (10.6)
10.35***(14)***	Settlement Agreement between CombiMatrix Corporation, Dr. Donald Montgomery, Acacia Research Corporation and Registrant, dated September 30, 2002
10.36***(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.
99.1	Chief Executive Officer and Chief Financial Officer Certification Letters, dated March 28, 2003
99.2	Nanogen, Inc. Ethics Policy

(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 Exhibit 10.38 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 1999.

(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 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.

(10) 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.

(11) 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.

(12) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002. 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 Exhibit 10.1 to the Registrant s Form S-8 filed on August 16, 2002.

(14) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 31, 2002.

(A) Indicates management compensatory plan or arrangement.

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

(b) Reports on Form 8-K

On November 21, 2002, we filed a report on Form 8-K announcing that Bruce A. Huebner had been named the Company s President and Chief Operating Officer, effective December 2, 2002. The Company also announced the resignations of Kieran T. Gallahue, our then current President, and Randy White, Phd., our then current Chief Executive Officer and a director of the Company. We also announced that effective December 2, 2002, Howard C. Birndorf, the Company s then Chairman of the Board and Executive Chairman, would then also assume the position of Chief Executive Officer.

SIGNATURES

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

NANOGEN, INC.

Date: March 28, 2003

By: /s/ HOWARD C. BIRNDORF
Howard C. Birndorf
Chairman of the Board,
Executive Chairman and Chief Executive Officer

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

Signature	Title	Date
/s/ HOWARD C. BIRNDORF Howard C. Birndorf	Chairman of the Board, Executive Chairman and Chief Executive Officer (Principal Executive Officer)	March 28, 2003
/s/ GERARD A. WILLS Gerard A. Wills	Vice President, Chief Financial Officer, and Treasurer (Principal Financial and Accounting Officer)	March 28, 2003
/s/ VAL BUONAIUTO Val Buonaiuto	Director	March 28, 2003
/s/ DAVID G. LUDVIGSON David G. Ludvigson	Director	March 28, 2003
/s/ STELIOS B. PAPADOPOULOS Stelios B. Papadopoulos	Director	March 28, 2003
/s/ ROBERT E. WHALEN Robert E. Whalen	Director	March 28, 2003

Chief Executive Officer Certification

I, Howard C. Birndorf, Chairman of the Board and Executive Chairman of Nanogen, Inc. certify that:

(1) I have reviewed this Annual Report on Form 10-K of Nanogen, Inc. (the registrant);

(2) Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

(3) Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

(4) The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(i) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

(ii) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the Evaluation Date); and

(iii) presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):

(i) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

(6) The registrant s other certifying officers and I have indicated in this Annual Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated: March 28, 2003

/s/ Howard C. Birndorf
Howard C. Birndorf
Chairman of the Board and
Executive Chairman of Nanogen, Inc.
(Principal Executive Officer)

Chief Financial Officer Certification

I, Gerard A. Wills, Vice President, Chief Financial Officer and Treasurer of Nanogen, Inc. certify that:

(1) I have reviewed this Annual Report on Form 10-K of Nanogen, Inc. (the registrant);

(2) Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

(3) Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

(4) The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(iii) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

(iv) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the Evaluation Date); and

(iii) presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

(5) The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):

(ii) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

(ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

(6) The registrant s other certifying officers and I have indicated in this Annual Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Dated March 28, 2003

/s/ Gerard A. Wills

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

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, 2002 and 2001, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2002. 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, 2002 and 2001 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

San Diego, California
January 24, 2003
except Note 15 as to which
the date is February 27, 2003

NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	December 31,	
	2002	**2001**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,353	$ 10,455
Short-term investments	43,376	57,069
Receivables, net	1,754	4,380
Inventories, net	4,717	4,688
Other current assets	1,781	2,473
Total current assets	60,981	79,065
Property and equipment, net	4,982	5,386
Acquired technology rights, net	4,544	4,183
Other assets, net	789	1,158
Restricted cash	64	299
	$ 71,360	$ 90,091
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 753	$ 1,051
Accrued liabilities	5,901	4,916
Deferred revenue	472	522
Current portion of capital lease obligations	805	1,060
Total current liabilities	7,931	7,549
Capital lease obligations, less current portion	1,134	1,755
Other long-term liabilities	3,085	1,675
Total long-term liabilities	4,219	3,430
Minority interest in consolidated subsidiary	1,817	4,183
Commitments and contingencies		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2002 and 2001; no shares issued and outstanding at December 31, 2002 and 2001		
	22	22

Common stock, $0.001 par value, 50,000,000 shares authorized at December 31, 2002 and 2001; 21,981,115 and 21,616,172 shares issued and outstanding at December 31, 2002 and 2001, respectively				
Additional paid-in capital		199,483		198,387
Accumulated other comprehensive income		4,926		1,253
Deferred compensation		(156)		(336)
Notes receivable from officers		(513)		(984)
Accumulated deficit		(145,659)		(123,413)
Treasury stock, at cost		(710)		
366,857 and no shares at December 31, 2002 and 2001, respectively				
Total stockholders equity		57,393		74,929
	$	71,360	$	90,091

See accompanying notes.

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years Ended December 31,		
	2002	**2001**	**2000**
Revenues:			
Product sales	$ 3,384	$ 2,245	$ 919
License fees	10,844		
Sponsored research	1,355	7,457	8,457
Contract and grant	1,596	1,467	1,856
Total revenues	17,179	11,169	11,232
Operating expenses:			
Cost of product sales	2,466	1,606	599
Research and development	21,020	18,597	18,905
Selling, general and administrative	20,540	22,032	15,267
Litigation and settlement of patent matters	(165)	6,900	
Total operating expenses	43,861	49,135	34,771
Loss from operations	(26,682)	(37,966)	(23,539)
Interest income, net	2,119	4,390	5,257
Other income	161	168	
Minority interest in loss of consolidated subsidiary	2,156	907	
Net loss	$ (22,246)	$ (32,501)	$ (18,282)
Net loss per share basic and diluted	$ (1.02)	$ (1.54)	$ (0.92)
Number of shares used in computing net loss per share basic and diluted	21,722	21,091	19,944

See accompanying notes.

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income	Deferred Compensation	Notes Receivable From Officers	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount							
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)
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
	(47)		(282)			11			(271)

Repurchase of common stock									
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
Components of comprehensive loss:									
Net loss								(22,246)	(22,246)
Unrealized gain on short-term investments					2,909				2,909
Cumulative currency translation adjustment					764				764
Total comprehensive loss									(18,573)
Issuance of common stock	82		177						177
Issuance of warrant for technology rights			122						122
Issuance of common stock for technology rights	254		750						750
Accrued interest on notes receivable from officers							(58)		(58)
Acquisition of common stock				(47)					(47)
Acquisition of common stock from officer				(663)			529		(134)
Issuance of common stock in connection with defined benefit plan, net of forfeitures	29		138			21			159
Stock based compensation expense			(133)			201			68
Options issued to consultants			42			(42)			
Balance at December 31, 2002	21,981	$ 22	$ 199,483	$ (710)	$ 4,926	$ (156)	$ (513)	$ (145,659)	$ 57,393

See accompanying notes.

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2002	**2001**	**2000**
Operating activities:			
Net loss	$ (22,246)	$ (32,501)	$ (18,282)
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	(2,156)	(907)	
Depreciation and amortization	4,088	3,475	2,553
Asset impairment and other non-cash charges	452		
Amortization (accretion) related to short-term investments	99	(53)	29
Stock-based compensation expense	68	367	947
Interest capitalized on notes receivable from officers	(58)	(63)	(57)
Gain on sale of short-term investments	(197)	(116)	
Common stock received for upfront licensing fees	(10,844)		
Changes in operating assets and liabilities:			
Receivables	2,626	(3,058)	(735)
Inventories	(1,440)	(2,398)	(2,289)
Other assets	581	(919)	47
Accounts payable	(298)	(172)	625
Accrued liabilities	923	610	369
Deferred revenue	(50)	162	(3,013)
Net cash used in operating activities	(28,452)	(33,073)	(19,806)
Investing activities:			
Purchase of short-term investments	(16,661)	(26,941)	(39,461)
Proceeds from sale of short-term investments	44,205	10,692	
Purchase of technology rights	(884)	(150)	(5,000)
Purchase of equipment	(135)	(652)	(59)
Net cash provided by (used in) investing activities	26,525	(17,051)	(44,520)
Financing activities:			
Proceeds from minority interest shareholder		4,794	
Proceeds from development partner	1,371	1,125	500
Proceeds (payments) from restricted cash balances	235	(135)	55
Proceeds from leasing company	222		
Principal payments on capital lease obligations	(1,471)	(1,818)	(2,335)
Issuance of common stock, net	177	1,149	80,139

Payments to acquire treasury stock	(181)		
Note receivable payments from officers		38	276
Net cash provided by financing activities	353	5,153	78,635
Effect of exchange rate changes	472	96	
Net increase (decrease) in cash and cash equivalents	(1,102)	(44,875)	14,309
Cash and cash equivalents at beginning of year	10,455	55,330	41,021
Cash and cash equivalents at end of year	$ 9,353	$ 10,455	$ 55,330
Supplemental disclosure of cash flow information:			
Interest paid	$ 220	$ 340	$ 461
Supplemental schedule of noncash investing and financing activities:			
Equipment acquired under capital leases	$ 400	$ 1,062	$ 944
Common stock issued for litigation settlement	$	$ 2,500	$
Common stock issued for technology	$ 750	$	$
Warrants issued for research and technology	$ 122	$ 1,200	$
Assets and liabilities contributed by minority shareholder	$	$ 307	$
Unrealized gain on short-term investments	$ 2,909	$ 892	$ 270
Common stock issued in connection with employee benefit plan, net of forfeitures	$ 138	$ 284	$
Cancellation of notes receivable related to unvested restricted stock, net of payments on notes receivable	$	$ 139	$ (56)
Options issued to non-employees for services	$ 42	$ 105	$
Cancellation of unvested restricted stock	$	$ 11	$ 201
Acquisition of treasury stock in exchange for cancellation of officer note receivable	$ 529	$	$
Inventory transferred to fixed assets	$ 1,411	$ 661	$

See accompanying notes.

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2002

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.

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 to fund all of the operating costs of the organization up to the amounts advanced. All significant intercompany transactions have been eliminated in consolidation.

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, 2002 include $2.0 million in net tangible assets, excluding intercompany balances, and an operating loss of $1.9 million for the year ended December 31, 2002 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, 2002 include $3.0 million in net tangible assets, excluding intercompany balances, of which $2.5 million consists of cash and cash equivalents, related to Nanogen Recognomics. An operating loss of $2.2 million for year ended December 31, 2002 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

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, 2002, 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.

Receivables

Accounts receivable are classified as short-term and reported at the net realizable value. Management estimates losses based on, but not limited to, such factors as specific identification, past due trends, and payment history. Estimated losses are recorded within an allowance for doubtful accounts and reported as a deduction from gross receivables.

Concentration of 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. As a result of a settlement agreement in September 2002 as discussed in Note 4, the Company received 4,016,346 shares of CombiMatrix common stock with a value of $14.6 million at December 31, 2002. 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 for the years ended December 31, 2002, 2001, and 2000. Refer to Note 15 on subsequent event activity.

Restricted Cash

Since 1994, the Company has maintained 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 and had a balance of approximately $64,000 at December 31, 2002.

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. 144, Accounting for the Impairment or Disposal of Long-Lived Assets , 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. During the year ended December 31, 2002, the Company recognized impairment losses totaling $452,000.

Revenue Recognition

Product revenue is generated by the sale of commercial products and services under various sales programs to the end user or through distribution channels. Revenue is recognized in accordance with Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements and recorded as follows:

The Company sells NanoChip® Molecular Biology Workstations under various commercial programs such as; direct sale, reagent rental programs, and cost-per-reportable agreements. Additionally, the Workstations are sold to customers under development site programs that may result in one of the above commercial transactions. The Company sells Workstations direct to the end user and to distributors. Revenue from the sale of consumables is recognized upon shipment (f.o.b. shipping point) as the Company does not sell consumables with a right of return.

Revenue from the direct sale of NanoChip® Molecular Biology Workstations is recognized following receipt of a purchase order, shipment (f.o.b. shipping point) of product, and transfer of title when sold directly to the end user or to a distributor. 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 sold with a one year warranty contract. The fair value of the warranty is recorded as deferred revenue and recognized ratably over the warranty period included in the customer contract. The fair value of the warranty is based on the renewal price paid by the same customer. This renewal price for the maintenance contract is consistent for all customers. The Company provides for the estimated cost of product warranty at the time revenue is recognized.

The Company also recognizes revenue from the sale of the NanoChip® System under reagent rental and cost-per-reportable transactions whereby customers pay a premium for consumable products (NanoChip® Cartridges or ASRs) over a number of years that is intended to cover the sales price of the NanoChip® Workstation, consumables and warranty. Under a reagent rental transaction, the customer commits to purchasing a fixed number of consumable products on a periodic basis for a specified period of time (i.e. a certain number of cartridges for a certain number of years). Revenue for the Workstation, consumables and warranty under reagent rental transactions is recognized as consumable products are shipped, over a period of generally two to five years, depending on the specific customer arrangement as they may vary by customer. The Company reclassifies the recorded value of the Workstation from

inventory to fixed assets, recognizing the depreciation expense as cost of sales ratably over the period of the arrangement. Under a cost-per-reportable transaction, the customer agrees to purchase a certain number of consumable products on a periodic basis determined by the customer s volume of reported test results (to third parties) from the use of consumable products. The Company recognizes revenue under this type of transaction at the time the Company receives evidence of the customer s test results reported to third parties. Under these arrangements, the Company provides product warranty coverage for the Workstation over the period of the contract. Under both of these sale transactions, the fair value of the warranty is recognized ratably over the warranty period included in the customer contract. The cost of sales related to the consumables is recorded in line with the revenue (i.e. as consumables are shipped or consumed, depending on the terms of the contract).

The Company also places NanoChip® Molecular Biology Workstations at customer sites under programs, such as development site arrangements, where title of the NanoChip® Workstation does not transfer to the customer. No revenues are recognized at the time of placement under these agreements. These arrangements are for a period normally between nine and twelve months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that the Company may license in the future. In

addition, a primary intent of the program is for the customer to purchase the NanoChip® Workstation during the period of the arrangement or at its expiration. The Company provides a warranty for these NanoChip® Workstations as well as insures them during the development site period. Warranty expense is recorded ratably over the period of the arrangement within selling, general, and administrative (SG&A) expenses. development site customers are normally required to purchase any consumables to be used on the instrument from the Company during the development site period. The Company classifies this inventory as consignment inventory and includes this within finished goods. The Company records a reserve for the refurbishment costs, recorded within SG&A, for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. This reserve totaled approximately $489,000 and $303,000 at December 31, 2002 and 2001, respectively, and is included in accrued liabilities. In addition, the Company has recorded a reserve related to the older production units that may be deemed obsolete or sold to the customer at a discount due to the age of the unit during the development site period. Transactions under these types of programs do not result in the recognition of revenue, however, if the customer opts to purchase the NanoChip® Workstation at any time, sales revenue is recognized upon receipt of a purchase order. Cost of sales for the Workstation is provided for at the time revenue is recognized.

Workstations sold to distributors are sold outright with title transferring at point of shipment (i.e. f.o.b. shipping point) without a right of return. Workstations are sold at a discount to the standard sales price (but not below the cost of manufacturing the instrument) and without warranty coverage.

Sales revenue is subject to fluctuation due to the type of acquisition program the Company s 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, contracts and grants are dependent upon the Company achieving specific contractual milestones.

License fees include nonrefundable fees generated from the licensing of the Company s technology. Revenue is recognized immediately when the Company has no further obligation to perform and collections are reasonably assured.

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, 2002, 2001, and 2000, common stock equivalents resulting from the assumed exercise of outstanding stock options and warrants have been excluded from the computation of diluted net loss per share as their effect would be anti-dilutive. The stock options and warrants that have been excluded from the computation of diluted net loss per share are as follows:

	Years Ended December 31,		
	2002	**2001**	**2000**
Stock options	4,459,428	2,951,564	2,292,424
Warrants outstanding	365,863	315,863	
	4,825,291	3,267,427	2,292,424

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.

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 2002, 2001, and 2000: a risk-free interest rate of 3.0%, 5.0%, and 6.0%, respectively, a dividend yield of zero; volatility factors of the expected market price of the Company s common stock of 83%, 65%, 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,		
	2002	2001	2000
Adjusted pro forma net loss	$ (28,372)	$ (38,438)	$ (26,197)
Adjusted pro forma net loss per share	$ (1.31)	$ (1.82)	$ (1.31)

The weighted average fair value of options granted during 2002, 2001 and 2000 was $1.77, $4.05 and $20.83 per share, respectively.

The pro forma effect on net loss for 2002, 2001 and 2000 is not necessarily indicative of potential pro forma effects on results for future years.

Periodically, the Company issues options to non-employees. The options are recorded at their fair value (using the Black-Scholes model) as determined in accordance with SFAS 123 and periodically remeasured in accordance with EITF 96-18 Accounting for Equity Instruments That Are Issued To Other Than Employees for Acquiring, or in Conjunction with Selling, Goods, or Services" and are recognized over the related service period.

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.

Reclassifications

Certain prior period amounts have been reclassified to conform to current period presentation. For the year ended December 31, 2001, research and development and minority interest in loss of consolidated subsidiary include $1,034,000 and $907,000, respectively, have been reclassified and presented on a gross basis. For the year ended December 31, 2001, litigation costs totaling $578,000 have been reclassified from selling, general and administrative to litigation and settlement of patent matters.

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 years 2002 and 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.

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. The adoption of these standards did not have a material impact on the Company s results of operations and financial position.

In June 2002, the FASB issued Statement No. 146, or SFAS No. 146, Accounting for Costs Associated with Exit or Disposal. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). The principal difference between Statement 146 and Issue 94-3 relates to Statement 146 s requirements for recognition of a liability for a cost associated with an exit or disposal activity. Statement 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. Under Issue 94-3, a liability for an exit cost as generally defined in Issue 94-3 was recognized at the date of an entity s commitment to an exit plan. The provisions of this Statement 146 are effective for exit or disposal activities that are initiated after December 31, 2002, with early application encouraged. We do not expect the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

In December 2002, the FASB issued Statement No. 148, Accounting for Stock-Based Compensation Transition and Disclosure to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method on reported results. The adoption of these standards did not 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 (in thousands) at December 31:

	Amortized Cost	Market Value	Unrealized Gain (loss)
2002			
Obligations of U.S. government agencies	$ 14,362	$ 14,483	$ 121
Corporate debt securities	5,212	5,271	59
Asset backed securities	8,887	9,003	116
Marketable equity securities	10,844	14,619	3,775
	$ 39,305	$ 43,376	$ 4,071
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

The estimated fair value of available for sale securities, excluding equity securities valued at $14.6 million, by contractual maturity at December 31, 2002 is as follows (in thousands):

	Amortized Cost	Market Value
Due in one year or less	$ 13,195	$ 13,307
Due between one and two years	12,194	12,357
Due between three and five years	3,072	3,093
	$ 28,461	$ 28,757

Realized gains from sale of securities totaled $197,000, for the year ended December 31, 2002 and $116,000 for the year ended December 31, 2001. There were no gains or losses realized from the sale of securities for the year ended December 31, 2000. Refer to Note 15 for subsequent event activity.

Receivables

Receivables are comprised of the following (in thousands) as of:

	December 31,	
	2002	2001
Product	$ 1,549	$ 1,569
Sponsored research		2,714
Contract and grant	246	296
	1,795	4,579
Allowance for doubtful accounts	(41)	(199)
	$ 1,754	$ 4,380

Inventories

Inventories consist of the following (in thousands) as of:

	December 31,	
	2002	2001
Raw materials	$ 1,062	$ 796
Work in process	1,485	1,436
Finished goods	4,428	3,956
	6,975	6,188
Reserve for obsolescence	(2,258)	(1,500)
	$ 4,717	$ 4,688

Finished goods includes $3.2 million and $2.0 million of NanoChip® Systems at December 31, 2002 and 2001, 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) as of:

	December 31,	
	2002	2001
Scientific equipment	$ 7,165	$ 5,356
Office furniture and equipment	3,323	3,155
Manufacturing equipment	387	334
Leasehold improvements	4,336	4,336
	15,211	13,181
Less accumulated depreciation and amortization	(10,229)	(7,795)
	$ 4,982	$ 5,386

For the years ended December 31, 2002, 2001, and 2000, depreciation expense totaled $2.4 million, $2.0 million, and $1.8 million, respectively.

Acquired Technology Rights

As of December 31, 2002 and 2001, acquired technology rights is presented net of accumulated amortization of $2.6 million and $2.0 million respectively. For the years ended December 31, 2002, 2001 and 2000, amortization totaled $1.2 million, $1.2 million, and $826,000, respectively. Amortization expense for the years ended December 31, 2003, 2004, 2005, 2006, and 2007 is estimated at $1.5 million, $1.0 million, $395,000, $20,000, and $20,000, respectively.

Accrued Liabilities

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

	December 31,	
	2002	2001
Accrued compensation and benefits	$ 2,683	$ 2,640
Accrued legal fees	639	628
Other	2,579	1,648
	$ 5,901	$ 4,916

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 $2.8 million, $2.3 million and $1.0 million from Hitachi pursuant to this agreement during the years ended December 31, 2002, 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, 2002, the Company had commitments to purchase approximately $2.4 million in NanoChip® Workstations through June 30, 2003. At December 31, 2002, the inventory under our purchase commitment with Hitachi is within our expected usage levels based upon current and estimated future demands.

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 $3.0 million and $1.6 million at December 31, 2002 and 2001, 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 was 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 $927,000, $783,000, and $631,000 in 2002, 2001 and 2000, respectively.

The Company leases certain equipment under capital lease obligations. Cost and accumulated amortization of equipment under capital lease were $14.1 million and $9.7 million at December 31, 2002 and $11.9 million and $7.6 million at December 31, 2001, 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, 2002 are as follows (in thousands):

	Operating Leases	Capital Lease Obligations
2003	1,028	997
2004	1,016	756
2005	1,252	396
2006		